



**Association of
American Medical Colleges**
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400 F 202 828 1125
www.aamc.org

July 5, 2023

National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Request for Comments; Notice to Announce NIH Updated Policy Guidance for Subaward/Consortium Written Agreements (88 FR 36603)

Submitted electronically at <https://rfi.grants.nih.gov/?s=646e6654a8ba09024f09e852>.

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide feedback to the National Institutes of Health (NIH) on updates to Section 15.2 of the NIH Grants Policy Statement (GPS) which outlines the requirements for consortium/subaward agreements on NIH-funded grants.

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.

The AAMC recognizes that the NIH takes seriously its obligations to ensure the stewardship of federal funds used for research conducted under its purview. This is of critical importance in advancing science and maintaining public trust in the work of the agency. We support a number of actions NIH has proposed toward this goal in response to recent recommendations from federal oversight bodies. However, we are also concerned that with this specific proposed revision to the GPS, the agency has moved too quickly to respond to certain aspects of reports on gaps in its oversight of foreign subrecipients without assessing the full impact of the change on the investigators, institutions, and therefore the research it funds. We recommend that the NIH work with the research community to improve its existing oversight and enforcement authority to address the

concerns raised by the Government Accountability Office (GAO)¹ and the Department of Health and Human Services Office of the Inspector General (OIG)² without creating new compliance burdens that could have a deleterious effect on collaborations with international researchers.

The GAO and OIG reports identified what the oversight bodies deemed to be gaps in NIH's obligation to ensure that foreign recipients and subrecipients complied with award terms and conditions. AAMC agrees with the overall recommendation to NIH in the GAO report that the agency "implement actions—such as changes to its internal processes—that would allow NIH to more quickly improve its oversight of awards involving foreign subrecipients." AAMC appreciates the detailed comments that NIH has provided in response to the recommendations from the OIG and agrees with the proposed actions outlined in response to Recommendations 1 and 3-8. AAMC also concurs that NIH should improve the effectiveness of its internal processes to monitor compliance, and take timely corrective actions as needed to mitigate any inherent risks from the research being conducted.

We we would like to specifically address the actions taken in response to OIG Recommendation 2 which calls for "enhanced monitoring, documentation, and reporting requirements for recipients with foreign subrecipients." An update³ from NIH to the Grants Policy Statement (GPS), Section 15.2, outlines new requirements for foreign consortium/subaward agreements on NIH-funded grants. The policy updates the necessary provisions of the written agreement to include the following language:

For foreign subrecipients, a provision requiring the foreign subrecipient to provide copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report. These supporting materials must be provided to prime recipient with each scientific update (no less than once every three months) in line with the timelines outlined in the agreement.

While we agree that risk assessment should play a key role in determining how best to improve oversight of research, AAMC has significant concerns with this update to the GPS, as outlined below. We also note an inconsistency with the time frames given between the guide notice ("no less than once every three months") and parallel notice in the Federal Register⁴ ("no less than once every six months, or more frequently based on risks").

¹ Government Accountability Office. NIH Could Take Additional Actions to Manage Risks Involving Foreign Subrecipients. GAO Publication No. 23-106119. June 2023. Available at: <https://www.gao.gov/assets/gao-23-106119.pdf>

² Office of the Inspector General. The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies (A-05-21-00025). January 2023. Available at: <https://oig.hhs.gov/oas/reports/region5/52100025.pdf>

³ NIH Updated Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-133). May 19, 2023. Available at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-133.html>.

⁴ Notice to Announce NIH Updated Policy Guidance for Subaward/Consortium Written Agreements. 88 FR 36603. June 5, 2023. Available at: <https://www.federalregister.gov/documents/2023/06/05/2023-11897/notice-to-announce-nih-updated-policy-guidance-for-subawardconsortium-written-agreements>

AAMC strongly recommends that NIH-employ a risk-based approach when determining how to effectively improve award oversight.

