



Opportunities Exist To Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interests and Other Support

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Why OIG Did This Review

In fiscal year (FY) 2020, the National Institutes of Health (NIH) awarded \$31 billion to grantee institutions (hereafter grantees) to support biomedical research. These grantees play key roles in protecting the integrity and security of U.S. biomedical research by requiring investigators to report (1) significant financial interests (hereafter financial interests) and (2) all sources of their other support (hereafter support), which includes all resources in support of and/or related to all of their research endeavors. This includes foreign financial interests and support. Failures by some investigators at these grantees to disclose substantial contributions of resources from foreign entities (including foreign governments) have raised concerns about threats to the integrity of NIH-supported research.

How OIG Did This Review

To determine how grantees (1) ensure that investigators disclose all foreign financial interests and support and (2) review this information prior to reporting information to NIH, we administered online surveys to 773 grantees that (as of July 1, 2020) received NIH funding for FY 2020. We administered online surveys from October 2020 to January 2021. We received responses from 617 grantees.

Opportunities Exist To Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interests and Other Support

Key Takeaway

Most grantees failed to meet at least one Federal requirement related to their investigators' foreign financial interests and support. In addition, many grantees lacked oversight practices that would help ensure that all materials submitted to NIH are complete and accurate. At the same time, some grantees reported promising practices that, if more widely adopted, present additional opportunities to strengthen oversight of investigators' foreign financial interests and support.

NIH grantees are responsible for ensuring that the investigators who conduct NIH-funded research disclose all required types of foreign financial interests and support. Grantees are also responsible for reviewing these disclosures; reporting them, as necessary, to NIH; and managing any associated conflicts. Failure to comply with these requirements hinders grantees' and NIH's ability to conduct effective oversight and may leave NIH-funded research vulnerable to foreign influence.

What OIG Found

Noncompliance with Federal requirements. More than two-thirds of grantees failed to meet one or more requirements for investigators' disclosure of all foreign financial interests and support. These problems often involved requirements to disclose nonpublicly traded equity interests from foreign entities and to disclose in-kind resources, professional affiliations, or participation in a foreign "talents" program. Some grantees also were unsure about whether or how disclosure requirements applied to R13 grants, which specifically support conferences and scientific meetings.

In addition, some grantees did not comply with Federal requirements to train investigators regarding disclosure of foreign financial interests. Further, 10 percent of grantees did not perform required reviews to determine whether investigators' foreign financial interests were conflicts that could bias their research.

Additional opportunities to strengthen oversight. In addition to having specific oversight requirements, grantees have general responsibilities for overseeing the disclosure and management of investigators' financial

interests and support. We found that many grantees could strengthen their oversight practices to better ensure that all materials submitted to NIH are complete and accurate. At the same time, some grantees have implemented promising practices that—if more widely adopted—would strengthen oversight of foreign financial interests and support. These practices include the following:

- Providing written guidance and training regarding investigators' disclosures of foreign *support*. (Only a quarter of grantees reported providing this guidance and/or training.)
- Distinguishing whether the sources of investigators' financial interests or support were from a foreign entity. (Less than two-thirds of grantees reported doing this.)
- Taking steps to validate investigators' reports or to identify financial interests and support that investigators failed to report. (Seventy-nine percent of grantees reported taking such steps.)

What OIG Recommends and How the Agency Responded

To address gaps in grantees' procedures regarding investigators' foreign financial interests and support, NIH should (1) ensure that grantees comply with Federal requirements to train investigators regarding disclosure of significant financial interests; (2) ensure that grantees conduct the required review of investigators' significant financial interests to determine whether conflicts exist; (3) specifically require grantees to provide trainings and to maintain a written policy regarding investigators' disclosure of other support; (4) modify its reporting mechanisms to require grantees to report whether investigators' significant financial interests and other support involve foreign entities; (5) conduct outreach to grantees with R13 conference grants to clarify requirements regarding the disclosure and review of investigators' significant financial interests and other support; (6) clarify whether and how grantees should verify investigators' significant financial interests and other support prior to submitting information to NIH; and (7) establish a method for grantees to share their best practices for identifying and reviewing investigators' foreign significant financial interests and other support. NIH concurred with all recommendations.

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OBJECTIVES

1. To determine how grantee institutions that are funded by the National Institutes of Health (NIH) ensure that investigators disclose all foreign significant financial interests and other support.
 2. To determine how NIH-funded grantee institutions review investigators' disclosures of foreign significant financial interests and other support prior to reporting information to NIH.
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In fiscal year (FY) 2020, NIH awarded \$31 billion for extramural research conducted by investigators working in universities and other grantee institutions (hereafter grantees). These grantees play a key role in protecting the integrity and security of U.S. biomedical research by requiring investigators¹ to report significant financial interests and other support (hereafter referred to as financial interests and support); identifying, managing, and reporting their investigators' financial conflicts of interest (FCOIs), and also reporting investigators' support—which includes all resources made available to an investigator in support of and/or related to their research endeavors.²

Concerns about foreign threats to research integrity

Despite Federal requirements for NIH-funded investigators to disclose financial interests and support to grantees, there have been instances in which some investigators failed to disclose substantial contributions of resources from other entities, including foreign governments, resulting in law enforcement action. For example, one grantee's NIH-funded investigators failed to disclose their Chinese government research grants and the grantee failed to adequately investigate information it had concerning the investigators' relationships and affiliations, resulting in the grantee paying False Claims Act settlements of \$6.6 million.³ In another example, an investigator was convicted on charges that included making false statements to NIH about funding he received from China's Thousand Talents Plan, a government-run program aimed at attracting scientists to further China's scientific development, economic prosperity, and national security.⁴ In August 2018, NIH issued a statement about its concerns about increasing risks to the security of intellectual property in its biomedical research enterprise.⁵ NIH stated that it would address these concerns—in part—by identifying ways to improve accurate reporting of all sources of financial interests and support.

