January 28, 2020

Kelvin Droegemeier
Director, White House Office of Science and Technology Policy

Re: Request for Information on the American Research Environment (84 FR 65194)

Submitted electronically to: JCORE@ostp.eop.gov

Dear Dr. Droegemeier:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the White House Office of Science and Technology Policy (OSTP) request for information on the American Research Environment. The AAMC applauds the work that the Joint Committee on the Research Environment (JCORE) is undertaking to improve and streamline many aspects of the research enterprise. The AAMC is a not-for-profit association representing all 154 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. These institutions conduct over half of the research funded by the National Institutes of Health (NIH), and through these institutions and organizations the AAMC represents nearly 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

Research Rigor and Integrity

1. Incentives and actions Federal agencies can take to facilitate the reproducibility, replicability, and quality of research

Many factors undermine research reproducibility, including but not limited to data reliability, underpowered studies, misapplication of statistical methods and software, mislabeled cell lines or other source materials, variability in research environments and approaches, insufficient documentation of methods, failure to adequately address biases across multiple stages of research (including in publication) exclusivity in posting results, and the growth and increasing complexity of science itself.

The AAMC supports the efforts currently being taken by the NIH to improve rigor and reproducibility, including the requirements for grant applications to focus on rigor of the prior research, robust experimental design, consideration of biological variables, and authentication of key biological and/or chemical resources. All research funding agencies should clearly define their goals for increasing the rigor of research, highlight any relevant application instructions and review criteria, and provide training and resources to assist investigators and trainees in most effectively incorporating these standards into their research. As with all federal policies, harmonization of requirements and expectations across funding agencies increases efficiency and consistent implementation by grantee organizations.

To incentivize efforts in rigor and reproducibility, agencies should be funding the inclusion of biostatisticians in project teams and should consider the strength of biostatistical methods in the review

process. Agencies can also provide funding for data management within grants, endorse or create data repositories, and designate funding opportunities specifically focused on data re-analysis or meta-analysis. Agencies can also ensure they are providing researchers with guidelines and resources for sharing data and the appropriate metadata in order for research findings to be reproduced, replicated, or generalized more readily, and subsequently crediting researchers for these efforts.[1]

2. How Federal agencies can work with other stakeholders to enhance research quality, reproducibility, and replicability

There are numerous pathways for federal agencies to work with the academic community, professional societies, and the private sector to enhance research quality, reproducibility, and replicability. To promote these practices within academia, agencies should clearly communicate the importance of integrating statistical training and principles of research design into scientific coursework, and whenever possible create or support training programs that serve this purpose. These efforts also need the full engagement of trainees, faculty, and leadership at institutions. The National Academies of Sciences, Engineering, and Medicine (NASEM) has proposed that there should be a coordinating body to "work with research institutions, institutional officials, and groups such as the new Association of Research Integrity Officers to identify and develop resources aimed at improving institutional capability to respond to research misconduct allegations and sustain environments that encourage responsible conduct."[2] We believe that any such efforts should be supported and informed by federal research funding agencies. We also note that the inability to replicate studies is more often a matter of poor study design or insufficient documentation of methods or variables than a result of intentional research misconduct, and this should be reflected in the allocation of resources to addressing each concern.

The NIH's National Institute of Neurological Disorders and Stroke has created the concept of "rigor champions,"[3] who are individuals at any career stage who can help drive the requisite culture change within their scientific institutions. This interesting model proposes promoting rigorous research practices and transparent reporting at the level of the institution, in addition to the "top-down" approaches from federal agencies and from institutional leaders. Professional societies can also play a key role in engaging their members to develop and promulgate discipline-specific guidelines for research data quality, as these standards can vary widely between fields.

Increasing data reproducibility and rigor also presents opportunities for collaboration with the private sector, including partnering to find solutions for data storage and developing tools and software for data curation and computation. Engaging industry, academia and professional societies can address the most significant impediments, which are 1) the current lack of incentives and funding for transparency efforts and 2) insufficient infrastructure for curation and dissemination of research methods and data.

