



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 <i>biohazard</i> and revise the definitions of <i>biological agent</i> , <i>toxin</i> , <i>genetic modification</i> , <i>laboratory</i>

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	<i>research</i> , and <i>genetically modified organism (GDMO)</i> 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, Pls, 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,

A handwritten signature in dark ink, reading "Robin Izzo". The signature is written in a cursive, flowing style with a prominent initial "R".

Robin Izzo
President
Campus Safety, Health, and Environmental Management Association