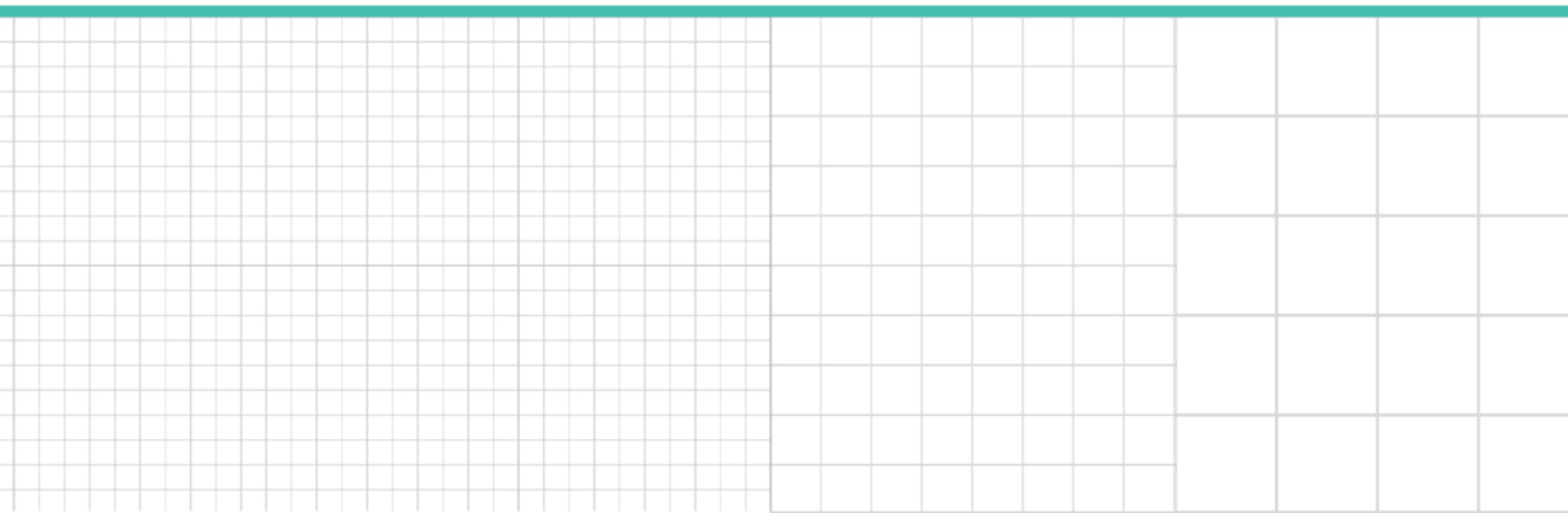


**Professional Perspective**

# **Expanding Regulatory Oversight of Foreign Influence in NIH-Funded Research**

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# Expanding Regulatory Oversight of Foreign Influence in NIH-Funded Research

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Federal interest and enforcement efforts are expanding around “foreign influence” in U.S.-funded research activities, affecting business operations and research collaboration at universities, academic medical centers, and other organizations receiving federal funding for research. Open science proponents and advocates for international scientific collaboration, like National Institutes of Health director Francis S. Collins, are among those sounding alarms about threats from foreign government-sponsored “talent programs,” which recruit scientists and investigators from U.S. institutions and abroad.

After the unusual step of sending a letter to more than 10,000 funding recipients with a “Statement on Protecting the Integrity of U.S. Biomedical Research,” NIH sent inquiry letters to more than 60 institutions, many concerning multiple investigators, and at least 18 cases were referred to the Department of Health and Human Services’ Office of Inspector General. More inquiries are expected.

In particular, the government appears concerned that certain investigator practices are a conduit for federally funded intellectual property to be transferred to foreign countries. To date, attention has focused largely on activities with China’s Thousand Talents Plan and other similar initiatives. NIH has expressed concern about scientists operating undisclosed foreign “shadow labs,” creating plausible claims that work generating intellectual property occurred outside the U.S.

Unauthorized disclosure and theft of biomedical intellectual capital, possibly including intellectual property, from confidential NIH grant applications is also of concern. NIH recently acknowledged that, in some respects, its foreign influence investigations reveal “a new kind of problem” for both awardees and government agencies.