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[1] Pierce HH, Dev A, Statham E, and Bierer BE, Credit Data Generators for Data Reuse, *Nature*, 570, 30-32 (2019), DOI:10.1038/d41586-019-01715-4 https://www.nature.com/articles/d41586-019-01715-4.

[2] National Academies of Sciences, Engineering, and Medicine. 2017. *Fostering Integrity in Research*. Washington, DC: The National Academies Press. https://doi.org/10.17226/21896.

[3] https://www.ninds.nih.gov/Current-Research/Trans-Agency-Activities/Rigor-Transparency/RigorChampionsAndResources

3. Ensuring that researchers are aware of the ethical principles of integrity

Agencies should create and/or facilitate dissemination of training programs on research integrity, both for students, and the faculty and staff who are responsible for training them. It is essential that these are taught not only in a theoretical format but integrated into laboratory practice. Relying solely on the heads of each laboratory to impart the ethical principles of research integrity in a consistent, meaningful way will not achieve the desired goals.

4. Incentivizing the reporting of null or negative research findings for both the progress of science and increased reproducibility and replicability

OSTP should support agencies in recognizing and integrating into policy the principle that all data (both positive and null/negative) can be shared as a stand-alone output of research in a repository, and do not necessarily need to be tied to a publication to be made available. Federal agency data sharing policies can be harmonized to support and promote this idea.

As current incentives for research only reward sharing and amplifying data that supports a publication, it will be necessary to find ways to incentivize researchers to release complete data sets that may support null or negative findings. Publishers can convene to agree on best practices for conveying experimental methods within a paper, encourage publication of data papers (which may include both positive and negative data), and more broadly, highlight special research articles based on data re-analysis or use of negative results. Finally, agencies and institutions should explore the establishment of partnerships with non-traditional publishers, such as pre-print servers, as well as investing in infrastructure that would make it easier for researchers to share and preserve larger volumes of data. Increased openness of research findings can better allow for the scientific community to determine and discuss limitations of a given research study or identify methodological issues that should be corrected, although sharing datasets will not alone allow the assessment of the quality of the study design or the conduct of research.

5. Aligning U.S. government efforts in rigor and reproducibility with international partners

As a first step, OSTP could create an inventory of international efforts in this area, from other scientific funders, societies, universities, journals, and academies. OSTP may want to consult with the NASEM Board on International Scientific Organizations as well as refer to the member organizations of the International Science Council and the International Committee of Medical Journal Editors to catalog and compare ongoing initiatives. Alignment of international efforts will also require the creation and wide dissemination of the expectations, best practices, and tools that U.S. agencies develop for their own grantee organizations.

Coordinating Administrative Requirements for Research

1. Reducing administrative burden associated with FCOI requirements

Recent reports have identified a need for federal agencies to reduce administrative workload and costs for federally funded researchers and research institutions, especially in the area of financial conflicts of

interest (FCOIs). Notably, reports from NASEM[4] and the U. S. Government Accountability Office (GAO)[5] cite the AAMC's Conflict of Interest Metrics Project (COI Metrics Project)[6] as an example of an effort quantifying the impact and burden of research regulations on academic institutions. The COI Metrics Project measured the cost and effectiveness of the 2011 final rule on FCOI in Public Health Service (PHS) funded research, surveying 74 member institutions over a course of three years (the year before implementation of the revised regulations and the two years following). The findings demonstrated a substantial increase the costs and resource requirements for compliance at medical schools and teaching hospitals without commensurate increases in number of financial conflicts of interest identified or addressed.

In addition to the specific recommendations for policy changes related to FCOI described in the following sections, there are also broader steps that federal officials can take to reduce burden across research funding agencies. The results from the COI Metrics Project and the recommendations from the Academies and GAO identify a pressing need to address the variation in FCOI policies and regulations across agencies which are often inconsistent in disclosure thresholds and reporting requirements. Further, any effort to harmonize FCOI requirements should be in conjunction with agency evidence-building activities, including the incorporation of robust evaluation into rulemaking processes.

