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Michael Kratsios
Director
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Re: Notice of Request for Information; Accelerating the American Scientific Enterprise (90 FR 54412,)

Submitted online via regulations.gov; Docket OSTP–TECH–2025–0100

Dear Mr. Kratsios:

The AAMC appreciates the opportunity to engage with the Office of Science and Technology Policy (OSTP) on its request for information (RFI) on federal policy updates that aim to accelerate the American scientific enterprise, enable groundbreaking discoveries, and ensure that scientific progress and technological innovation benefit all Americans.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 162 U.S. medical schools accredited by the Liaison Committee on Medical Education; nearly 500 academic health systems and teaching hospitals; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 210,000 full-time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

The AAMC is committed to supporting the effective and efficient use of federal research funds to drive discovery, capitalize on the ideas and successes of the nation's scientists, and improve health through research. We are pleased to respond to the following questions posted in the RFI, focusing on the biomedical research conducted at AAMC member institutions.

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?

Fruitful public-private collaboration and the translation of basic biomedical research into therapies and cures requires a strong foundation of federally-funded academic institutions. AAMC member medical schools and teaching hospitals conduct the exploratory, fundamental research which underlies much of the work of private industry. Academic medicine is a critical partner in this effort and an essential component of the overall ecosystem that seeds the ideas which lead to commercial products. Maintaining this partnership requires ongoing trust and sustained federal investment in academic research.

In developing policies and processes to accelerate the translation of early-stage research into applications to improve human health, OSTP should ensure that the expertise, experience, and insights of academic institutions are considered through early engagement and consultation as public-private partnerships are being developed.

How can the Federal government better support the translation of scientific discoveries from academia, national laboratories, and other research institutions into practical applications? Specifically, what changes to technology transfer policies, translational programs, or commercial incentives would accelerate the path from laboratory to market?

The groundbreaking Bayh-Dole Act, signed into law 45 years ago this month, allows academic institutions to license their patents directly to the private sector and enables industry to employ its resources and expertise to bring those inventions to market. This paradigm-shifting set of incentives and requirements not only gives institutions the right to retain title to the patents on their inventions arising from federal grants, but also highlights the obligation of these institutions to diligently commercialize discoveries resulting from federally sponsored research. By strengthening the nation's commitment to uphold the provisions and tenets of the Bayh-Dole Act, OSTP has the opportunity to build on the tremendous impact of this law, which continues to bolster economic growth, create jobs, and catalyzed the success of thousands of startup companies.[1] The AAMC has long supported a strong commitment to the Bayh-Dole Act and urges OSTP to reinforce the administration's dedication to these impactful technology transfer policies, thereby ensuring incentives for industry to partner with academic institutions and capitalize on federally-funded research and maintain the nation's global competitiveness.

[1] "The Legacy of Bayh-Dole's Success on U.S. Global Competitiveness Today." Center for Strategic and International Studies. Available at: https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today.

What empirically grounded findings from metascience research and progress studies could inform Federal grantmaking processes to maximize scientific productivity and increase total return on investment? Please provide specific examples of evidence-based reforms that could improve funding allocation, peer review, or grant evaluation.

The AAMC appreciates the government's obligations to ensure the stewardship of federal funds used for research conducted under its purview. The AAMC has a long history of supporting federal grantmaking processes that maximize taxpayer investment and facilitate rigorous scientific investigation across the full spectrum of research.

Among these processes, the scientific peer review process is essential in ensuring that the federal government funds a broad portfolio of high-quality research across agencies. Those agencies, with the support of OSTP, should: ensure that peer review activities remain aligned with current and emerging areas of science that reflect the health needs of the nation; include a broad pool of researchers to serve on study sections; ensure requisite experience and field-specific expertise of reviewers; and create clear evaluation criteria and guidelines to ensure that the review process is effective and fair. Transparent, science-based grant review is of critical importance in advancing science and maintaining public trust in the work of federal agencies.

Existing mechanisms at federal research agencies which facilitate scientific progress include the requirements to adhere to the terms of awards, submit progress reports during the life cycle of a grant to help identify and address any challenges or potential issues, and comply with data sharing policies intended to maximize the dissemination and reuse of data resulting from federally-funded projects.

