PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

December 23, 2025

Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

RE: Request for Public Comment, Docket No. 2025-21150; Citation No.: 90 FR 54412

To whom it may concern:

Public Responsibility in Medicine & Research (PRIM&R), which has more than 3,500 active members throughout the research enterprise, and the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) appreciate the opportunity to respond to the Office of Science and Technology Policy's (OSTP) request for public comment on "Accelerating the American Scientific Enterprise." The request for comment was published in the *Federal Register* on November 26, 2025. (Docket No. 2025-21150) Although AAHRPP and PRIM&R are responding with the same comments, our organizations submitted them separately to underscore that they reflect the thinking of more than one entity.

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.

AAHRPP, founded in 2001, is a nonprofit organization that accredits human research protection programs. Currently, more than 600 entities from diverse research settings—including hospitals, independent review boards, clinical research organizations, universities, and Veterans Affairs facilities—are accredited.

Below, please find the replies to a selection of the questions posed in OSTP's Request for Information. PRIM&R and AAHRPP will focus their comments on the following key areas identified by the OSTP:

(i) What policy changes to Federal funding mechanisms, procurement processes, or partnership authorities would enable stronger public-private collaboration and allow America to tap into its vast private sector to better drive use-inspired basic and early-stage applied research?

To enable stronger public-private collaboration and more effectively leverage private-sector capacity, federal policy should prioritize continued investment in public-private partnership mechanisms, particularly those involving academic institutions.

If indirect costs are significantly reduced for organizations, we encourage OSTP to develop mechanisms to provide researchers with access to the equipment, facilities, and space they need to carry out science, which could include an effort similar to the former National Center for Research Resources or an expansion of the role of the National Center for Advancing Translational Science (NCATS).

For example, the NCATS Clinical and Translational Science Awards (CTSA) Program led to increased resource sharing among research organizations, encouraged cross-disciplinary research, translation of bench research to clinical research, and clinical research for treatments and programs to improve health care.

In short, CTSA provided resources for organizations to ensure the research included and met the needs of all Americans. The CTSA program model, which "supports a national network of medical institutions that speeds the translation of research discoveries into improved care," could be expanded to help meet today's needs. [1]

(vi) What reforms will enable the American scientific enterprise to pursue more high-risk, high-reward research that could transform our scientific understanding and unlock new technologies, while sustaining the incremental science essential for cumulative production of knowledge?

While our current system has supported the most innovative research in the world, we encourage sound reforms that transform our scientific understanding and unlock new technologies. From an oversight perspective, we encourage the development and availability of frameworks and clear guidance with respect to emerging technologies like AI and the use of pervasive data.

This research raises complex, ethical considerations related to consent, privacy, data security, and potential harms to individuals and society.

Establishing clear, comprehensive, and thoughtfully crafted ethical guidelines for rapidly evolving technologies that compliment existing regulations and standards will strengthen the American scientific enterprise and increase our ability to develop knowledge to benefit society.

Additionally, PRIM&R and AAHRPP recommend increasing investment throughout the U.S. scientific enterprise, including the National Institutes of Health (NIH) and the U.S. National Science Foundation (NSF), to help meet our shared goals of transforming our scientific understanding and unlocking new technologies.

(viii) How can the Federal government leverage and prepare for advances in AI systems that may transform scientific research—including automated hypothesis generation, experimental design, literature synthesis, and autonomous experimentation? What infrastructure investments, organizational models, and workforce development strategies are needed to realize these capabilities while maintaining scientific rigor and research integrity?

[1] Clinical and Translational Science Awards (CTSA) Program; https://ncats.nih.gov/research/research-activities/ctsa

The Federal government can prepare for AI advances of this kind through the creation and support of expert panels with a clear mission to develop and issue best practices and national standards for use of AI in scientific research, focusing on data governance, model evaluation and reproducibility. This panel could develop and recommend training, education materials, and modules to ensure appropriate use. Additionally, a public-private partnership could foster the creation of clear ethical frameworks that guide the development and deployment of transformative AI systems.

PRIM&R and AAHRPP also believe research funding should be directed toward validating new AI-driven methodologies, preventing the deployment of unreliable data and unintentionally biased algorithms.

(ix) What specific Federal statutes, regulations, or policies create unnecessary barriers to scientific research or the deployment of research outcomes? Please describe the barrier, its impact on scientific progress, and potential remedies that would preserve legitimate policy objectives while enabling innovation.

With respect to unnecessary barriers to research, the 2025 National Academies of Sciences, Engineering, and Medicine (NASEM) report, *Simplifying Research Regulations and Policies: Optimizing American Science,* identifies systemic challenges arising from duplicative requirements, inconsistent definitions and thresholds across federal agencies, as well as the absence of proportionate, risk-tiered regulatory approaches. The report documents these issues and proposes actionable options and remedies that maintain essential research oversight and protections while better enabling scientific innovation and the timely translation of research outcomes.