This article summarizes the governing law for the primary areas of concern that NIH has been examining—disclosure of foreign components of NIH-funded projects, other support for NIH-funded researchers, and unreported foreign affiliations, including guidance documents released in July 2019. Recipients of federal research funds need to understand these requirements both to satisfy duties for specific awards and to anticipate future expectations that may affect their business practices.

## Defining the Problem

International and inter-institutional collaboration are critical to the advancement of science and the translation of basic science discoveries into technology and tools to benefit society. For federally funded research, several checks on international engagement are applied to ensure that U.S. taxpayer dollars are expended appropriately and in accord with public policy priorities. These checks include duties of disclosure. Incomplete disclosure by investigators and their institutions of parts of research conducted outside the U.S.—referred to as “foreign components”—can, the NIH asserts, distort its funding decisions, by implication depriving NIH of the ability to deny or reduce the scope of funding to projects of investigators receiving other support from foreign sites or adding undisclosed foreign components for the performance of the federal award.

To address these concerns, NIH has issued clarifying guidance on several occasions in the last year, most recently in July 2019. These new [documents](#) include an NIH Guide Notice, NOT-OD-19-114, *Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interest and Foreign Components*, a series of Frequently Asked Questions on *Other Support and Foreign Components*, and a blog, *Clarifying Long-Standing NIH Policies on Disclosing Other Support*. They focus on three main regulatory obligations of investigators and their institutions: financial conflict of interest (COI) reporting, “other support” disclosures, and foreign component disclosures, with prior review and approval of those foreign components.

## Financial Conflict of Interest

The Public Health Service, of which NIH is a component, has promulgated rules for promoting objectivity in research, found at 42 C.F.R. Part 50, Subpart F. These rules require awardees to have detailed policies in place to gather information on

the significant financial interests of all investigators participating in NIH-funded research. NIH's rules set a minimum standard for the reporting of SFIs and adjudication of COIs, and individual institutional policies may be more stringent. Under NIH rules, investigators must report all SFIs to their institutions. This duty to disclose income related to an investigator's institutional responsibilities is distinct from, and in addition to, the "other support" and "foreign component" disclosures that must be made to the NIH.

Under 42 C.F.R. Part 50, Subpart F, investigators must report their relevant SFIs, as well as those of their spouse and dependent children, to their institution's designated officials before an initial application for any NIH funding, at least annually thereafter and within 30 days of acquiring or discovering a new SFI. Covered investigators include "all individuals responsible for design, conduct or reporting of research." This often includes persons in addition to the principal investigator, program director, or senior and key personnel.

An SFI is defined as any financial interest of monetary value "that reasonably appears to be related to the Investigator's Institutional responsibilities" as a scientist and researcher. This includes specific remuneration, equity interests, income from intellectual property rights or interests, and any reimbursed or sponsored travel received in the preceding 12 months that meets or exceeds NIH's prescribed thresholds.

One point of frequent confusion surrounding the definition of reportable financial interests arises from a distinction NIH draws between U.S. and foreign sources of investigators' financial interests and income. Under the regulation, income from seminars, lectures, or teaching sponsored by U.S.-based institutions is excepted from reporting requirements. These institutions include U.S. federal, state, or local government agencies, U.S. higher education institutions as defined at 20 U.S.C.1001(a), and U.S. academic teaching hospitals, medical centers, and research institutes affiliated with an institution of U.S. higher education. Indeed, in March 2018, NIH clarified in NOT-18-160 that this regulatory exception should only be read to apply to U.S. governmental entities and institutions. By contrast, the same types of income or support from foreign entities and governments, including foreign universities, are not exempt and must be reported.

## Foreign Components

If individual funding opportunity announcements permit "foreign components," and if applicants disclose their foreign component plans in a funding application, then NIH may approve the grant's foreign component. As set forth in the NIH's Grants Policy Statement at section 8.1, foreign component can also be added during the performance of the award by obtaining NIH's prior approval.

