

NIH Concerns and Actions Related to Undue Foreign Influence at U.S. Research Institutions

In the past year Congress, federal science agencies, and the media have highlighted concerns about the impact of undue foreign influence in U.S. federally funded research. In a series of AAMC communications on the topic, we will provide background information, relevant federal policies, and institutional considerations related to this issue. **This first document focuses on the NIH's actions and communications to the grantee community.**

Key Dates: NIH Communications Regarding Threats to the Integrity of U.S. Biomedical Research

August 2018: NIH Director Francis Collins issued a [statement](#) and sent [a letter](#) to over 10,000 grantee institutions, outlining three areas of concern for the agency:

- Diversion of intellectual property to other entities, including other countries
- Sharing of confidential information on grant applications by NIH peer reviewers with others
- Failure by researchers working at NIH-funded institutions to disclose substantial resources from other organizations

The letter also noted that the NIH Office of Extramural Research (OER) would reach out to specific institutions “regarding grant administration or oversight questions or requests about specific applications, progress reports, policies, or personnel.”

December 2018: An NIH Advisory Committee to the Director released a Dec. 2018 [report](#) on foreign influences and research integrity, containing recommendations for recipient organizations related to:

- Communicating with investigators (education campaigns on disclosure requirements; guidelines for visitors)
- Mitigating risk (assessment of internal controls, proactively notifying NIH about breaches)
- Ongoing monitoring (developing ‘flags’ for audit, considering post-travel questionnaires for select countries, and working with federal security agencies on best practices)

July 2019: NIH released relevant [guide notice](#) and [FAQs](#) (see below)

Scope of NIH investigations

As of July 2019, the NIH has contacted over 60 research institutions regarding 180 individual scientists that the agency believes have failed to disclose substantial financial ties to foreign agencies or have failed to uphold the confidentiality of the peer review process. Investigations conducted in collaboration with awardee institutions are ongoing and several institutions have returned grant funds to the NIH and in some cases dismissed researchers for violations of agency and/or institutional policies. The NIH has recently sent at least a dozen cases to the Department of Health and Human Services Office of the Inspector General for external review, and OIG has referred some cases to the Department of Justice for prosecution.

The NIH is directing questions to its Division of Grants Compliance Oversight and has also encouraged institutions to work directly with their local FBI offices.

Applicable NIH Policies and Guidance

As described in a July 2019 [guidance document](#), institutions receiving extramural funding from the NIH are subject to several relevant policies and regulations:

- The [NIH Grants Policy Statement](#) (NIHGPS) requires grant applicants to disclose *Other Support* to ensure no scientific, budgetary or commitment overlap, including “all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors.” (Section 2.5.1)
- The NIHGPS also requires recipients to determine whether activities it supports include a foreign component, which may or may not involve the direct use of NIH grant funds (e.g. performance of work by a researcher or recipient in a foreign location or a collaborator outside of the U.S. who performs experiments in support of an NIH-funded project or with an expected co-authorship).
- Federal conflict of interest regulations ([42 CFR Part 50, Subpart F](#)) include a requirement for researchers to disclose to their institutions significant financial interests (SFIs) in addition to any reporting required by NIH policy. (See more generally at www.aamc.org/coi)
 - NIH [clarified in 2018](#) that while these regulations do not require disclosure of certain SFIs from “an Institution of higher education,” this is only for U.S. institutions, and remuneration from foreign institutions is a disclosable SFI.

A related [FAQ](#) updated July 11, 2019 confirms that these policies and regulations are already in place and that the guide notice serves as a reminder to the community, not an expansion of the Other Support policy. Institutions should note that one [FAQ](#) instructs that “Outside Activities such as teaching or consulting that may be compensated or uncompensated constitute Other Support if they are in any way related to the investigator’s research endeavors or expertise.” [Update: As of July 23, 2019, the FAQ in question was removed after the community expressed concerns about its scope to NIH].

A [blog post](#) from the NIH OER, provides additional context for the timing of the guide notice and states that “depending on the severity and duration of the noncompliance... (it) may contact the affected institutions, impose specific award conditions, disallow costs, withhold future awards for the project or program, suspend the award activities, make a referral for investigator suspension or debarment, or terminate the award.”

Institutional Responses and Next Steps

Individual institutions have taken a number of steps to address this issue, including clarifying existing institutional policies for disclosure and reporting, and reminding investigators of appropriate university resources to assist with compliance and conflict of interest management. Many institutions have also issued statements of support of international collaborations and researchers. In addition to this document and the recent [AAMC News](#) article, the AAMC will continue to develop resources for the community.

For questions, please contact Ross McKinney, MD, Chief Scientific Officer (rmckinney@aamc.org) and Heather Pierce, JD, Senior Director of Science Policy and Regulatory Counsel (hpierce@aamc.org).