2. Reporting unreported or unmanaged FCOI

Achieving a balance of policies to appropriately identify and address financial conflicts of interest without being overly inclusive and thus contributing to unnecessary burden and "noise" should be an exercise in evidence-based policymaking. Studies like the COI Metrics Project, conducted on a larger scale, can provide better indications of what types of information, dollar thresholds, and relationships should be disclosed in order to identify potentially problematic payments or relationships.

In addition to the concern that research will be compromised because of an unmanaged financial interest is the equally worrisome concern that the existence of unreported conflicts of interest will decrease public trust in research. This mistrust can be compounded by disclosure forms, processes, and databases that provide inconsistent information about a single researcher. In addition to the essential harmonization of federal agency disclosure and reporting requirements, we need to consider as a whole the impact of publicly available information that comes from different sources and requirements, including journal disclosures connected with manuscripts, the Centers for Medicare and Medicaid Services' Open Payments database, continuing medical education disclosures for learning activities, reports to federal funding agencies acquired and made public through Freedom of Information Act requests, and financial interest information included on institutional websites. These disparate transparency initiatives, while responding to real concerns about conflicts of interest, may be increasing skepticism about whether many or most conflicts of interest are unreported or underreported intentionally. Initiatives like the Harmonization of Disclosures work being undertaken by AAMC, the American Society of Clinical Oncology, Council of Medical Specialty Societies,

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[4] *Optimizing the Nation's Investment in Academic Research, A New Regulatory Framework for the 21st Century.* National Academies of Sciences, Engineering, and Medicine, Washington DC (2016).

[5] *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements* (2016).

[6] For additional information, see: https://www.aamc.org/metricsproject.

JAMA, and Memorial Sloan Kettering Cancer[7] represent one multi-stakeholder effort to harmonize FCOI information, and similar efforts could be coordinated across federal agencies.

3.   Impact of the revised PHS FCOI regulations

The AAMC COI Metrics Project found that participating institutions incurred substantial costs beyond their ongoing program administration costs to fully implement the regulations. The total investment across 72 institutions was close to $23 million (average $318,163 per institution) to implement the revised rule. Most institutions hired new personnel and IT staff ($11,652,031), invested in electronic disclosure systems ($10,033,421), and incurred other expenditures ($1,222,292), including software licensing fees and faculty training.

With respect to the change from a $10,000 disclosure threshold to a $5,000 threshold, many institutions saw a substantial increase in the number of "significant financial interests" (SFIs) disclosed by investigators in the first year after implementation of the regulations (53,095 SFIs one year before implementation rose to 63,752 SFIs in the year after). Notably, the increase in disclosed SFIs required institutions to spend additional resources to assist with the review of these SFIs for potential conflicts of interest. Despite the increased volume of information provided to the institutions, there was only a small increase in the number of SFIs identified as FCOIs that required review and management. Underscoring the worry from many institutions that this increased volume led to increased "noise" in the review process, for institutions that provided AAMC with data on both SFIs and FCOIs, the percentage of SFIs found to be FCOIs decreased from 4.5% prior to the revisions to 1.6% in the year after implementation and 1.3% two years after the rule went into effect.

The added requirement that researchers disclose all sponsored and reimbursed travel to their institutions for evaluation as a potential FCOI was also cited as a cause of substantial increase in the disclosed SFIs under the revised rule. Despite the increase in SFIs disclosed as a result of the travel provision, only one institution identified any FCOIs based solely on a travel disclosure in the first year after implementation, and just two institutions identified FCOIs related to travel in the second year.

It is clear from these findings that the minimal increases in FCOI do not justify the significant administrative and financial burden nor the time taken away from research. The results also highlight several areas where burden could be mitigated or eliminated, including but not limited to:
- ensuring that the definitions of "conflict of interest" and "significant financial interest" are aligned across agency policies;
- adjusting the disclosure threshold from $5,000 back to $10,000, consistent with the National Science Foundation disclosure threshold;
- eliminating the burdensome and limited value "retrospective review" requirement; and
- eliminating the requirement that researchers disclose travel as a significant financial interest that is distinct from the researcher's other relationships with the entity covering the travel.