To guide future decision making on research regulations and policies at both the system level and across each of the regulatory areas: a) Harmonize regulations and requirements across federal and state agencies and research institutions to the furthest extent possible; b) Take an approach tiered to the nature, likelihood, and potential consequences of risks for each new regulation or requirement; c) Use technology to simplify the process of complying with regulations and requirements to the greatest extent possible.

Additionally, PRIM&R and AAHRPP believe there are opportunities to streamline the annual reporting process to enhance efficiency and support timely compliance while supporting the current ethical and safety standards. In addition to reducing or eliminating redundant requirements, OSTP could investigate technological solutions that could streamline reporting. For instance, OSTP could explore whether it would be possible to have a single reporting portal for a project, not just for the funding agency, but for all compliance bodies that oversee the project.

Further, innovation is often slowed when research findings are not reproducible. Government funding should increase its focus on reproducible results. This could be done by developing quality standards for government-funded research, even if done in academia, and funding grants sufficiently to enable projects to meet those standards.

Additionally, to reduce burden on scientists, we recommend aligning the Federal conflict of

interest disclosure requirements used by the FDA, NSF, and NIH.

We also encourage the alignment of the FDA's human subjects regulations at 21 CFR 56 with the "Common Rule" (45 CFR 46) to include the single IRB requirement. Harmonization of these regulations creates an environment for collaboration and innovation by eliminating the current parallel system which creates unnecessary burdens. FDA could adopt a single IRB review, creating clear guidance to support such a rollout. We recommend the FDA leverage public-private partnerships to help create single IRB guidance for the regulated community and to lead education efforts in this area. PRIM&R and AAHRPP are well positioned to assist in this capacity.

(xi) How can the Federal government foster closer collaboration among scientists, engineers, and skilled technical workers, and better integrate training pathways, recognizing that breakthrough research often requires deep collaboration between theoretical and applied expertise?

Enhanced funding for the NIH and NSF serves an essential role in transforming collaboration from a theoretical ideal into a functional reality. By dedicating resources to specific funding opportunities that mandate or incentivize cross-disciplinary partnerships, these agencies can break down traditional academic silos that often stifle innovation.

A critical component of this strategy is the implementation of integrated training pathways, which move beyond narrow specialization to provide researchers with the skills needed to simultaneously navigate complex regulatory, ethical, and scientific landscapes.

This structural shift, supported by robust financial backing, ensures researchers are not only encouraged to work together, but are also provided with the formal professional frameworks and administrative support necessary to sustain long-term, high-impact collaborations.

PRIM&R and AAHRPP also suggest the allocation of federal funding to specifically support the establishment of interdisciplinary teams to promote development of proposals (R01) research project grants and (R21) exploratory and developmental research grants.

Further, the federal government could implement a harmonized research ethics framework. This would involve inter-agency collaboration dedicated to advancing ethical research with both animals and humans. By implementing a foundation of ethics for all involved in science and research, we can deepen collaboration, foster trust, and advance the field of science and medicine.

The OSTP should consider creating policies to facilitate the U.S. playing a leading role in harmonizing a global research ethics framework. This will lead to cross training among professionals, creating greater knowledge sharing, which will foster a healthy research enterprise that benefits everyone.

(xii) What policy mechanisms would ensure that the benefits of federally-funded research—including access to resulting technologies, economic opportunities, and improved quality of life—reach all Americans?

To maximize the impact of federally funded research, OSTP should consider requiring dissemination of research results as a condition of funding. This shift requires integrating comprehensive dissemination strategies directly into the proposal phase, ensuring that the sharing of results is thoughtful, feasible, and an expectation of the research. We recognize this recommendation is contextual and must reflect the type of research and data collected, thus requiring inclusion of researchers and oversight experts in partnership with the government to shape the requirements for dissemination of research results. Creation of a standardized infrastructure would ensure that findings are not just published but are permanently discoverable and accessible to the public.

Providing specific line items for the dissemination of research results in grant budgets, separate from the conduct of research, would enable broad communication of research across multiple domains for all stakeholders and would be extremely effective in achieving this goal.

PRIM&R and AAHRPP also recommend the FDA promulgate regulations that permit patient access to rare disease medications, when justified, by enabling rapid labeling updates as evidence changes and by studying how best to clearly communicate uncertainty to patients.

Many genetic medicines (gene therapy, gene editing, antisense RNA) target rare diseases. However, data supporting the safety and efficacy of a rare disease drug are gradually accumulated from smaller single-arm trials and real-world evidence over a prolonged period of time. Current FDA regulations do not easily accommodate rare disease indications, as the small number of patients, severity of disease, and ethical issues can prevent the conduct of randomized control trials and consequently inhibit the development of innovative treatments. As a result, the ability for people with rare diseases to have access to these treatments is limited.

We hope our comments are useful to OSTP. PRIM&R and AAHRPP stand ready to provide any further assistance or input that might be of use. Once again, thank you for the opportunity to provide feedback on this critical issue and for your commitment to developing ethical research practices, as we work together to accelerate the American scientific enterprise.

Sincerely,

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