Dated: September 8, 2026.

Matthew J. Memoli,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2026–18647 Filed 9–11–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NIH Biosafety Policy for Research Involving Biohazards

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: As the world's largest public funder of biomedical research, the National Institutes of Health (NIH) is committed to ensuring that gold-standard science is conducted under gold-standard biosafety conditions. To achieve this goal, NIH is proposing a new policy that modernizes and strengthens biosafety practices to ensure that oversight keeps pace with evolving risks. NIH is requesting public input on a new, comprehensive biosafety policy proposal that, when finalized, will replace the current NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf*).

DATES: To ensure consideration, comments must be submitted on or before October 19, 2026.

ADDRESSES: Comments must be submitted electronically to: *https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/*.

Comments are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After the NIH Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

FOR FURTHER INFORMATION CONTACT: Cari Young, Sc.M., Director of the Biosafety, Biosecurity, and Emerging Biotechnology Policy Division, Office of Science Policy, (301) 496–9838 or *SciencePolicy@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

Nearly 50 years ago, NIH introduced the foundational Guidelines for Research Involving Recombinant DNA Molecules (*https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf*), which established the biosafety framework for much of today's research enterprise. However, the increasingly multi-disciplinary, cross-sector, and global nature of modern science calls for a paradigm shift and, on September 9, 2025, NIH announced (*https://www.nih.gov/about-nih/nih-director/statements/nih-launches-initiative-modernize-strengthen-biosafety-oversight*) it was beginning a process to modernize and strengthen the oversight of biosafety, to ensure that it is transparent, adaptive, and accountable.

To inform the initial policy proposal, NIH undertook an intensive community outreach and engagement effort (*https://osp.od.nih.gov/table-of-biosafety-engagements-modernizing-and-strengthening-biosafety-oversight/*), hearing from researchers, biosafety professionals, members of the public, and more. Comments were solicited through six regional listening sessions, smaller engagements with groups throughout the United States, and an on-demand portal to receive individual comments for the duration of the community engagement effort.

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. As part of this modernization, 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.

Through this draft policy, NIH aims to augment public safety, transparency, and accountability in its stewardship of the biomedical research enterprise. NIH recognizes that resources and guidance will be required to achieve successful implementation of a modernized biosafety policy. 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 (*https://osp.od.nih.gov/wp-content/uploads/2024/03/gdmo-reference.pdf*), 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).

Draft NIH Biosafety Policy for Research Involving Biohazards

Scope and Applicability

Section I. Purpose

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.

Section II. Scope

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.

This Policy applies to research supported in whole or in part by NIH, regardless of NIH funding level or funding mechanism, including the NIH Intramural Research Program. 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.

Based on risk, different categories of research will require different levels of oversight as described in Section IV.

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.

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 source 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). In cases where NIH proposes to suspend, limit, or terminate financial assistance because of noncompliance with the Policy, applicable HHS and Public Health Service procedures shall govern.

Voluntary Compliance

This Policy outlines fundamental biosafety principles and practices that serve as a foundation for biomedical research. The Policy may serve globally as a model framework for biosafety oversight, and entities not otherwise subject are encouraged to follow the Policy principles and implement commensurate oversight procedures to enable safe, responsible, and secure research regardless of funding source.

General Definitions

The following terms, which are used throughout the NIH Biosafety Policy, are defined as follows:

Biological agent: Bacteria, viruses, fungi or parasites that cause human disease.

Biomedical research: Research on a topic that is within the mission of the NIH (*https://www.nih.gov/about-nih/mission-goals*), including applicability to: research supported by NIH, and non-NIH funded research that is conducted at an institution that receives any NIH funding.

Biosafety Assurance: Documentation from an institution, through the Authorized Organizational Representative (AOR), assuring institutional compliance with this Policy.

Emerging agent or organism: An agent or organism newly identified in nature.

Gene drive: Technology whereby a particular heritable element biases inheritance in its favor, resulting in the heritable element becoming more prevalent than predicted by Mendelian laws of inheritance in a population over successive generations.

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.

Institutional Biosafety Committee (IBC): A committee that meets the requirements for membership, and reviews, approves, and oversees projects in accordance with the responsibilities defined in Section III–B.