The travel disclosure requirement has not been useful in identifying conflicts of interest that exist outside another relationship. For example, if a researcher traveled to a scientific advisory board for a

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pharmaceutical company, that consulting or advisory relationship would likely be compensated and would be disclosed to the institution. The AAMC recognizes that institutions are likely to be collecting travel information from their faculty and trainees, particularly with respect to international travel to help in the assessment of conflict of commitment and foreign influence issues. These are not, however, conflict of interest matters as defined in the PHS regulations, and information collected specifically to address the research security aspects discuss in this letter should not be conflated with the FCOI review process designed to protect the integrity of research data and subject safety.

4. Developing a Federal-wide conflict of interest policy

The NASEM report on decreasing regulatory burden recommended that OSTP, in concert with research institutions, develop a federal-wide FCOI policy to be used by all funding agencies. [8] The AAMC recognizes the benefits of a harmonized policy with a consistent definition of conflict of interest, identical disclosure thresholds for financial interests, streamlined agency reporting requirements, and therefore less variability in COI policy across institutions. While supporting the development of a harmonized policy, we caution that such an effort could initially serve to greatly increase burden and costs by requiring institutions to overhaul existing policies, software, and training in a manner similar to when the PHS regulations were revised in 2011. Such an effort could be accomplished without spurring the same level of effort as the overhaul of the PHS FCOI regulations, but would need to be done thoughtfully, with the expertise and engagement of the research institutions on the front lines of this information collection and review processes.

We suggest that before issuing specific proposals for a harmonized policy, that OSTP engage with the AAMC's Forum on Conflict of Interest in Academe (FOCI)[9] to develop and discuss the impact of a uniform policy. The members of the FOCI community, which consists of over 600 individuals who are engaged in conflict of interest policies and administration from over 200 institutions, are uniquely positioned to provide meaningful feedback on the development of a such a harmonized policy and the advantages of moving toward a model similar to the simplified PHS requirements or in the direction of the NSF approach.

5. Decreasing burden associated with applying for federal grants

The administrative workload associated with varying policies and regulations across federal agencies is also complicated by inconsistent grant procedures which tend to vary from grant to grant and in some cases, within the agency itself. The AAMC is supportive of moving many aspects of the grant application process to "just-in-time" submission, recognizing that much of the information needed for the awarding and administration of a grant is not necessary for peer reviewers to assess the scientific merit of a grant. We recommend that only those elements essential for scientific review or making funding decisions be required at the time of application and all others by moved until after the merit determination is made.

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[8] Supra Note 4.
[9] *AAMC Forum on Conflict of Interest in Academe*: https://www.aamc.org/foci.

Research Security

1. Managing and mitigating the risk of misappropriation funds through unethical behaviors

Addressing the risk of unethical behaviors that threaten the integrity and security of the research environment is a priority for the AAMC and for our member institutions. Equally important is balancing the threats to security with the need for open science and international collaboration to advance discovery and spur innovation.

Currently, disclosure requirements that have been cited as methods to identify and address undue foreign government influence are spread across multiple mechanisms, each of which was designed to address a different type of concern. Using the NIH as an example, the existence of relationships with foreign governments are expected to be disclosed to the agency through one of three mechanisms: the "other support" designation which is designed to ensure proper stewardship of NIH funds through understanding how the proposed research is being funded or supported, the PHS conflict of interest regulations to address investigator bias, and the "foreign component" section of the grant application which identifies when parts of the research will be conducted in another country. None of these were designed to address research security threats. The required disclosure of relationships and support from foreign governments or institutions should be consolidated into a single reporting mechanism that specifically serves that purpose and should not be conflated with other disclosure requirements.

There should be a clear division about what should be accomplished through institutional policy, and what should be required to be disclosed to the federal agencies. Institutional policies often require internal disclosure of all relationships that obligate faculty to commit significant time or resources to another organization, for purposes of review and management. Federal policies should clearly delineate the circumstances under which those relationships must also be reported to Federal agencies, including when Federal agencies should be notified of faculty participation in foreign talent recruitment programs.

