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June 2, 2023

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

Re: Request for Information; NSPM-33 Research Security Programs Standard Requirement (88 FR 14187)

Submitted electronically to researchsecurity@ostp.eop.gov.

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide feedback to the White House Office of Science and Technology Policy (OSTP) on the draft Research Security Programs Standard Requirement, developed in response to National Security Presidential Memorandum 33

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

As AAMC has emphasized in previous comments¹²³, we strongly support the ongoing work of OSTP to standardize and streamline research security requirements for academic institutions across federal agencies. This is particularly important in developing the standard requirements for a research security program, which will require significant time, resources, and a wide-ranging effort for institutions to implement.

¹ AAMC Comments to NSF re: Request for Comment Regarding Common Disclosure Forms for the Biographical Sketch and Current and Pending (Other) Support (87 FR 53505). Oct. 31, 2022. <https://www.aamc.org/media/63221/download>

² AAMC Joint Comments to OSTP re: NSPM-33 implementation. Sept. 30, 2021. <https://www.aamc.org/media/56926/download>

³ AAMC Comments to OSTP re: Request for Information on the American Research Environment (84 FR 65194). Jan. 28, 2020. <https://www.aamc.org/media/41581/download>

Before commenting on the specifics of the draft, we would like to emphasize the following points:

- **AAMC member institutions have already established and implemented effective programs that address many of the components proposed here, and the standard requirement should grant institutions the flexibility to leverage existing programs and activities to fulfill requirements.** Some of these programs were instituted following the 2018 letter on foreign interference to grantee institutions from the National Institutes of Health (NIH) in 2018, and subsequent federal policies and changes to reporting requirements. Many institutional processes and procedures also far predate the last several years, including those to address conflict of interest and conflict of commitment, international travel, export control, and cybersecurity. The current standard requirement as proposed does not take into consideration how institutions currently operationalize many of these programs, which will lead to significant undue burden to meet the standard requirement as written. For these reasons we request that OSTP grant maximum flexibility to institutions in structuring, assessing, and monitoring research security programs. This should include removal of the provision to “manage the required elements as an integrated program” as long as the institutions are able to describe the individual components.
- **A maximally efficient and effective 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.** We are concerned that the requirements proposed in the current draft are so broad in both content and scope that they will cause significant burden without accompanying benefits. Institutions should be very clearly presented with minimum required elements and baseline practices upon which they can tailor institutional policies that best meet their needs while remaining compliant with federal requirements.
- **The draft should be carefully reviewed to ensure consistency and clarity throughout.** Many of the terms used to define a similar activity vary throughout the sections and may or may not appear in the Definitional Appendix. For example, the language currently used throughout the document to define a reportable event is variable (e.g., research security incident, security incident, incident of research security violation, research security breach), and uses terms that may not appear in the Definitional Appendix. The document should be updated to use standard terms that are also clearly defined.
- **AAMC is concerned about the burden that meeting the proposed requirements will have on smaller and less well-resourced institutions, many of which are minority serving institutions.** We stress the importance of the Research Security & Integrity Information Sharing Analysis Organization in providing support that is specific to the development of a research security program. The standard requirement should also clearly state that for those institutions that do not reach the \$50 million threshold, they will not be penalized in federal grant competitions if they do not have a research security program in place.
- **Finally, AAMC would like to emphasize the continued importance that any requirements do not codify discriminatory practices or undermine institutional efforts to build trust with faculty.** Institutions must be able to maintain an environment that is not only permissive of but welcoming to talented researchers from across the globe and international collaboration.

Below, we provide further input on the draft document, focusing on the topics of (1) equity, (2) clarity, (3) feasibility, (4) burden, and (5) compliance. As requested, we have noted the corresponding numbers to which the comments pertain. These comments have been developed with extensive input from AAMC member institutions and after joint discussions with partner higher education organizations.

Covered Research Organizations

A critical determination for institutions to make is whether they are subject to the standard requirement, defined as those which “have received at least \$50 million per year in Federal science and engineering support for each of the previous two consecutive fiscal years.” While the draft refers institutions to usaspending.gov in addition to their own financial records for this information, feedback from institutions indicates this guidance is insufficient and that more specific instructions are needed. The current proposal of self-determination is burdensome, unclear, and creates difficulties for institutions in understanding whether they are subject to the standard requirement.

Several changes would fix these issues. We recommend: the use of usaspending.gov as the single source for determining the amount of support; a detailed template is provided to institutions which identifies the search fields and filters on usaspending.gov which should be checked to make the determination; and that OSTP assume the responsibility of notifying institutions when they have crossed the financial threshold and are responsible for complying with the requirement. Regarding the implementation timeline proposed in this section, we ask that the final draft of the standard requirement contain a specific effective date for compliance, and that newly identified covered research institutions should have one year from reaching the threshold to establish a research security program. We additionally recommend that unless a specific justification can be given for the requested 120-day status update, that this provision be removed. (*Topics: 2, 3, 5*)

Overarching Program Requirements and Certification

The requirement for posting about the research security program on a publicly accessible site as well as providing documentation when asked to a federal agency are currently described in very broad terms. We request that the minimum standards for this description and documentation are clearly described, along with further guidelines on the process of self-certification on [SAM.gov](https://sam.gov). To satisfy the requirement but not introduce any unnecessary security compromises, our recommendation would be that a minimum amount of information to satisfy the requirement for public documentation. We also note the need for consistency and transparency regarding how compliance with the standard requirement will be determined, and which agency will be making that determination. To have oversight of this requirement from multiple places within the government will create confusion and complicate the process of compliance for institutions.