Laboratory research: Research conducted within Biosafety Level/Animal Biosafety Level (BSL/ABSL) 1–4 containment facilities, including spaces such as vivarium, core facilities, or clinical settings. It does not include the deliberate release of a biohazard outside of biocontainment, such as field release research.

National Biosafety Data and Safety Analysis Center: A Federally Funded Research and Development Center (FFRDC) established under this policy to independently aggregate, de-identify, and analyze laboratory biosafety incident data, near-misses, and anomalies for the purpose of advancing the metascience of biosafety.

NIH-supported research: All research funded in whole or in part by NIH. This includes research conducted by the NIH intramural research program, and funded or conducted by extramural grants, contracts, other transactions, or other funding agreements, regardless of NIH funding level or funding mechanism.

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).

Prions and self-aggregating proteins: Misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals.

Toxin: A protein or peptide produced by living organisms that causes harm in humans.

Wild type: Naturally occurring organisms, cells, or viruses without deliberately introduced genetic modifications.

Zoonotic: An agent reasonably suspected of transmission from animals to humans with the potential to cause human disease.

Section III. Roles and Responsibilities

Section III–A Responsibilities of the Institution

An institution conducting or sponsoring research subject to the NIH Biosafety Policy is responsible for ensuring that such research is conducted in full compliance with the Policy as a term and condition of NIH funding. 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) (*https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.1.2_recipient_staff.htm*) 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 BSL3/ABSL–3 or BSL4/ABSL–4 laboratory, research with GDMOs, has a BSO, receives NIH funding, and/or has an externally administered IBC.

- Other pertinent information requested by NIH.

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 addition, IBC meeting minutes and incident reports must be publicly posted for a minimum of five years. Records may need to be retained for longer durations in accordance with other requirements of the NIH GPS as applicable. When incident reports or meeting minutes contain records related to awards, they must be maintained for at least as long as stated in this requirement and must be made available to the public during this time if requested.

Incident reports may contain records related to multiple protocols which may be in different stages of the grant cycle.

The institution is responsible for ensuring appropriate training regarding laboratory safety and implementation for the IBC Chair and members, the BSO and other containment experts (when applicable), Principal Investigators (PI), and laboratory staff.

The institution may be required to establish and maintain an occupational health and safety program (OHSP) based on other regulations and policies. If an OHSP is required under those regulations and policies, or if it is needed based on research conducted, it should be maintained as part of the overall biosafety program. The role of the OHSP to support biosafety will depend on the facility, research activities, and biohazards involved.

Section III–B Responsibilities of the Institutional Biosafety Committee (IBC)

The institution shall establish an IBC to meet the criteria outlined in this Policy. Additional responsibilities may be added, as needed by the institution, whose responsibilities need not be restricted to research within the scope of the Policy. The IBC must meet the following minimum requirements.

IBC Membership

The IBC must have at least five members who have appropriate expertise, experience, and the capability to assess research involving biohazards and identify any potential risk to institutional personnel, public health, or the environment, and to determine the appropriate biosafety, and biosecurity measures, when appropriate, to mitigate those risks. The IBC should include individuals with expertise in biological safety and physical containment, and include, or have available on an *ad hoc* basis, individuals knowledgeable in institutional commitments and policies, applicable law, security, standards of professional conduct and practice, community attitudes, and the environment, as appropriate.

The following individuals must be appointed as voting members:

- A BSO, when the institution conducts research at BSL–3, BSL–4 or research involving GDMOs.
- At least one member with expertise in animal containment principles, when the institution conducts research, subject to the Policy, in animals that are of a size or have growth requirements that preclude housing in primary containment isolators, or an equivalent means of primary containment, including but not limited to agricultural animals and other animal species.
- At least one member with adequate expertise in ecological or environmental risk assessment, when reviewing and approving research involving GDMOs. *Ad hoc* consultants may be used if necessary.
- 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.

The institution should appoint other individuals to the IBC, as needed for the types of research conducted at the institution, or use *ad hoc* consultants, as appropriate.

