

Foreign Interests and Conflicts of Interest in Research

Insights

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Institutions that receive certain federal funding for research are required to take steps to identify and manage financial conflicts of interest, including, without limitation, requiring investigators to disclose certain financial relationships, adopting a conflict of interest policy and making such policy publicly available, and providing training to investigators on the topic. Over the past year, government officials and academic research institutions have grown increasingly concerned that foreign countries may be taking advantage of United States-funded research by diverting U.S. intellectual property, and have identified the failure of some investigators to disclose financial relationships with foreign entities as a related issue. Due to this increased scrutiny, institutions should consider assessing their current conflict of interest program to assess compliance with the applicable regulations.

In March of 2018, the National Institutes of Health (NIH) issued [Notice NOT-OD-18-160, Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests](#), as a reminder that disclosures under 42 CFR Part 50 Subpart F (which, as described further below, requires institutions to take certain steps to identify and manage financial conflicts of interest) must include disclosures of financial interests received from a foreign institution of higher education or foreign government. In August of 2018, NIH posted a [Statement on Protecting the Integrity of U.S. Biomedical Research](#) on its website and sent letters to approximately 10,000 institutions, stating that “some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers,” and identifying three areas of concern: (1) failures by some researchers at NIH-funded institutions to disclose substantial resources from foreign entities, (2) diversion of intellectual property, and (3) sharing of confidential information on grant applications with foreign entities.

In January 2019, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued [a letter to Senator Grassley](#) in response to the senator’s inquiries regarding the growing threat of foreign government interference in taxpayer-funded medical research.[1] The letter addressed how OIG conducts investigations of foreign interests and integrity of U.S. research, including how OIG, the Department of Justice, the Federal Bureau of Investigation, and NIH coordinate to address such issues. According to OIG’s letter to Senator Grassley, NIH recently referred 12 institutions for noncompliance related to research, primarily involving investigators at academic institutions who allegedly failed to disclose foreign affiliations on grant applications.

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In addition, Congress recently appropriated funds to OIG to oversee NIH efforts to ensure the integrity of the grant process.[2] In February 2019, OIG posted multiple items to its [Work Plan](#), reflecting this directive, including examination and monitoring of financial conflicts of interest reported by grantee institutions, audits of NIH's pre-award and post-award process based on potential risks identified in grant applications, and a review to "determine whether NIH has policies, procedures, and controls in place for ensuring that both foreign and domestic grantees disclose all sources of research support, financial interests, and affiliations."

Of course, while there has been a recent focus on foreign governmental activity, the potential for conflicts of interest impacting objectivity in the research context has been a source of scrutiny and regulation for quite some time. Although relationships between research institutions, investigators, and industry may foster innovation, such relationships also create the potential for bias. The issue recently has garnered national attention more generally due to multiple recent high profile news stories revealing the failure of researchers to disclose financial interests with certain companies in publications. Along these lines, a [study published in JAMA in November 2018](#) found that potential conflicts of interest were only disclosed in 37% of the articles published by the 100 physicians receiving the highest compensation from device manufacturers (based on data available on the CMS Open Payments website).

Although scrutiny of conflict of interest protocols has increased recently, the applicable rules have not changed at this point. Pursuant to 42 CFR Part 50, Subpart F, institutions that apply for or receive Public Health Service (PHS) funding for research (and investigators and other key research personnel and sub-recipients, by virtue of implementation of the regulations by institutions) are required to take a number of actions, including, without limitation, requiring disclosure by investigators of any significant financial interest (SFI) for the institution's review and evaluation, determination of whether the SFI constitutes an actual or perceived financial conflict of interest (FCOI), development of a FCOI management plan, and submission of a FCOI report to the PHS-awarding component, including an explanation of how the conflict has been managed, reduced, or eliminated.[3] These regulations exclude from the definition of SFI income received from an institution of higher education as defined in 20 USC 1001(a) or a federal, state or local government agency, however this exclusion does not extend to include foreign institutions or governments.

Increased scrutiny likely will continue in the months to come, along with a potential increase in enforcement activity and regulatory guidance. Given the additional scrutiny by regulators, institutions should consider a close review of their current conflict of interest policies, if they have not done so recently, to assess how well their process currently works and whether any revisions are needed to ensure conflicts of interest are appropriately disclosed and managed. Some additional proactive steps could be to consider additional training regarding what constitutes an SFI and other requirements under the institution's COI policy, posting frequently asked questions to assist investigators in navigating the process, or otherwise finding ways to make expectations and consequences clear, as well as building in more robust auditing to periodically assess compliance with the institution's policies and to ensure the policies are uniformly and consistently implemented.

Hooper, Lundy & Bookman's Academic Medical Center/Teaching Hospital Working Group provides assistance to health care providers in all aspects of research compliance. For more assistance, please contact [Amy Joseph](#) in Boston, [Kelly Carroll](#) in Washington, D.C., and [Andrea Frey](#) or [Katrina Pagonis](#) in San Francisco.

[1] Senator Grassley also made inquiries directly with NIH and with DOJ. See <https://www.grassley.senate.gov/news/news-releases/nih-research-projects-referred-inspector-general-failure-disclose-foreign>.

[2] See Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Pub. L. No. 115-245).

[3] *Responsibility of Applicants for Promoting Objectivity for which PHS Funding is Sought* (42 CFR Part 50, Subpart F, 76 Fed. Reg. 53256 (Aug. 25, 2011)). The U.S. Food and Drug Administration (FDA) and the National Science Foundation (NSF) also impose conflict of interest requirements, which include different requirements and are triggered under different circumstances. Notably, pursuant to Section 2034 of the 21st Century Cures Act, HHS is required to review the conflict of interest requirements of various funding agencies, for potential harmonization moving forward.