The relationship between institutions and their faculty is built on an assumption of honesty, integrity, and an alignment of the mission to advance discovery. Institutions should be responsible for requiring compliance with institutional policies and federal requirements related to grant awards, and for assessing and following up on the information provided through the disclosures. While academic institutions do not have the investigative resources of law enforcement agencies, once an institution becomes aware of a suspected violation of policy or behavior that jeopardizes the security of research, it should act quickly and in concert with relevant federal agencies to assess and address the threats.

2 and 3. Partnering across the research enterprise to enhance research security and other practices to adopt

To assist organizations in assessing risks to research security and integrity, the AAMC supports the recommendations in the JASON Fundamental Research Security report[10] that federal agencies should work with law enforcement and intelligence agencies to "communicate to academic leadership and faculty an evidence-based description of the scale and scope of problems posed by foreign influence in

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[10] JASON Fundamental Security Report (JSR-19-2I), available at:
https://www.nsf.gov/news/special_reports/jasonsecurity/JSR-19-2IFundamentalResearchSecurity_12062019FINAL.pdf.

fundamental research." Although the JASON report was directed at NSF, the AAMC encourages application of these recommendations to all federal research agencies. Additionally, processes for federal consequences for policy violations should be clearly communicated. If grant funds are held during the course of investigation, the institution and or investigator should be given notice and a proposed timeline for resolution.

It is critical that both federal agencies and research institutions consider and balance both benefits and risks associated with international research cooperation when making decisions regarding research security. This can involve keeping institutional metrics on international collaborations and grant funding, jointly published research papers, and faculty and trainees from other countries, as well as the assembly of cross-functional teams to conduct an institution-wide risk assessment. Some institutions have developed university-wide committees on undue foreign influence to ensure that different schools, departments, and offices are aware of processes and actions that the others are doing, as well as undertaking an audit to identify risks related to foreign influence.

To proactively address these issues, institutions should create resource portals and frequently communicate with the university community to reinforce and remind researchers of obligations to federal sponsors, as well as internal policies that relate to foreign influence. There are a number of organizational measures that research institutions can adopt and follow to improve research security, including clarifying policies and procedures on conflict of interest and commitment, export controls, and technology transfer.

To facilitate awareness of relevant issues and disclosure processes, institutions may want to streamline their own processes for obtaining institutional approval for grant applications, to ensure that the relevant university offices are aware of an investigator's awards and sources of financial support. Expanding the information requested in the annual faculty review to include international activities and engagements, honorary appointments, consulting activities, corporate boards, and government advisory committees can ensure that the institution is kept up to date on relevant information.

Additionally, it can be useful to formalize institutional collaborations, through the use of materials transfer agreements, data use agreements, or nondisclosure agreements. Sharing materials or data with other individuals and organizations may be prohibited in the absence of an appropriate agreement and institutional sign-off. Finally, the institution can assist with appointment and registration processes for international researchers and faculty, including ensuring appropriate screening and access to university space and systems, and provide additional oversight for faculty traveling internationally on university-related business.

Safe and Inclusive Research Environments

1. Fostering a culture of safe and inclusive environments

Diversity and inclusion are key organizational priorities for the AAMC and its member institutions, and these organizations are committed to ensuring that researchers and trainees throughout the academic environment feel safe, free from harassment, and aware of available resources to protect and support them in their pursuit of successful research careers. In order to foster a safe and inclusive culture in research environments, the leadership of these institutions have recognized that they should

implement a number of actions to prevent and address harassment. The AAMC supports the work of Federal funding agencies to identify, encourage, research, and facilitate these practices.

A report from the NIH Advisory Committee to the Director and the NASEM report entitled *Sexual harassment of women: climate, culture, and consequences in academic sciences, engineering, and medicine*[11] each set forth a number of useful findings and recommendations, including suggesting that an institution assess its current culture through a survey of its community and create public pledges to create a safe and inclusive culture and demonstrate an institution's commitment to accountability. Organizations have recognized that training programs that address topics such as unconscious bias, allyship, and how to be an effective bystander can be effective in improving the research environment. Fostering diversity at all levels can be improved through providing avenues to give anonymous feedback, recruiting diverse leadership and workforce, and ensuring diversity on committees that influence the research enterprise at academic institutions.