The GAO report recommends that NIH evaluate ways to improve risk management of awards. While in some cases research involving foreign subrecipients may require closer and more frequent monitoring, the location of a recipient or subrecipient does not necessarily indicate risk, nor is it the only possible indicator of risk. Holding awardees to a more stringent standard for reporting or documentation requirements should be based on a review of all aspects of the grant which could contribute to increased risk, including but not limited to the awardee entity, its location, whether the entity has previously been a subrecipient or direct recipient of a federal award, and the type of research being conducted. Wherever possible, these risks should be determined using existing federal frameworks which inform whole of government research security policies, such as identified countries of concern or biosafety and biosecurity guidelines.

Efforts to increase research oversight should utilize and better enforce existing NIH policies and enforcement authority rather than creating new, potentially conflicting requirements.

The NIH has responded to concerns about foreign subaward oversight by implementing a requirement that all foreign subrecipients regularly send grant awardees documents, lab notebooks, and research records, some of which are not typically collected by or required by a prime recipient. This change does not automatically lead to improvements in research oversight without considering the identity of the subawardee or the characteristics of the research. NIH already has policies at its disposal that allow the agency to request additional data and information, both prior to and during the course of an award. The NIH Data Management and Sharing Policy⁵ requires grantees to submit a data management and sharing plan with the initial grant application. Applications that are going to be funded must have the plan approved by an NIH program officer, after which adherence to the plan becomes a term and condition of award. Should NIH determine that additional data reporting is necessary, it can be communicated to grantees upfront and through a binding requirement. Institutes, Centers, and Offices can make individual determinations about which data should be shared.

In particular, requiring subrecipients to provide copies of lab notebooks is incongruous with existing NIH policy and would substantially increase burden on researchers without improving award oversight.

The time, effort, and people-hours to collect, organize, and digitize raw data and experimental notes from lab notebooks is significant. In the case of research with human subjects or vulnerable populations, these records may require deidentification prior to electronic transfer or storage of the data in a place accessible to the prime recipient, an expensive and time-consuming task. Not only that, but it can be extremely difficult to obtain any meaningful information or insight from data at this stage and in this condition. NIH itself in the Grants Policy Statement explicitly excludes laboratory notebooks and preliminary analyses from the definition of scientific data. It is unclear how the prime recipient is expected to evaluate these experimental observations and notes and how they would assist in improving project oversight.

⁵ Final NIH Policy for Data Management and Sharing (NOT-OD-21-013). October 29, 2020, Available at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html>.

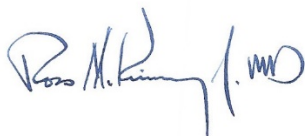
This policy change as written does not align with research security principles and will result in a negative impact on international scientific collaborations.

The current policy change does not consider international standards for data transfer, privacy, and confidentiality. The increased reporting solely for foreign subrecipients also does not align with the three key priorities⁶ of research security and integrity developed by the government: protecting security and openness, creating policies that are minimally burdensome, and ensuring that policies do not fuel xenophobia or prejudice.

AAMC supports the efforts of NIH to improve oversight of recipients and subrecipients of grant funding through actions that are intentional in their efforts to meet this goal effectively while minimizing any increase in excessive regulatory burden. We urge NIH to remove the update to the GPS and consider policy updates which utilize existing agency mechanisms and employ a risk-based framework for increased reporting, rather than a blanket policy change focused on foreign subrecipients regardless of the research being conducted.

We appreciate the opportunity to provide feedback on this important issue and finding solutions that promote the transparency, productivity, and integrity of scientific research. We look forward to working with the agency moving forward. 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 for Science Policy and Regulatory Counsel (hpierce@aamc.org) with any questions about these comments.

Sincerely,



Ross McKinney, MD
Chief Scientific Officer

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

⁶ Subcommittee on Research Security, National Science and Technology Council. Office of Science and Technology Policy. Draft Research Security Programs Standard Requirement. February 2023. Available at: https://www.whitehouse.gov/wp-content/uploads/2023/02/RS_Programs_Guidance_public_comment.pdf.