IBC Functions

The IBC, or its delegate as applicable, is responsible for:

- 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. This review shall include: (1) independent risk assessment (see Section V ''Risk Assessment and Mitigation for Research Involving Biohazards'') of the biocontainment levels required for the proposed research; (2) assessment of the facilities, procedures, practices, training, and expertise of personnel involved in the research; (3) in cases of research involving human research participants, the assessment should focus on biosafety issues (*e.g.,* product administration, shedding). IBC oversight may conclude after the last participant is administered the final dose of product. However, IBCs may choose to establish other endpoints for oversight, based on their biosafety assessment of the proposed research.
  - 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.
  - When possible and consistent with protection of privacy, proprietary interests, and national security concerns, the institution is encouraged to be maximally transparent and open its IBC meetings to the public.
- Taking IBC meeting minutes and approving them no later than their next convened meeting. The IBC must post the approved minutes on a public-facing web page on the website of the institution, using the required meeting minutes template. Minutes should be posted immediately after approval and once all appropriate and allowable redactions have been made.
- Notifying the PI when the research is approved, including the required biocontainment level, any biosafety requirements, or any other conditions specified as part of the approval. Approval should be granted for a period not to exceed three years, at which time a *de novo* registration submission and review is required. 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.
- Lowering containment levels for certain experiments conducted at BSL–2, as specified in Section IV ''Categories of Oversight for Research Based on Risk.''
- 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 (*https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf*). The IBC may not approve such research until authorized by NIH and any other applicable Federal, State, or local entities.

- Petitioning NIH to determine the appropriate biocontainment level for research involving emerging, novel, or zoonotic biological agents, or to lower the minimum containment for research involving RG3 and RG4 agents that have not previously been approved by NIH. Initial requests should be submitted to NIH by the IBC Chair or BSO and include a full description of:
  - The agent and specific modifications to the agent (*e.g.,* attenuation);
  - The biological system(s) and experimental manipulations that will be employed, such as:
    - All biological reagents (*e.g.,* plasmids, cell lines, prokaryotic hosts) that will be used in the experiment(s), and
    - Types of experiments to be performed (*e.g.,* tissue culture, animal work).
  - The IBC's risk assessment of the proposed research activities and the proposed BSLs at which each of these operations will occur, along with any special practices or procedures;
  - Supporting documentation such as published or investigator-generated data demonstrating the attenuation or loss of function of the agent that the IBC reviewed as part of its risk assessment; and
  - Other pertinent information.

  The IBC may not approve the lowering of biocontainment for such research until authorized by NIH and any other applicable Federal, State or local entities.
- 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.
- Adopting plans which include 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.
- Reviewing incidents that occur during the conduct of research subject to the Policy, to ensure the appropriate response occurred, and to determine if additional biosafety measures are warranted to mitigate the risk of future similar incidents.
- Reporting certain incidents to NIH that pose a significant risk to human health, using the required incident reporting template. Such incidents require immediate notification to NIH (within 24 hours or as soon as the institution becomes aware of the incident), followed by a full report once all information is gathered (no later than 30 days). This includes incidents that involve:
  - A confirmed or potential laboratory-acquired infection (LAI);
  - Any loss of containment/release that has the potential for community risk;
  - Any incident at BSL–3/ABSL–3 or BSL–4/ABSL–4, including:
    - Potential exposures involving a personal injury, and/or when medical treatment is sought after the incident to address the possibility of a LAI;
    - 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;
    - Biological agent inventory and security issues that may have public health consequences.
  - Any incidents involving exposures at BSL–2/ABSL–2 that require agent-specific treatment beyond basic first aid; and
  - 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.

  If treatment is provided to an exposed individual due to the potential presence of adventitious agents (*e.g.,* non-human primate Herpes B or blood borne pathogen prophylaxis) and not agent(s) deliberately involved in the research, no report is required unless a LAI results from the exposure, in which case the incident must be reported to NIH.
- Reviewing certain lower-risk incidents described below that do not require reporting to NIH. Such incidents must be reported to and addressed by the IBC. The IBC should determine whether the appropriate response occurred, and if additional biosafety measures are warranted to mitigate the risk of future similar incidents. Such incidents include:
  - 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)
  - 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.

