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Submitted electronically via the NIH Office of Science Policy comment portal

Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 630,
Bethesda, MD, 20892

RE: Comments of the Federation of American Societies for Experimental Biology (FASEB) in response to a request for information on Draft National Institutes of Health (NIH) Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112

Dear NIH Office of Science Policy:

On behalf of the Federation of American Societies for Experimental Biology (FASEB), a federation of 21 scientific societies representing more than 100,000 biological and biomedical researchers, we appreciate the opportunity to respond to NIH's Request for Information on the Draft NIH Biosafety Policy for Research Involving Biohazards. FASEB commends NIH for the extensive community engagement undertaken during development of the proposal, including regional listening sessions and direct stakeholder engagement, and welcomes continued dialogue as the Policy is finalized.

FASEB thanks NIH for taking on a need the research community has long recognized. The NIH Guidelines were built around recombinant DNA, while the biological systems and hazards investigators work with today extend well beyond that frame. The draft Policy addresses a long-standing mismatch in which work with a wild-type Risk Group 3 pathogen could fall outside the purview of an Institutional Biosafety Committee (IBC), while work with a low-risk reporter plasmid, such as one expressing green fluorescent protein (GFP), requires registration. By extending the scope of oversight to biohazards generally and tiering review by risk, the draft Policy moves institutional oversight closer to the realities scientists face in the laboratory.

FASEB further recognizes the need for biosafety oversight to evolve alongside advances in biomedical science. Modern research increasingly involves genetically modified organisms and biological agents, synthetic biology, emerging pathogens, complex experimental systems, and research that may not fit neatly within the categories established when the current NIH Guidelines were developed. The draft policy appropriately recognizes these changes and proposes a broader framework that places risk assessment at the center of biosafety decision-making.

As NIH considers the final policy, FASEB encourages particular attention to ensuring that the framework remains risk-based, scientifically grounded, predictable, and proportionate to the risks associated with individual research activities. For researchers, the success of the policy will depend not only on what

research falls within its scope but also on how readily investigators can determine what requirements apply to their work, how much documentation and review are required, and how quickly questions can be resolved when the existing guidance does not provide a clear answer.

1. The Scope of Policy Should Be Clearly Defined While Preserving A Risk-Based Approach

FASEB recognizes the need for expanding NIH biosafety oversight beyond the current focus on recombinant or synthetic nucleic acid molecules. The proposed policy would encompass a substantially broader range of biohazards present in modern labs, bringing oversight closer to actual risk. FASEB also appreciates that the draft Policy's four-part definition of "research involving biohazards" (Section II) gives investigators a single, citable reference point.

FASEB's principal concern is that the operative threshold of research presenting "known or potential risk to human health" is not sufficiently defined for consistent application. In practice, interpretation of this threshold will fall largely to local IBCs and, by extension, to the investigators whose protocols they review. Because IBC composition, experience, and institutional practices vary, comparable protocols could be scoped differently depending on where an investigator conducts the research. This has practical consequences for individual investigators, particularly those establishing new research programs, because the initial scope determination may determine whether a project requires full IBC review, delegated review, or no review under the Policy. FASEB recommends that NIH supplement the final Policy with a non-exhaustive set of worked scope examples, ideally developed with input from practicing biosafety professionals and investigators, to promote greater consistency in application.

FASEB also asks NIH to address potential gaps at the boundaries of the proposed framework. First, the definition of "laboratory research" excludes deliberate release of a biohazard outside of biocontainment, including field-release research. NIH should clarify what oversight framework governs field-release research involving gene drive modified organisms conducted with NIH funds and how that framework relates to the Policy's broader biosafety oversight structure. Second, the Table of Changes indicates that genetically modified plants and plant pathogens that do not cause human disease would no longer be covered by the Biosafety Policy. FASEB assumes this reflects existing oversight through USDA-APHIS or other applicable frameworks but recommends that NIH confirm this explicitly so that investigators working at the boundary of plant, human, and animal pathology can readily determine which oversight requirements apply.