NIH defines a foreign component in its Grants Policy Statement as "the performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended." NIH's July 2019 guidance documents emphasize how geography is a critical element to distinguishing foreign components from other support. The agency offers a formula for assessment: first determine if any activities will be performed outside of the U.S., and, second, determine if those activities are significant.

Among other activities, the following types of work qualify as significant scientific elements or segments triggering foreign component disclosure and prior approval: involvement of human subjects, extensive foreign travel, and activities that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. If the foreign activities are significant, NIH's prior authorization is required to add them as foreign components to the project.

One ready way to detect collaboration that may have resulted in a significant number of foreign component reporting errors (i.e., foreign component collaborations for which prior approval was not sought) is to identify publications and presentations co-authored with foreign investigators at a foreign site. Simple co-authorship with ex-U.S. scientists is not itself dispositive evidence of a foreign component of an NIH award, but if the content of the publication overlaps with the scope of work of the award, or if the publication was cited in a progress report to NIH, then the presumption will be that there was a foreign component in play.

Because authorship is not always clear at the outset of a project, and it can change during the course of a project, whether a project involves a foreign component must be assessed throughout the life of an NIH award.

## Other Support

By contrast, if all research activities for a project occur in the U.S., but an investigator or researcher receives any other sources of support, either for that project or others, then it must be disclosed to the NIH as “other support” for the investigator's research efforts. Thus, foreign sources of support can be included within the definition of “other support.” For example, NIH would not typically regard a visiting researcher with a salary paid by her foreign institution to be a “foreign component” requiring prior approval if she works in a laboratory in the U.S. on an NIH-supported project. However, her service would likely be considered “other support” for senior/key personnel and would be reportable to NIH as such.

While “foreign components” relate to a specific project or group of projects under a single award, “other support” is about the totality of support available to an individual investigator or individual personnel on any given award. NIH collects this information in order to ensure that sufficient levels of effort are committed and available for the proposed project, sufficient funding and no surplus is included in an award, and there is no unacceptable overlap between the scientific, budgetary, or commitment of effort between the proposed project and other activities the investigator is undertaking. NIH's Grants Policy Statement at section 2.5 explains that “other support” must be disclosed to NIH as part of initial grant reporting (i.e., just in time) and in ongoing grant reports.

NIH defines “other support” in the Grants Policy Statement, as “all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.” NIH's July 2019 Guide Notice emphasizes that “other support” includes:

- All positions and appointments held by senior/key personnel relevant to an application, including domestic or foreign, full or part time, paid or unpaid, adjunct, visiting, or honorary
- All resources for senior/key personnel, regardless of “whether such support is provided through the applicant organization, through another domestic or foreign organization, or is provided directly to an individual that supports the senior/key personnel's research efforts”
- All current projects and activities for senior/key personnel, including “in-kind (e.g. office/laboratory space, equipment, supplies, employees)” and “foreign financial support, research or laboratory personnel, lab space, scientific materials, selection to a foreign ‘talents’ or similar-type program....”

Additionally, the Frequently Asked Questions relay that the scope of “other support” includes all lab space, materials, staff, travel and living expenses for appointments, paid or unpaid, at foreign universities; outside consulting and teaching activities, whether paid or unpaid, that relate to research activities or expertise; and start-up packages for investigators and research grants.

A number of questions arise regarding the vast scope of “other support” that must be reported under a literal reading of the guidance. For example, the guidance includes all foreign relationships, appointments, and even compensation arrangements in support of the senior/key personnel's research. How to distinguish this other support from, for example, personal consulting income may be less than clear under this new guidance.

Similarly, start-up packages can include direct funding, space, general funding, salary, compensation and more. Disclosing all of these sources of support is not necessarily relevant to the question of whether there are one or more foreign sources of support, which appears to be the agency's primary goal. Nonetheless, it appears to be required for all senior/key personnel, regardless of whether they are employed by the prime awardee. We understand from NIH sources that actual dollar amounts of start up packages are not expected to be reported, but the research community would benefit from additional clarification from NIH.

## Responding to Inquiries

NIH identifies individuals for inquiry from an array of sources. These include referrals from law enforcement, such as the FBI; reports from co-workers, colleagues, or competitor research scientists from the field; observations of NIH staff finding

inconsistencies in publicly available information, like publications, and application documents; and institutional self-reporting.