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?(and) How can the Federal government support novel institutional models for research that complement traditional university structures and enable projects that require vast resources, interdisciplinary coordination, or extended timelines?

Supporting the full spectrum of biomedical research—from basic discovery to translational and clinical science—requires sustainable, predictable funding. AAMC agrees that funding projects in incremental science which add to the growing knowledge base of scientific understanding is key, as is the opportunity to engage in transformative work. This should also include considerations of funding individual investigators to pursue multiple lines of inquiry over multiple years as well as funding specific projects, including investigator-initiated research. We support current federal efforts to use designated funds to fund high-risk, high-reward research, such as those projects under the National Institutes of Health (NIH) Common Fund which allow

scientists to pursue "highly innovative research with the potential for broad impact." Facilitating this type of flexibility in varying funding mechanisms also allows individual institutions and investigators to determine the best process for their specific resources, capability, and field of science, and will contribute to a maximally effective and efficient application of federal funding. While there will be instances where agencies seek ideas to answer specific scientific questions, maximizing innovation also benefits from scientific curiosity and an openness to exploring areas of inquiry that may not yet have extensive preliminary data or are entirely new.

How can Federal programs better identify and develop scientific talent across the country, particularly leveraging digital tools and distributed research models to engage researchers outside traditional academic centers?

The future of biomedical research depends on the successful development, retention, and support of graduate students, postdoctoral scholars, and other early-career scientists. It has long been the role of academic institutions to support the scientific enterprise by recruiting widely and training the best individuals in scientific research. These individuals bring different experiences and perspectives to identifying and solving research questions, which is vital to ensure that all people benefit from scientific progress. OSTP should support agency efforts to identify pathways for talent from all backgrounds to enter scientific careers and expand those careers through established, well-developed training programs. Applying mechanisms that encourage community building and facilitate networking opportunities will help attract a broad base of talent that will make up the next generation of scientists.

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?

The AAMC strongly supports team science and interdisciplinary collaboration as essential elements to move science forward and foster breakthroughs in research. Continuing to fund research training and career development grants, particularly those which encourage or allow interdisciplinary work, is an essential step in supporting a research workforce which can apply a new lens to existing challenges. Federal agencies, in partnership with scientific societies and associations, can also help to collect and curate databases of curricula and resources to promote training in new and emerging fields of science, technology, and engineering.

Additionally, the federal government can facilitate productive cross-sector collaboration by reducing barriers through the harmonization of reporting and compliance requirements. When different agencies and disciplines have divergent obligations such as conflict of interest reporting

guidelines, data sharing requirements, or terms and conditions of awards, this variation creates disincentives for collaboration and increases regulatory burden overall.

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.

The AAMC is keenly attuned to the difficult balance between necessary oversight for the stewardship of federal funds and the creation of unnecessary regulatory burden. One area in which the AAMC has seen both significant progress and avenues for continued work is in interagency collaboration across the federal government, led by OSTP, to streamline and standardize requirements for grantees of different agencies. This harmonization has the potential to promote compliance and reduce administrative burden while addressing federal funding agencies' need to for oversight of research funding. For many years AAMC has strongly advocated for federal agencies to reduce administrative burden and costs for federally-funded researchers and academic institutions in order to optimize the time and effort that researchers dedicate to their research.

However, we also caution that substantial changes to current forms and practices could initially increase administrative burden and associated costs by requiring institutions to overhaul existing policies, software, and training, especially if changes are implemented with insufficient time for these modifications. Thus, the expertise and engagement of research institutions is key for achieving the most effective and efficient processes, and we hope this engagement will continue as further policies are developed. Policy development should focus on balancing the consistency that comes from rigorous requirements with institutions' need for flexibility as they address a wide range of situations.

The AAMC has long supported the development of a research policy board to look across agencies at oversight and regulatory burden. The creation of this board was a key component of the 21st Century Cures Act and was enthusiastically supported by the biomedical research community. Unfortunately, despite the statutory requirement for the implementation of the board, to date the research policy board has not been formed. The AAMC still supports the creation of this board, with the statutorily required representation of members from across the biomedical research community, as a powerful tool in transparency and in reducing regulatory burden. We encourage activities that would facilitate the implementation of the research policy board.