  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.
- Posting all incident reports on a public-facing web page on the website of the institution, using the required incident reporting template. Final incident reports should be posted within 30 days of NIH's final response (when reportable to NIH) or IBC/institutional review and finalization (when not reportable to NIH) and once all appropriate and allowable redactions have been made. For incidents reportable to NIH, NIH's final response must be posted along with the final incident report.
- Performing other functions as may be delegated to the IBC by the institution.

Biological Safety Officer (BSO)

A BSO must be appointed when the institution conducts research subject to the Policy i) at BSL–3 or 4, or ii) involving GDMOs.

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.
- Reporting to the IBC and the institution any significant problems, violations of the Policy, or any significant research-related incidents of which the BSO becomes aware.
- Responding to and investigating research-related incidents occurring during the conduct of research subject to the Policy.
- Providing technical advice to research personnel and the IBC.

If an institution does not designate a BSO, the institution must assign another official to take on these responsibilities.

Section III–C Responsibilities of the Principal Investigator

The responsibilities of the PI include:

- Ensuring no research within the scope of this Policy is conducted until approved by the IBC, or IBC delegate, and has met all other requirements of the Policy.
- Reporting any incidents occurring during the conduct of research subject to the Policy (See incident reporting requirements in Section III–B for further details).
- Ensuring all laboratory personnel under their supervision understand the

requirements of the Policy and have received adequate biosafety training for the research they will be conducting.

- 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.
- Making an initial risk assessment to determine a risk mitigation strategy, including levels of physical containment and other biosafety practices as appropriate for the safe conduct of the proposed research.
- Selecting appropriate biocontainment facilities and equipment, and biosafety practices and procedures for the safe conduct of proposed research.
- 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.
- Making available to all laboratory personnel the protocols that describe all biohazards and the biosafety precautions to be taken.
- 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.
- Informing the laboratory staff of the reasons and provisions for any occupational health or exposure response procedures, advised or required.
- Supervising the performance of laboratory staff to ensure that the required safety practices and techniques are employed and correcting any errors.
- Ensuring the integrity, maintenance, and correct functioning of facilities, physical containment equipment, and personal protective equipment.

Institutions are further authorized and encouraged to submit voluntary, confidential reports regarding near-misses, secondary failures, or procedural issues to the National Biosafety Data and Safety Analysis Center (NBDSAC). The NIH shall not utilize the voluntarily submitted data for enforcement or action on funding, provided the incident did not result in an environmental release or a LAI. All data maintained within the NBDSAC repository must be de-identified to protect individual and institutional privacy, but institutions have flexibility in what scientific information they choose to share.

Section III–D Responsibilities of the National Institutes of Health

NIH is responsible for:

- Promulgating requirements and guidance necessary to implement the NIH Biosafety Policy.
- 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.
- Determining the appropriate containment level for research involving wild type or genetically modified RG3 or RG4 biological agents (*e.g.,* experiments with attenuated or replication-defective constructs) for initial requests to lower containment.
- Publishing approved determinations of appropriate lower containment for research involving wild type or genetically modified RG3 or RG4 biological agents.
- Reviewing requests for lowering containment levels in a timely manner and revising the risk classification of biological agents in conjunction with other Federal agencies as applicable.
- Interpreting this Policy for cases in which the Policy does not specifically assign containment levels.
- Requesting and negotiating, approving or disapproving, and as necessary, restricting or withdrawing approval of Assurances.
- Reviewing and responding in a timely manner to reports of incidents subject to the Policy, that require reporting to NIH.
- Verifying the institutional response to incidents subject to the Policy is appropriate, and when applicable, indicating when additional action is required by the institution.
- Generating and publishing an Annual Incident Summary Report that allows for trends to be identified, promote transparency, and to provide assurance that NIH is aware of and has oversight of incidents occurring at our grantee institutions.
- Conducting outreach and education on biosafety and the requirements of the Policy.

Section IV Categories of Oversight for Research Based on Risk

The scope of biohazards defined in the Policy is broad; however, different categories of research will require different levels of oversight based on risk. Certain research associated with higher levels of risk or uncertainty must be reviewed and approved at the Federal level by NIH. This research also must be reviewed and approved by the IBC, who may require additional biosafety provisions based upon its risk assessment of the research and local knowledge of facilities features and personnel capacities. Other research must be reviewed and approved by the IBC or delegated for review and approval by an individual or sub-group of the IBC for research of lower risk.

