EBRC Engineering Biology Research Consortium

Response to NIH Request for Information on
Draft NIH Biosafety Policy for Research Involving Biohazards

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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.