As AAMC described to the White House Office of Management and Budget in a May 12, 2025 letter[2] detailing proposed reductions in regulatory burden that would improve the biomedical research environment, AAMC urges OSTP to consider how to better ensure that regulatory requirements and compliance obligations do not differ across federal agencies, since variation in requirements and obligations requires that institutions create different internal policies for investigators who are funded by different agencies. Key AAMC recommendations for policy harmonization include:

- **Harmonize Federal Conflict of Interest Disclosure Requirements Across Agencies**
  Researchers and institutions are subject to multiple, overlapping disclosure requirements across federal agencies, including the Food and Drug Administration (FDA) (21 C.F.R Part 54), NIH (42 CFR Part 50, Subpart F & 45 CFR Part 94), Centers for Medicare and Medicaid Services (42 CFR Part 403, Subpart I), and the National Science Foundation (NSF Proposal & Award Policies & Procedures Guide, Chapter IX.A). Notably, these requirements differ in definitions, disclosure thresholds, and reporting timelines. As the AAMC noted in its comments to the FDA on its Regulatory Reform Agenda: such variation in COI requirements, "imposes significant financial and administrative burden on institutions and researchers, diminishing the productivity and return of federal investment in research."
- **Harmonize FDA's Single IRB Requirement with the Common Rule and NIH Single IRB Policy**
  The AAMC has recommended that FDA align its single institutional review board (sIRB) requirement for cooperative research (21 C.F.R. Part 56) with those rules established under HHS' revised Common Rule (45 C.F.R. §46.114), and NIH Single IRB policy. We have encouraged the FDA to work closely with HHS and the regulated community to finalize the cooperative research proposed rule in a way that promotes coordinated oversight, consistent guidance, and supports shared best practices in the conduct of cooperative research.
- **Align USDA's Protocol Review Requirement with PHS Continuing Review Standards**
  To reduce administrative burden and improve regulatory consistency in the use of laboratory animals for research, we have recommended that the U.S. Department of Agriculture amend 9 CFR §2.31(d)(5) to align with the Public Health Service Policy on Human Care and Use of Laboratory Animals. This change would preserve rigorous oversight while reducing unnecessary protocol revisions for studies that remain scientifically valid and in compliance with animal welfare standards.

[2] AAMC Comments to OMB on Deregulation, https://www.aamc.org/media/83446/download, (May 2025).

OSTP has long played a key role in facilitating the harmonization of regulatory requirements across federal agencies, as it did in 2021 during the first Trump Administration with the issuance of National Security Presidential Memorandum 33, or NSPM-33. This document initiated a multi-year initiative to align research security standards across all federal agencies, an effort that continues to this day. The AAMC encourages OSTP to continue its coordination and leadership of this effort, which both reduces regulatory burden and aligns expectations for the research community, as further discussed below.

How can the Federal government strengthen research security to protect sensitive technologies and dual-use research while minimizing compliance burdens on researchers?

AAMC strongly supports the efforts of OSTP to address research security concerns by creating requirements that are clear, equitable, feasible, to reduce burden, facilitate compliance, and, most importantly, achieve the stated goals of protecting security and openness.

AAMC has been actively engaged with the ongoing federal efforts from OSTP, in collaboration with the National Science Foundation and National Institutes of Health, to develop a set of harmonized research security policies with the input of security and intelligence agencies. Collaborating with OSTP and other relevant agencies in order to streamline requirements and ensure their alignment is critical to ensure that institutions are not subject to dual or conflicting regulations and policies.

A maximally efficient and effective research security program must allow institutions to take a risk-based approach and prioritize the policies, procedures, and training which will have the greatest impact on strengthening research security in their specific environment, without causing undue burden. Institutions should receive clear direction on the required elements and baseline practices upon which they can tailor institutional policies that best meet their needs while remaining compliant with federal requirements. Institutions must also have access to the time and resources required to implement those changes.

AAMC-member medical schools and teaching hospitals routinely engage in collaborative work, conducting and managing biomedical and health research that is increasingly data-driven and often national or international in scope. International collaboration is a key component of the U.S. research enterprise and greatly strengthens both our capacity and ability to advance scientific knowledge. Any new policies or regulations put in place should preserve the ability to share scientific data and samples as appropriate and align with the three key priorities of research security developed by the government: protecting security and openness, creating policies that are minimally burdensome, and ensuring that policies do not encourage xenophobia or prejudice. Institutions must be able to maintain an environment that is not simply permissive of but welcoming to talented researchers from across the globe and international collaboration.