Section IV–1 Research That Requires NIH and IBC Approval Before Initiation

Review and approval for determination of appropriate containment and biosafety practices and procedures must be obtained from NIH for higher risk research including:

- 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.
- 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).
- Initial requests for NIH to lower containment below BSL–2 for research involving GDMOs.

Initiation of research may proceed after approvals from both NIH and the IBC. The IBC may stipulate higher containment or additional biosafety precautions.

Section IV–2 Research That Requires IBC Review and Approval Before Initiation

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:

- Research involving RG3 or RG4 wild-type biological agents.
- Research involving genetically modified cells, viruses, or organisms, other than plants (*e.g.,* certain vectors, replicons, gene drive modified biological agents, GDMOs).
- Research involving toxins listed as Select Agents (*https://www.selectagents.gov/sat/list.htm*), prions, or other self-aggregating proteins.
- Research with primary cells that may be contaminated by adventitious agents.
- 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.
- 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.

The deliberate transfer of a clinical product, that would otherwise fall under the scope of this Policy, into one human research participant conducted under a Food and Drug Administration (FDA) regulated individual patient expanded access Investigational New Drug (IND), or protocol, including for emergency use, is not research subject to this Policy and does not need to be submitted to an IBC for review and approval.

Section IV–3 Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members

Review and approval must be obtained before initiation from an individual or a subgroup of IBC members for minor amendments to previously IBC approved submissions or for research including:

- 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.

Individuals or a subgroup of IBC members conducting delegated reviews may elevate review and approval to the full IBC as necessary. The IBC must be notified of all approvals granted by delegated review when granted, and the approval must be reported in full to the IBC at its next scheduled meeting for inclusion in the minutes.

Section V. Risk Assessment and Mitigation for Research Involving Biohazards

Investigators and IBCs must conduct a comprehensive risk assessment prior to initiating research involving biohazards. Conducting a risk assessment is required as a key part of the responsibilities of investigators and IBCs to provide for the safe conduct of the research. A risk assessment is essential to identify the likelihood of an accidental exposure to, or release of, a biohazard during the conduct of research, and the potential severity of harm to research personnel, the public, or the environment. Based on the risk assessment, an appropriate risk mitigation strategy must be developed to lower the risks associated with the research to an acceptable level.

A risk assessment is a multistep process that involves consideration of:

- The characteristics of the biohazard.
- Manipulations of the biohazard.
- Genetic modifications, if any.

All of these steps are critical to assessing the risks associated with constructing or handling the biohazard. The risks are addressed in the risk mitigation strategy through determination of appropriate physical and biological containment, laboratory safety procedures and practices, personal protective equipment, and training.

Based on the specific research to be conducted, the factors to consider in the risk assessment will differ. The considerations for risk assessment in this document are harmonized with the BMBL, and the BMBL should serve as a primary handbook for conducting risk assessments. Additional requirements and considerations specific to NIH-supported research, including genetic modification of agents or organisms and manipulations, are presented here.

Section V–A. Requirements and Considerations for Risk Assessment of the Characteristics of the Biohazard

The first step of risk assessment must be to understand the risks associated with the types of biohazards involved in the research. The characteristics of wild-type bacteria, viruses, fungi, or parasites must be evaluated for their ability to cause disease in humans, population impact, and the availability of countermeasures for that disease. Certain transgenic animals or GDMOs present different risks and may also impact populations or the environment. Risks associated with handling cells or tissues *in vitro* culture may vary depending on whether the research involves a well-established cell line, or primary cells, or tissues that may harbor adventitious agents, which may carry additional risks. Work with many proteins presents risks more akin to chemical hazards because they are incapable of replicating. Prions, and other proteins that aggregate, are capable of spreading and causing neurodegenerative diseases. Risks associated with toxins may differ depending on the potency, amounts used, and whether they are in a form allowing intracellular access (*e.g.,* toxin single subunit or holoenzyme).