FASEB also recommends that NIH establish a defined transition period for implementation. The draft Policy would apply to all existing awards and agreements as of the effective date, yet many active projects were designed and initiated under the current, narrower Guidelines. Investigators should not be required to interrupt ongoing work or undertake substantial new registration requirements without

adequate lead time. A phased transition would reduce disruption to ongoing research while allowing institutions and investigators to bring active protocols into compliance.

FASEB also asks NIH to help institutions and investigators navigate the relationship between this draft Policy and the U.S. Government Policy for Stopping High-Risk Life Sciences Research issued on July 20, 2026, which addresses dangerous gain-of-function (DGOF) research and international research of concern (IROC). The policies seem to overlap in scope, particularly in the case of DGOF, but institute different frameworks and requirements for compliance: e.g., two separate committees of at least five members each (the Institutional Review Entity and the IBC); two definitions of "biological agent"; two 24-hour notification requirements with different triggers and different recipients; and two risk vocabularies (Risk Groups and Biosafety Levels in this Policy; DGOF, potential DGOF, and risk-benefit analysis in the other). Because the two frameworks are being implemented on different timelines, with federally funded potential DGOF research remaining suspended until agency guidance and review mechanisms are in place, institutions are effectively building two oversight structures at once with uncertainty over final implementation. FASEB respectfully suggests that NIH, in the final Policy or accompanying implementation resources, clarify how the two frameworks are intended to operate together and note where institutions should expect differences, so that investigators and institutions are not left to reconcile them on their own.

2. Tiered Oversight Should Translate the Risk-Based Principle Into Proportionate Review

FASEB supports the overall architecture of tiered oversight described in Sections III and IV, which calibrates review by NIH and IBCs to the degree of risk and uncertainty presented by the research. FASEB particularly welcomes delegated review (Section IV-3), which creates an opportunity to reduce full-committee review for lower-risk, well-characterized research, including certain RG1 genetically modified agents, well-characterized cell lines, and standard reporter or replication-incompetent viral vector systems.

From the perspective of the individual investigator, however, the value of delegated review will be determined by whether it produces a meaningful improvement in review timeliness. The draft requires delegated approvals to be reported to the full IBC and included in meeting minutes, but it does not establish an expectation for how quickly a delegated reviewer should act. Without such an expectation, delegated review could become an additional administrative queue rather than a streamlined alternative to full-committee review. FASEB recommends that NIH establish a reasonable turnaround-time expectation for delegated determinations or encourage transparent reporting of delegated-review timelines so that the pathway's effectiveness can be evaluated.

A related burden can arise during the approved research period itself, apart from renewal. Gene therapy platforms built on well-characterized vector backbones, such as adeno-associated virus (AAV) or adenoviral systems, are commonly used to test a large number of candidate transgenes or therapeutic

targets in preclinical models, with the specific payload often revised iteratively as early results inform the next round of testing. Section III-B requires IBC review and approval of any change with the potential to affect the original biosafety assessment but does not clarify whether a change limited to the transgene or therapeutic target, within an already-characterized and approved vector platform, necessarily requires a new risk assessment each time, as opposed to an expedited or delegated amendment review. Left unclarified, this could impose a substantial and recurring administrative burden on investigators conducting iterative preclinical work even where the vector platform's own biosafety profile has not changed. FASEB recommends that NIH clarify how payload-only amendments to a previously assessed platform should be reviewed, and consider making this category of change explicitly eligible for delegated review, consistent with the existing delegated-review category for replication-incompetent, non-integrating viral vectors expressing low-risk transgenes (Section IV-3), where the modification does not alter the vector's containment-relevant characteristics such as tropism, replication competence, or shedding potential.