With specific regard to dual-use research of concern, the AAMC strongly supports engaging relevant experts from the academic scientific community and the NIH on the creation of a biosecurity framework which ensures safety and security while allowing scientists to continue research that develops a vital understanding of new and existing health threats and pathogens.

These suggestions and concerns are offered to ensure that the United States remains globally competitive, fully engaged in the international research community, and able to meaningfully contribute to the threat of emerging diseases and to global health needs.

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?

We appreciate OSTP's commitment to ensuring that the benefits of federally funded research reach all Americans. As federal data and public health systems evolve, individuals and families must be confident that decisions regarding federal research priorities are grounded in valid, reliable information and reflect their health needs. To this end, federal policy should strengthen the data systems used to set research agendas and measure progress. OSTP can support this direction by encouraging an interagency effort to assess existing data sources and invest in new or harmonized data sources that capture disease prevalence and burden, particularly following the retirement of longstanding collections such as the Pregnancy Risk Assessment Monitoring System, the Behavioral Risk Factor Surveillance System, and others. We also recommend that OSTP lead an interagency effort which engages a broad cross-section of the public to develop updated federal population health benchmarks in the absence of *Healthy People 2030* indicators.[3]

Communities must also have meaningful opportunities to participate in and benefit from federally-supported science across all research modalities. Agencies should elevate community engagement as a scientific discipline, drawing on frameworks such as the National Academies of Science, Engineering, and Medicine assessment model[4] and institutionalizing the bi-directional engagement outlined in the AAMC's 2022 letter to OSTP[5] and its 2024 letter to the OMB on strengthening community participation in federal decision-making.[6] Adopting the AAMC's

[3]AAMC Comments on Healthy People 2030, https://www.aamc.org/media/64101/download?attachment (December, 2022).
[4] Assessing Meaningful Community Engagement: A Conceptual Model to Advance Health Equity through Transformed Systems for Health, https://nam.edu/perspectives/assessing-meaningful-community-engagement-a-conceptual-model-to-advance-health-equity-through-transformed-systems-for-health/ (February 2022).
[5] Request for Information on Strengthening Community Health Through Technology https://www.aamc.org/media/60171/download?attachment (March 2022).
[6] Methods and Leading Practices for Advancing Public Participation and Community Engagement With the Federal Government, Document Number: 2024-05882 (88 FR 19885) (May 2024).

Principles of Trustworthiness can help ensure that partnerships are grounded in transparency and long-term commitment.[7]

Ensuring that communities can learn about and access federally-funded innovations will also require strengthened policies related to public dissemination and access. OSTP, in coordination with the OMB, should direct agencies to embed clear dissemination expectations into grants, program evaluations, and data-sharing policies, and to develop plans that extend beyond peer-reviewed journals to include open access, local communication strategies, and partnerships with trusted messengers. Strengthening access pathways is equally essential— such as safeguarding programs that support safety-net providers (e.g., 340B Program), narrowing gaps between private and public payor coverage, and ensuring affordability of innovations developed with public investment. OSTP should also encourage enforcement of Phase IV clinical trial requirements to determine which communities do, or do not, experience real-world benefit and to guide course correction when needed. Finally, agencies should issue RFIs in accessible language and distribute them broadly so individuals can meaningfully inform scientific priorities and policy development.

We appreciate the opportunity to provide feedback on this RFI. The AAMC looks forward to continued engagement with OSTP on strengthening the American scientific enterprise. The AAMC and its members take seriously the responsibility entrusted in awardees to ensure that federal funds advance our understanding of medicine and health. We also recommend that OSTP continue to solicit community input as it considers new initiatives and directions, whether through town halls, webinars, or formal requests for information. For any questions about these comments, please contact Heather Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel (hpierce@aamc.org).

Sincerely,

Elena Fuentes-Afflick, MD, MPH
Chief Scientific Officer

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer

[7] *AAMC Principles of Trustworthiness Toolkit*, https://www.aamchealthjustice.org/key-topics/trustworthiness/trustworthiness-toolkit