Biological agents that cause disease in humans are classified into four RGs based on pathogen characteristics and population impacts. Pathogen characteristics include severity of illness, case fatality rate, route of exposure, infectious dose, rate of transmission, and environmental prevalence and stability. Population impacts include status of immunity in humans, availability of preventive or therapeutic countermeasures, vulnerable individuals or groups within populations, and burden on health care systems.

Representative genera and species of bacteria, viruses, fungal and parasitic agents are classified into RGs based on the potential effect on a healthy human adult; however, some individuals may have increased susceptibility, due to preexisting conditions, prescribed medications, compromised immunity, pregnancy, or breast feeding (which may increase exposure of infants to some biological agents), among other factors. Absence of agent specification in the list of RG2- RG4 does not imply automatic or implicit classification as RG1. A risk assessment must be conducted based on the known and potential properties of the agents not listed and their relationship to agents that are listed. Special attention should be given to novel, emerging, or zoonotic agents (Refer to Section IV–1 of this Policy ''Research That Requires NIH and IBC Approval Before Initiation'').

Additional resources can be found in the agent summary statements and minimum BSL recommendations in the BMBL. The BMBL also provides information regarding prions and some agents that infect animals. The Federal Select Agent Program (*https://www.selectagents.gov/index.htm*) oversees the possession, use, and transfer of Select Agents and Toxins, which pose a threat to the public and animal or plant health. All entities must follow the requirements laid out in the Select Agent Regulations (*https://www.selectagents.gov/regulations/index.htm*).

Section V–B. Requirements and Considerations for Risk Assessment for Genetically Modified Biological Agents, Cells, or Organisms

The starting point for risk assessment must be based on the risks associated

with the parent agent, cell, or organism; but those risks may be affected by changes due to genetic modifications, which must also be assessed. Changes to agent pathogenicity, transmissibility, host or tissue range, etc., may increase risks compared to the parent. Genetic modifications may be used to create attenuated or replication-defective agents with less risk than the parent. Modifications may affect toxicity, physiological activity, or allergenicity. The source and function of the nucleic acid sequence altered, introduced, or deleted in a genetically modified biohazard affects risk (*e.g.,* modifications to RG 2–4 agents versus introduction of RG 2–4 sequence into non-pathogenic prokaryotes or lower eukaryotes).

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. Specific attention must be paid to risks of an unintended release from the laboratory and the potential impact on humans, other populations of organisms, and the environment.

Section V–C. Requirements and Considerations for Risk Assessment for Synthetic Biological Agents or Emerging Technologies

As synthetic biology and other uses of emerging technologies move forward, it may become easier to develop an organism containing genetic sequences from multiple sources such that the parent agent may not be obvious when examined out of context. In such cases, the risk assessment must include at least three levels of analysis:

- The first involves the RG, if available, of the source(s) of the sequences.
- The second involves an assessment of the functions that may be encoded by these sequences (*e.g.,* virulence or transmissibility).
- The third involves the probability of any synergistic effects of the genetic sequences.

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, and the predicted function or intended purpose of each contributing sequence. The initial assumption should be that all sequences will function as they did in the original host context.

The combination of certain sequences in a new biological context may result in an organism whose risk profile could be higher than that of the contributing organisms or sequences. The synergistic function of these sequences may be one of the key attributes to consider in deciding whether a higher containment level is warranted, at least until further assessments can be carried out. 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.

Section V–D. Requirements and Considerations for Risk Assessment of Manipulations of Biohazards

Manipulations of the biohazard must also be considered as they may alter the risks of personnel exposure or release to the environment. Different manipulations may introduce different levels of risk (*e.g.,* use of sharps, generation of aerosols, tissue culture, animal procedures, large culture volumes). For work with biological agents, investigators and IBCs must assess whether handling could result in an exposure through possible routes of transmission (*e.g.,* inoculation, animal bite, aerosolization of respiratory viruses, etc.).

Section V–E. Risk Mitigation Strategies and Laboratory Containment

Informed by the risk assessment, investigators and IBCs must develop a risk mitigation strategy to help minimize the identified risks of exposure or release of the biohazard. Combinations of mitigation measures to be applied include:

- Physical containment through facility design (*e.g.,* ventilation, decontamination systems, laboratory configuration) and primary barriers such as biosafety cabinets.
- Biological containment based on the design of the agent or organism, with consideration of the potential for and probability of off-target effects.
- Safety equipment and personal protective equipment (PPE).
- Standard and special practices, procedures, and training.