FASEB is also concerned about the requirement that IBC approval not exceed three years, after which a full *de novo* registration and review is required (Section III-B), regardless of whether the approved research has changed. For investigators working under longer award cycles, including training grants and multi-year research awards, this could create recurring review obligations that are not responsive to any change in risk. The Policy already requires IBC review of changes that have the potential to affect the original biosafety assessment. FASEB therefore recommends an abbreviated renewal pathway for protocols that remain materially unchanged, such as investigator attestation of no material change subject to IBC or delegated confirmation, with full *de novo* review reserved for research that has changed in scope, agent, or risk profile.

FASEB recognizes that the draft's transparency and accountability measures, including public assurances, rosters, and meeting minutes, serve legitimate public interests. Our recommendations are intended to preserve those objectives while ensuring that the administrative costs associated with them remain proportionate and do not fall disproportionately on investigators, particularly early-career researchers who may have limited administrative support.

3. Risk Groups Should Remain a Useful Starting Point Within a Protocol-Specific BMBL Framework

FASEB supports retaining Risk Groups (RGs) as the baseline framework for risk assessment. RGs are the classification system most researchers encounter through biosafety training, the BMBL agent summary statements, and the scientific literature. Complementing this, Biosafety Levels (BSLs) describe containment practices and safeguards rather than the intrinsic biological properties of an agent. The final Policy should therefore preserve the distinction, which is present in the draft policy, and treat RG classification as a biological baseline, with BSL and ABSL determinations informed by protocol-specific risk assessment.

FASEB encourages NIH to develop implementation resources that make this relationship explicit through practical examples. Researchers would benefit from examples showing how an initial RG classification is incorporated into the risk assessment, how specific manipulations may change the risk profile, and how those considerations ultimately inform the selection of a BSL or additional safeguards.

FASEB also asks NIH to ensure that Appendix B (RG classifications) and any implementation guidance NIH issues remain actively synchronized with the BMBL, which the draft Policy designates as the "primary handbook" for risk assessment (Section V). Investigators should not encounter a situation in which NIH's own appendix and the BMBL's agent summary statements diverge, even temporarily, as this creates exactly the kind of interpretive ambiguity this section is otherwise trying to eliminate.

4. Novel, Emerging, and Synthetic Biological Systems Require a Clear and Timely Pathway for Risk Determination

The draft policy appropriately recognizes that rapidly advancing technologies can produce biological systems for which conventional classification schemes are insufficient. Section V-C's three-part framework for synthetic and chimeric constructs, which considers the Risk Groups of sequence sources, the functions encoded by those sequences, and the potential for synergistic effects in a new biological context, appropriately acknowledges the uncertainty researchers are likely to face. The risk profile of a novel construct may not be readily inferred from any single parent organism or sequence.

Operationalizing this framework, however, may prove challenging. Its application may require investigators to undertake a level of risk synthesis for which many have not received formal training, particularly where empirical information sufficient to characterize the resulting system is limited. These circumstances also create the greatest potential for inconsistent interpretation across IBCs. The draft policy further provides that IBCs must petition NIH for a determination when the relevant Risk Group classification or containment recommendation is not available in the BMBL. While this provides an important safeguard, its effectiveness will depend on a clear and timely process for resolving such requests.

FASEB recommends that NIH develop and periodically update worked examples for synthetic and chimeric constructs, potentially as a living resource that can evolve as the underlying science develops. Such examples would help investigators and IBCs apply the framework consistently as new classes of biological systems emerge.

The need for a predictable process is not merely administrative. Research on hantaviruses illustrates how quickly the underlying science can move: shifts in reservoir host range, transmission patterns, or clinical presentation can emerge with little warning, and investigators studying these changes may need a biocontainment determination quickly in order to generate timely public health information. Under the draft Policy, such research cannot proceed until NIH completes its determination if the relevant

classification or containment recommendation is not already available in the BMBL. FASEB therefore encourages NIH to establish a clear, predictable, and timely process for NIH-level determination requests, including what information must be submitted, how requests will be evaluated, which NIH entity is responsible for the determination, and what timeframe investigators should generally expect, with a mechanism for expedited handling when research responds to an emerging public health threat. Without predictable timelines, research involving emerging agents or technologies could be delayed not because the scientific risk is necessarily high, but because the applicable oversight pathway is uncertain.