Upon receipt or identification of a question about an individual researcher or award, NIH typically sends an inquiry letter to the institution's signing official or a senior research official to review and address the questions raised. NIH inquiries may parallel related inquiries from other federal research funders, the FBI, or other law enforcement officials. Generally, NIH's goals are to notify the institution about NIH's questions or concerns, open a dialogue, and enable the awardee institution to assist NIH to resolve the issues described. These letters typically include a response date so that matters will be addressed promptly. When needed, an extension may be sought.

Several strategies are useful for NIH awardees to know and consider adopting or adapting to respond to NIH inquiry letters.

**Upon receipt of an inquiry letter** from NIH (or other federal funders):

- Immediately freeze emails and other records relevant to the scope of the inquiry. The NIH's Advisory Committee to the Director recommended treating the examination like a scientific misconduct investigation from an operational perspective, and this kind of approach will best protect the institution's ability to identify and learn the facts about what happened.
- Review the subject's research portfolio, financial conflict of interest and travel reporting, all sources of support, recent publications (to identify research collaborations with ex-U.S. investigators), and grant documentation
- Look for overlap between NIH funding and any other sources of funding or support, e.g., a foreign talent recruitment program, a foreign government grant
- Determine whether all disclosures of "foreign components," "other support" and personal income from all ex-U.S. sources were made to the institution and thence, as needed, to the NIH in a timely and complete manner
- Consider independent review by outside consultants or counsel. The advantages of independent review can include immediately establishing credibility for the fact-finding, enabling "fresh eyes" on the internal processes and procedures to illuminate possible sources of error or misunderstanding, and insulating leadership from direct engagement in the review process.

**Prepare a response** that tells the story of the inquiry subject's actions and any omissions and the specific institutional efforts to remediate any errors or omissions:

- Be complete and transparent
- Include specific dates, grant numbers, publications, etc.
- If there are relationships with a foreign talent recruitment program (previously disclosed or not), find all agreements or other documentation of the terms of the relationship and include those in both original and translated version
- Include a description of new steps or processes developed to enhance reporting, if any, as highlighted in the risk management discussion, below

**Recognize that the NIH may reply with more facts** that the institution has not found, such as grant numbers or documentation from foreign universities or funders. In this case, institutions should continue dialogue with NIH and take efforts to identify actions that may compromise the integrity of the award process.

**Consider whether funds should be returned or foregone.** Just as in other cases where funds may need to be returned, institutions should be aware of the risk of penalties, suspension or debarment.

## Risk Management Best Practices

In addition to strategies for responding to specific NIH inquiries, institutions should consider proactive risk management even before receiving an inquiry from NIH or other federal funding agencies. Institutions must ensure that their pro-active compliance measures proceed in way that is compliant with applicable federal and state anti-discrimination laws. For example, compliance measures should never be focused on persons based on their racial group or ethnic origin.

Among other options, awardees may wish to:

- Review institutional guidance documents and policies to ensure that they are up to date in light of recent NIH guidance and applicable laws.
- Consider conducting a targeted audit or case study review of a sample of awards to assess whether reporting is complete and accurate. An audit of awards with known foreign components and other support, as well as those with none, may yield useful insight about current faculty understanding. Focusing on recently completed awards, for which manuscripts are published or in process, may enable a fuller picture of the support landscape. With all of the attention in this arena, proactive internal examination is a critical component of risk management and plans should be made, in advance, for how problems will be addressed.
- Consider self-disclosure of any significant problems identified. However, institutions need to collect underlying facts necessary to evaluate whether a particular investigator's activities are a concern before raising unnecessary alarm bells.

## Conclusion

Pressure on awardees likely will continue to mount, as law enforcement officials and members of Congress push the NIH and other agencies to take further actions to minimize perceived threats to national and economic security. At the same time, actions that limit academic freedom, foreign collaboration, and educational exchanges raise concerns about possible discrimination and chilling scientific progress.

Given the changing landscape and acute scrutiny being applied, it is critical that universities, academic medical centers, and other entities receiving federal research funding continue to monitor the regulatory developments in this space and be prepared to respond to funders' oversight questions.