This section also states that covered research organizations must “address reported allegations of research security non-compliance” and “report incidents of research security violations to the federal awarding agency or agencies.” As previously noted, it is critical that that a consistent term with a clearly defined scope is used throughout the document to indicate a reportable event. Research security non-compliance is not only undefined, but so broad as to make it very difficult for institutions to maintain effective noncompliance procedures. (*Topics: 2, 3, 4, 5*)

Foreign Travel Security

Academic institutions already maintain policies and procedures for monitoring travel. In order to be effective and not create undue financial and administrative burden, the requirement to “establish and maintain international travel policies for covered individuals” should be risk-based, only cover travel that has a nexus to the institution and to federally funded research activities and allow for institutions to develop controls tailored to the risks presented by the location of the travel and the type and circumstances of the research activities. The definitions for ‘covered individual,’ ‘covered international travel,’ and ‘international travel’ must also be streamlined to avoid confusion about what travel is subject to the requirements and what needs to be disclosed.

We also request that institutions be given the flexibility to establish disclosure and authorization requirements, particularly given existing federal requirements for travel disclosures for Public Health Service- funded investigators, and that OSTP should identify any additional factors which are necessary to develop these criteria. Finally, we note that being able to clearly justify, identify and communicate the purpose and need for travel disclosures is a key component of ensuring equity and preventing discrimination against international students, staff, and investigators in the implementation of any travel policies. (*Topics: 1, 2, 3, 4, 5*)

Research Security Training

AAMC recommends that the proposed research security training requirements be modified to increase the efficiency and effectiveness of any training that must be administered. We understand the need to educate, raise awareness, and communicate with institutional personnel on the topic of research security, and to assist them in understanding how to manage these risks in their own research. However, the requirement as currently written contains a number of provisions specifying the methods, organization, audience, and frequency of training that will be difficult for institutions to implement while not improving the usefulness of the training.

We recommend that institutions be able to align and utilize existing training requirements to satisfy the requested areas of instruction. The requirements should afford sufficient flexibility to institutions with respect to how, when, and where they address the training topics so long as the topics themselves are fully covered, as well as flexibility to determine how they will track the completion of any required training. We propose that the definition of ‘covered individual’ should be employed in this section to identify who is to receive research security training, to avoid the confusion that would result from the current use of ‘appropriate personnel’ and ‘faculty, staff, and students.’

Finally, the burden for institutions to develop training modules to satisfy all topics listed will be significant, particularly for smaller or less-resourced institutions. We understand NSF is currently funding development of several modules. We request that compliance effective dates for training do not go into effect until the federal government is able to provide training materials that cover all requested areas of instruction. (*Topics: 2, 3, 4, 5*)

Cybersecurity

The current cybersecurity requirement to “implement baseline safeguarding protocols and procedures for information systems used to store, transmit, and conduct federally funded R&D” is so broad in

scope that it will not be feasible for most institutions to implement, and overly complex to integrate into established practices for cybersecurity, which are already tightly regulated and governed by the institution.

Instead of a long list of required protocols, we recommend that institutions are given the flexibility to institute protocols and procedures that are risk-based, and address clearly-defined key security objectives. This would allow institutions to match requirements and resources to actual needs, facilitating continuous improvement in cybersecurity without unduly burdening research projects. In the case that institutions are required to implement specific protocols, we ask that there is flexibility to meet this requirement through the use of alternative measures, as long as they are adequately documented by the institution, and additionally that less-resourced institutions are granted a path to compliance by allowing for Plans of Action and Milestones (POAMs) to bridge compliance with current capabilities. *(Topics: 3, 4, 5)*

Export Control Training

We appreciate that the draft requirements for export control training focus on “ensuring compliance with Federal export control requirements and restricted entities lists,” and maximize institutions’ ability to utilize their current export control training programs. We urge that institutions are provided with the discretion to determine the personnel who are subject to this requirement, as well as the content of the training, based on their own processes for managing export control issues. Finally, we ask for removal of the provided example in this section, which is inconsistent with the definition of fundamental research. *(Topics: 2, 4, 5)*

AAMC strongly supports the efforts of OSTP to address research security concerns by creating requirements that are clear, equitable, feasible, intentional in efforts to reduce burden and facilitate compliance, and most importantly, effective in achieving the stated goals of protecting security and openness. We look forward to continued engagement with OSTP as the requirements for a research security program are finalized and would be glad to identify AAMC member institutions to participate in conversations regarding any specific topics. Please feel free to contact me or my colleagues Anurupa Dev, PhD, Director, Science Policy and Strategy (adev@aamc.org) and Heather Pierce, JD, MPH, Senior Director, Science Policy (hpierce@aamc.org) with any questions about these comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ross McKinney, Jr., MD". The signature is stylized and includes a small circular mark at the end.

Ross McKinney, Jr., MD
Chief Scientific Officer

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