Finally, the policy should clarify how investigators should proceed when additional information is needed to characterize the risks associated with a novel biological system. Risk assessment is inherently iterative, and the BMBL recognizes that new information may alter the appropriate mitigation strategy. The policy should facilitate a process in which researchers can update and refine biosafety determinations as evidence develops rather than creating incentives to avoid innovative research because the initial classification is uncertain.

5. Researchers Need Clear Expectations for Compliance and Incident Reporting

FASEB supports the creation of the National Biosafety Data and Safety Analysis Center (NBDSAC) and, in particular, the proposed protection against using voluntarily submitted near-miss data for enforcement or funding decisions when the incident did not result in an environmental release or laboratory-acquired infection. A protected, non-punitive reporting channel can help surface near-misses and procedural weaknesses that might otherwise remain unreported. FASEB encourages NIH to promote NBDSAC directly to investigators and laboratory personnel, as well as institutions and IBCs, so that those closest to laboratory operations understand how the mechanism works and what protections apply.

FASEB notes one practical difficulty with the protection as drafted. It applies only if the incident did not result in an environmental release or a laboratory-acquired infection, but an institution deciding on whether to submit a near-miss report generally cannot know at that point whether either outcome will later materialize. That uncertainty could lead institutions and investigators to hesitate or to forgo reporting, which is the opposite of what the mechanism is meant to achieve. FASEB asks NIH to clarify how and when this condition will be assessed, and to consider whether the protection can attach to good-faith reports based on what was known at the time of submission.

FASEB raises a significant concern regarding the incident-reporting requirements as currently drafted. The incident-reporting template requires disclosure of the name of the principal investigator responsible for the research as a non-redactable data element in every public incident report, while other individuals involved are identified only by position or role. The practical effect is that a PI's name may become permanently and publicly associated with an incident, including events arising from equipment failures, PPE failures, or compliance deficiencies that may not reflect the PI's individual conduct. The concern is

particularly acute for early-career investigators, for whom a public record may remain readily discoverable for years.

FASEB is concerned that this asymmetry may undermine the transparency objectives the reporting framework is intended to advance. Reporting systems function most effectively when individuals can disclose errors, near-misses, and other concerns without an undue expectation of personal attribution. FASEB therefore asks NIH to distinguish between information necessary for Federal oversight and information that must be made public. NIH could retain full identifying information in its non-public records while considering role-based or otherwise limited public attribution when individual responsibility has not been established.

FASEB asks NIH to reconsider whether identifying the PI by name is necessary to achieve the Policy's public transparency goals, as distinct from what NIH needs for its own internal oversight and enforcement purposes. Possible alternatives NIH may wish to consider include identifying the PI by role (consistent with how other individuals are treated) in the public-facing report while retaining full identifying information in the non-public submission to NIH or establishing a delayed or aggregated public reporting mechanism for lower-severity incidents that does not require individual attribution. FASEB recognizes that accountability is a legitimate and necessary goal of this Policy and does not ask NIH to abandon it; we ask that NIH weigh it against the risk of discouraging the very reporting behavior the Policy is designed to surface, and welcome further dialogue with NIH on this question as the Policy is finalized.

FASEB also asks NIH to clarify how enforcement measures tied to institutional noncompliance will be applied when the underlying deficiency is outside an individual investigator's control. For example, an investigator should not be subject to adverse consequences for an institutional lapse in IBC administration, assurance management, or recordkeeping absent a basis for attributing responsibility to that investigator. Implementation guidance should clearly distinguish institutional compliance failures from individual investigator conduct when funding-related consequences are considered.

