

October 19, 2026

Office of Science Policy
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Submitted electronically

Re: Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards;
release date, August 19, 2026 (NOT-OD-26-112)

To the NIH Office of Science Policy:

Public Responsibility in Medicine and Research (PRIM&R), which has more than 3,200 active members throughout the research enterprise, appreciates the opportunity to respond to the NIH on this matter. PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community. PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science. Our perspective is informed by the experiences of professionals responsible for implementing federal research regulations across academic, healthcare, government, and independent research institutions.

NIH states that it is seeking 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.”¹

According to the draft policy, “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.”²

The draft NIH Biosafety Policy describes Institutional Biosafety Committee (IBC) review of certain clinical research, including challenge studies with RG2 or higher wild-type agents. NIH states that it aims to reinforce consistency with IRBs, but the draft does not describe how IBC and IRB review should be coordinated. PRIM&R requests guidance on review sequencing, information sharing between committees, and whether and how biosafety information should be addressed in the informed consent document.

¹ “Request for Information”; <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html>

² “Background”; <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html>

Further, the draft NIH Biosafety Policy requires IBC review and approval for research with primary cells that may be contaminated by “adventitious agents.” It is unclear, however, whether NIH intends this category to include research with human tissue and specimens, which may also be subject to IRB review. We request NIH clarify the intended scope.

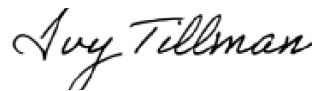
With respect to incident reporting, PRIM&R notes that certain incidents in clinical research may be reportable both under human subjects regulations and under the draft policy’s requirement to notify NIH within 24 hours of incidents that pose a significant risk to human health. These obligations involve different committees, different timelines, and potentially different federal agencies. The draft policy does not appear to address how they should be coordinated. PRIM&R requests guidance on harmonizing these reporting processes.

Lastly, the draft NIH Biosafety Policy states, “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.”³ The draft also states that “clinical research cannot be initiated until IBC, and all other applicable institutional and regulatory authorization(s) and approvals have been obtained.”⁴ The draft policy does not explain, however, how these provisions apply to FDA-regulated trials, including whether IBC review is still required. PRIM&R requests that NIH clarify these requirements, as IRBs and institutions will need this information to fulfill their oversight responsibilities and avoid potential duplicative or conflicting review requirements.

As biosafety oversight continues to evolve, particularly in light of ongoing discussions around dual-use research of concern and the expanding scope of federally funded biomedical research, PRIM&R looks forward to serving as a resource and thought partner to NIH and other federal agencies on these issues.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in cursive script that reads "Ivy Tillman".

Ivy R. Tillman, EdD, CIP
Executive Director
Public Responsibility in Medicine and Research (PRIM&R)

³ Section II, “Scope”; <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html>

⁴ Section IV-2, “Research That Requires IBC Review and Approval Before Initiation”; <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html>