Four BSLs based on these combinations are described in the BMBL. The BMBL provides the elements for each BSL with protections that increase as the risks associated with the research increase. The BMBL also provides criteria for the animal biosafety level (ABSL) required for work with animals, including in loose housing or open pens. The agent summary sections of the BMBL include some recommendations for the minimum BSL for work with known wild-type agents, toxins, or prions using certain standard procedures. However, investigators and IBCs must conduct a risk assessment for each specific experiment. While both RGs and BSLs/ABSLs have four classification categories (RG1–RG4), these concepts are related but not equivalent. RGs describe the biological properties of the agent, and depending on the work proposed, the appropriate BSL/ABSL used to safely handle the agent may be lower or higher. For instance, while research with an RG3 agent often may be conducted at BSL–3, the research may be conducted at a lower or higher level of laboratory containment based on a thorough consideration of how the agent is going to be manipulated, and if applicable, what genetic modifications are applied to the agent. Also, depending on the specific research to be conducted, the BSL may be combined with enhancements (*e.g.,* work with a respiratory virus in a BSL–2 laboratory may require additional respiratory PPE).

Certain research is required to be conducted at a minimum BSL.

- Research involving GDMOs must be conducted at a minimum of BSL–2 containment.
- Experiments with influenza viruses (*e.g.,* reassortants, generation by reverse genetics of chimeric viruses with reassorted segments, introduction of specific mutations) must be conducted at the BSL containment corresponding to the RG of the virus that was the source of the majority of segments in the virus (*e.g.,* experiments with viruses containing a majority of segments from a RG3 virus must be conducted at BSL–3).
- Experiments with influenza viruses containing genes or segments from 1918–1919 H1N1 (1918 H1N1), human H2N2 (1957–1968) and highly pathogenic avian influenza H5N1 strains within the Goose/Guangdong/96-like H5 lineage (HPAI H5N1), including, but not limited to, strains of HPAI H5N1 virus that are transmissible among mammals by respiratory droplets, as demonstrated in an appropriate animal model or clinically in humans, must be conducted at BSL–3 enhanced containment and an occupational health plan is required.

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 universal precautions such as

gloves, and eye and respiratory protection.

In addition to physical containment, biological or environmental risk mitigation strategies may be applicable for certain biohazards. Biological containment may involve genetically modified biohazards that have been altered to decrease risks by limiting infectivity or replication in specific hosts, or dissemination and survival in the environment outside the laboratory. Environmental containment strategies may include conducting research in a geographically isolated area, an environment in which biohazard organisms are not able to survive (*e.g.,* tropical organism in an arctic climate) or a genetically isolated environment (*e.g.,* an area with no native organisms that could mate with non-native laboratory organisms).

Request for Input

NIH seeks 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. Respondents are free to address any or all of the topics listed or any other relevant topics for NIH to consider. Respondents should not feel compelled to address all items. NIH will consider all comments received. Comments are welcome on all aspects of the draft policy, including the scope, risk assessment, categories of oversight based on risk, roles and responsibilities, IBC functions, and procedures. NIH is also seeking comments on draft incident reporting and IBC meeting minute templates which can be found here (*https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2.*

NIH also seeks comments on specific topics listed below:

- 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.
- 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.
- 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) (*https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf*).
- 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.
- Feedback on the implementation resources and areas in which additional guidance would be beneficial.

This notice is being published in accordance with a statement made by the NIH Director found here (*https://www.nih.gov/about-nih/nih-director/statements/nih-launches-initiative-modernize-strengthen-biosafety-oversight*).

Dated: September 8, 2026.

Matthew Memoli,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2026–18646 Filed 9–11–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0037]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Refugee/Asylee Relative Petition

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until November 13, 2026.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0037 in the body of the letter, the agency name and Docket ID USCIS–2007–0030. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2007–0030.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, John R. Pfirrmann-Powell, Acting Deputy Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov*, or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2007–0030 in the search box. Comments must be submitted in English, or an English translation must be provided. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov*, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov*.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;