Finally, with respect to voluntary compliance for non-NIH-funded research, FASEB defers substantially to institutional and research-administration stakeholders that are better positioned to assess incentives for adoption. FASEB notes, however, that voluntary uptake will depend in part on whether the framework is regarded as scientifically credible, operationally feasible, and proportionate to the safety benefit it provides. Institutions outside NIH's direct funding leverage will assess the framework primarily on those merits.

6. Implementation Guidance Should Include Clear, Researcher-Facing Materials

FASEB appreciates NIH's decision to release draft implementation templates alongside the Policy itself, rather than finalizing the Policy first and addressing implementation mechanics later. This sequencing

allows stakeholders to evaluate the Policy's practical operation, not just its stated requirements, and FASEB encourages NIH to continue this practice for the additional implementation resources described in the RFI's background section (IBC function guidance, GDMO biosafety considerations, RG3 influenza containment requirements).

IBC Meeting Minutes Template

The draft template requires, for each new registration and amendment, a "Project Overview" sufficient to document the agent, relevant characteristics, nucleic acid sequences and modifications, experimental manipulations, and proposed containment level, at a level of detail suitable for permanent public posting. In practice, much of this information will originate in the PI's protocol submission. Investigators are therefore being asked not only to document the scientific and biosafety basis for their work, but also to translate that information into public-facing language. FASEB does not object to the transparency objective, but recommends that NIH recognize this as a distinct documentation responsibility and provide PI-facing guidance and model language. Investigators, particularly trainees preparing their first registration, would benefit from examples calibrated to different levels of research complexity.

FASEB also asks NIH to consider the cumulative volume of public documentation that this requirement will generate. Active laboratories may submit multiple registrations and amendments each year, each potentially requiring narrative language suitable for public posting. Clear guidance on the expected level of detail would reduce unnecessary iteration between investigators and IBC staff and help ensure that the transparency requirement does not become a recurrent source of administrative delay.

Incident Reporting Template

Beyond the concern about PI attribution discussed above, FASEB offers three additional observations regarding the incident-reporting template. First, the "nature of the incident" checklist encompasses events spanning a wide range of severity, from failure to obtain IBC approval to needlestick exposures and relatively minor equipment malfunctions, yet the template applies a common reporting structure that includes detailed narrative and root-cause analysis. FASEB recommends that the level of documentation required under Parts 3 and 4 be proportionate to the severity and potential consequences of the incident. Lower-risk, non-NIH-reportable incidents should not necessarily be subject to the same documentation standard as events involving laboratory-acquired infection, significant exposure, or potential community release.

Second, FASEB asks NIH to clarify the "judicious" redaction standard that applies to both templates. The current language leaves substantial discretion to individual institutions and creates risks in both directions. Insufficient guidance could result in public disclosure of technically sensitive construct, vector, or protocol information, including information with potential biosecurity implications, while overly broad redaction could undermine the Policy's transparency objectives. FASEB recommends that NIH establish

concrete, illustrated redaction criteria, developed as appropriate with biosecurity expertise, rather than leaving this determination entirely to individual institutions.

Third, the Policy requires incident reports to be released publicly. Given the structure of the draft reporting form, this public posting could pose security and reputation risk for institutions and investigators. The draft forms expressly include agent inventory and security issues (Section III-B, for BSL-3/ABSL-3 and BSL-4/ABSL-4 work). Together, the public release of this information could reveal which agents are held at which institutions and when controls failed, which may expose institutions and investigators to undue media exposure and reputation harm for what are often routine incidents. It could also lead to additional security concerns and increase security management requirements. FASEB asks NIH to consider whether incidents involving inventory or security issues warrant distinct handling for public posting.

Conclusion: Supporting Safe Research Through Proportionate, Predictable Oversight

FASEB appreciates NIH's continued commitment to a transparent and collaborative process in developing this Policy and looks forward to supporting successful implementation. We would welcome the opportunity to discuss these comments further with NIH staff.

Respectfully,



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