The AAMC is proud to support its member institutions in their efforts to address harassment and with the American Association for the Advancement of Science and the American Geophysical Union has launched the Societies Consortium on Sexual Harassment in STEMM with 53 inaugural member societies. [12]

2. Strategies to improve recruitment and retention of diverse researchers

Promising practices to increase recruitment and retention of scientists from underrepresented groups in research include:
- gathering data to create and support best practices to increase and protect diversity;
- providing mentorship and mentorship training at all career stages;
- inviting scientists at all levels to give seminars and network outside of a job search;
- valuing all work that benefits the research community (including scholarship, mentorship, service, teaching, community engagement, and entrepreneurship) in the tenure and promotion process as well as giving additional awards and recognition; and
- asking researchers what needs to be improved at their own institutions.

Making all of the data, resources, and evidence-based practices for creating a diverse workforce and inclusive environment available in a centralized, online location would ensure access for all, from trainees to organizational leadership. While recommendations suggested here will help to increase recruitment and retention at all levels, it should be noted that a significant portion of diverse biomedical researchers leave academia during the transition from postdoctoral researcher to faculty[13,14]

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[11] National Academies of Sciences, Engineering, and Medicine. 2018. Sexual Harassment of Women: Climate, Culture, and Consequences in Academic Sciences, Engineering, and Medicine. Washington, DC: The National Academies Press. https://doi.org/10.17226/24994.

[12] New Initiative: Societies Consortium on Sexual Harassment in STEMM , AAMC News, Feb. 14, 2019. https://www.aamc.org/news-insights/press-releases/new-initiative-societies-consortium-sexual-harassment-stemm.

[13] K. D. Gibbs et al., "Decoupling of the Minority Phd Talent Pool and Assistant Professor Hiring in Medical School Basic Science Departments in the Us," *Elife* 5 (2016).

[14] L. C. Meyers et al., "Survey of Checkpoints Along the Pathway to Diverse Biomedical Research Faculty," *PLoS One* 13, no. 1 (2018).

and so data collection and interventions should especially focus on this time point in the research career.

3. Federal agency policies can better support organizational policies

Federal agencies must harmonize policies to ensure more consistent implementation and application. These harmonized federal agency policies should include clear procedures for what type of incidents need to be reported and when during the investigation process they need to be reported, a procedure for individuals to report directly and anonymously, a process for removal of an investigator from a grant or a grant from an institution if necessary, and consideration of mechanisms that mitigate the power differential between principal investigators and lab members. Consistent requirements across all funding agencies are essential in this regard, and while NIH has taken first steps in this area, the other funding agencies must agree on common standards.

We urge that the timing of these reports is especially important, as requiring an institution to report to a funding agency too early in the investigation process risks the inconsistent implementation of the policy across institutions, disincentives for reporting harassment, or damage to the careers of those later found not to have engaged in prohibited actions. Federal policy should require notification of funding agencies 1) once the institution has concluded its investigation and found an individual has violated institutional of federal policy, or 2) if the institutions takes an action that affects the research, such as removing an investigator form the laboratory or the campus.

4. Collecting metrics to assess progress towards a safer and more inclusive environment

The federal government can use several metrics to assess progress in promoting safer and more inclusive research environments, including the number of reported incidents per year and the actions taken in response to these reports. Much of the work to improve and evaluate the research environment, however, should be retained at the institutional level, and the federal agencies could facilitate the collection and use of this data by suggesting common metrics and tools to be used across institutions.

The AAMC would be happy to provide any additional information or clarification on these comments or other activities JCORE or your office is undertaking. Please feel free to contact me directly or my colleague Heather Pierce, JD, MPH Senior Director for Science Policy, at hpierce@aamc.org.

Sincerely,

Ross E. McKinney, Jr., MD
Chief Scientific Officer