

Submission by the American Association of Immunologists (AAI) in response to the National Institutes of Health (NIH) Request for Information (RFI): Draft NIH Biosafety Policy for Research Involving Biohazards

October 19, 2026

The American Association of Immunologists (AAI) appreciates NIH's efforts to modernize and strengthen biosafety practices when conducting biomedical research. AAI supports NIH's goals of augmenting public safety, transparency, and accountability when it comes to biosafety, but believes that this policy, as written, would not make meaningful progress toward these goals. It would, however, significantly increase the burden on researchers and institutions and slow scientific progress. AAI elaborates on these concerns in each of the categories below.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.

The draft policy significantly expands the scope of research covered by NIH's current biosafety framework beyond research involving recombinant and synthetic nucleic acids to include all wild-type pathogens that cause disease in humans; all genetically modified cells, viruses, and organisms (other than plants) toxins, prions, and other self-aggregating proteins; and, cells and organisms (other than plants) that contain any of the above. This proposal appears to bring many experiments and types of research that have historically been considered to have no or low risk and to be exempt from Institutional Biosafety Committee (IBC) review into the new oversight framework (see Appendix C. Exemptions Under Section III-F-8 of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules). Much of this previously exempt and low-risk research will now require review and approval before initiation. While research listed under Section IV-3 of the current draft policy may be delegated to an individual or subgroup of IBC members, AAI is deeply concerned about the significant increase in administrative burden imposed on investigators, institutions, and IBCs. Further, AAI has significant hesitation about the feasibility of IBCs reviewing and approving such a vast expanse of research, especially when this additional review is unlikely to result in any meaningful improvement in biosafety. AAI urges NIH to carefully consider meaningful exemptions for research that is well characterized, routinely performed, and associated with little to no biosafety risk. Without such exemptions, as were previously allowed, AAI is concerned that IBCs will become overwhelmed with large volumes of low-risk protocols, potentially diverting attention from higher-risk activities that deserve more intensive scrutiny.

AAI is similarly alarmed about the substantial administrative burden imposed by the policy applying to all existing awards and ongoing research activities rather than only newly funded projects. Requiring



institutions to retrospectively review large numbers of ongoing experiments will create substantial workload for investigators, IBCs, and institutions, potentially halting or delaying active research without a corresponding improvement in safety. AAI urges NIH to consider ways to reduce this burden and prioritize the review of higher-risk research.

The draft policy states that “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.” While AAI appreciates NIH’s intent to standardize biosafety across the biomedical research enterprise, AAI is troubled that the policy would expand NIH oversight and authority to non-NIH funded projects. Any effort to harmonize how potentially risky research is conducted across federal agencies should be led by an entity that has broad oversight over federally funded scientific research, not by a single funding agency.

In addition, AAI believes that requiring “*de novo* registration submission and review” every three years, a new obligation not previously required under the old policy, is unnecessarily burdensome and disruptive for the investigator and IBC. Overall, many aspects of this policy place substantial workload and capacity requirements upon the IBC and individual investigators, without additional support. AAI is particularly concerned that smaller institutions with less resources may be excessively burdened by this policy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).

AAI supports the principle that biosafety oversight should be calibrated to risk, and that higher-risk research should receive greater examination than lower-risk research. The delegated review pathway under Section IV-3 is well-intentioned; however, AAI believes the draft policy should provide clearer oversight mechanisms for institutions to conduct streamlined or minimal reviews (if not exemptions) of research previously known to be low risk (e.g., research conducted with transgenic organisms at BSL-1/ABSL-1). Delegating review and approval to one or a subgroup of IBC members only increases the burden on one or more individuals who may or may not have the expertise to accurately determine biosafety risk. Research exempt under the previous policy should, at minimum, undergo an expedited or streamlined review process to reduce administrative burden that otherwise has no clear safety benefit. This approach would better align oversight requirements with actual risk and preserve IBC capacity for activities with true biosafety concerns.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates.

AAI appreciates that NIH places transparency at the forefront of its biosafety policy and supports efforts to standardize incident reporting in ways that facilitate the identification of systemic biosafety issues and promote continuous improvement. At the same time, AAI encourages NIH to carefully consider the



unintended consequences of requiring public posting of all incident reports, in part because incidence reports must contain identifiable information such as principal investigator names and position titles of individuals involved in an incident. Providing even this information, alongside publicly available lab websites that list personnel, enables easy identification of those involved. This raises privacy and security concerns for investigators, research staff, and institutions. In some research areas, including clinical studies and research involving animals, researchers and institutions may be subject to heightened public attention or scrutiny. To balance transparency with safety and privacy concerns, NIH should consider limiting the disclosure of and protecting personally identifiable information.

In addition, mandatory public posting of all incidents, including low-risk incidents, could have the unintended consequence of discouraging reporting if public disclosure carries reputational or personal concerns. If NIH's objective is to strengthen biosecurity practices and identify meaningful areas of improvement or risk across the biomedical research enterprise, AAI encourages NIH to consider mechanisms that better protect individual identities, including anonymous reporting.

6. Feedback on the implementation resources and areas in which additional guidance would be beneficial.

AAI appreciates NIH's commitment to providing additional guidance through supplemental materials and implementation resources. Given the significant expansion in scope of the draft policy, AAI urges NIH to provide specific guidance for the newly covered areas (wild-type pathogens, toxins, etc.) since institutions and IBCs may need to build oversight capacity from scratch. Similarly, guidance should include concrete risk-assessment examples across a range of research types. NIH may also consider developing a tool for investigators and IBCs to quickly determine which oversight tier is appropriate for assessment of a proposal. These resources should be made available well before the implementation date.

Finally, AAI worries that the proposed implementation deadline of six months from final policy publication is inadequate, especially for smaller institutions and/or those without an existing IBC or biosafety oversight infrastructure. In addition, given the expanded scope, current IBCs may lack members with relevant expertise and need sufficient time to establish an appropriate roster.