OIG received congressional appropriations in FYs 2019, 2020, and 2021 to conduct oversight of NIH grant programs and operations.⁶ The Appropriations Committees have specifically identified foreign threats to research integrity as among the concerns for which they are looking for OIG oversight. This review is part of that larger body of OIG work.

Federal requirements for investigators' disclosure of financial interests and support

The *NIH Grants Policy Statement* and Department of Health and Human Services (HHS) regulations specify the types of information that investigators must disclose to grantees and which information grantees must then report to NIH during the grant application and awarding process. For significant financial interests, HHS regulations require disclosure so that NIH can ensure that the research will be free from bias resulting from any investigators' FCOIs. For other support, NIH policy requires disclosure so that NIH can ensure that all resources made available to an investigator, including any foreign activities, are considered prior to making an award.

Required disclosure of significant financial interests

Investigators must disclose to grantees all of their significant financial interests (hereafter financial interests) that reasonably appear to be related to the investigator's institutional responsibilities, including those shown in Exhibit 1.⁷ Grantees must review these financial interests and determine whether a financial conflict of interest exists.⁸ If an FCOI exists, the grantee must develop and implement a plan that specifies how it will manage the FCOI to safeguard objectivity in the research project. Once NIH has awarded a grant, but prior to expending any funds, grantees must report investigators' FCOIs and the key elements of the corresponding management plans to NIH through the electronic Research Administration (eRA) Commons FCOI Module.^{9, 10} NIH reviews this information to ensure, in part, that the grantee's management plan is designed to safeguard objectivity in the research project.

Exhibit 1. Types of Financial Interests That Investigators Must Disclose To Grantees

- ▶ Income from intellectual property rights and interests (e.g., patents and copyrights) exceeding \$5,000 per year
- ▶ Salary and payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship) exceeding \$5,000 per year
- ▶ Equity interest from a publicly traded entity exceeding \$5,000
- ▶ Any equity interest from a nonpublicly traded entity
- ▶ Sponsored or reimbursed travel

Source: 42 CFR § 50.603.

Required disclosure of other support

Investigators also must disclose to grantees all sources of their other support (hereafter support), which includes *all* resources made available to an investigator in support of and/or related to *all* of their research endeavors, including those shown in Exhibit 2.¹¹ Once a grant application is under consideration for funding, but before funds are awarded, the grantee must report investigators' support to NIH on the Biographical Sketch (Biosketch) Format Page and the Other Support Format Page.¹² NIH reviews this information to ensure, in part, that there is no scientific, budgetary, or commitment overlap.¹³ If an investigator obtains support after the initial NIH award period, the details must be disclosed in the annual research performance progress report.¹⁴

Exhibit 2. Types of Support That Investigators Must Disclose To Grantees

- Resources and financial support from contracts; cooperative agreements; other awards; and active and pending grants
- Professional affiliations (e.g., positions and scientific appointments)
- In-kind resources (e.g., office or laboratory space; equipment; supplies; employees; students; and visiting scholars)
- Selection to "talents" or similar-type programs
- Items or services given with the expectation of an associated time commitment or other condition

Sources: *NIH Grants Policy Statement* and NOT-OD-19-114.

Types of grant awards subject to these requirements

Investigators must disclose financial interests and support to grantees for a variety of funding mechanisms, including research grants, center grants, individual fellowship awards, infrastructure awards, and research resources awards.¹⁵ Within these categories, there are specific types of grant awards. For example, research grants include (but are not limited to) R01 grants, which support a discrete, specified research project; R03 grants, which provide limited funding for a short period of time to support a variety of types of projects; and R13 grants, which support high-quality conferences and scientific meetings.¹⁶ The only types of grant awards that are not subject to Federal requirements for disclosure of investigators' financial interests are applications for Phase I Small Business Innovative Research (SBIR) Program and Small Business Technology Transfer Research (STTR) Program funding.¹⁷

Federal requirements for grantee oversight of investigators' financial interests and support

General requirements for grantee oversight

As the applicants for and recipients of NIH funding, grantees are responsible for ensuring that all materials submitted to NIH are complete and accurate. This includes ensuring that investigators make all appropriate disclosures regarding foreign financial interests and support.¹⁸ In addition, grantees must have systems, policies, and procedures to manage funds and activities.¹⁹ These include written policies and procedures, training, management controls, and other internal controls to ensure compliance with all Federal requirements.

Specific requirements for grantee oversight of financial interests

There also are specific requirements for grantee oversight of financial interests, including ensuring that each grantee:

- establishes and maintains a written FCOI policy that includes investigators' responsibilities to disclose financial interests to grantees and posts this policy on its publicly accessible website;²⁰
- requires investigators to complete FCOI training that includes training regarding the disclosure of financial interests prior to engaging in NIH-funded research and at least every 4 years thereafter;²¹ and
- take actions as necessary to identify, manage, and report FCOIs.²²

NIH oversight activities

The NIH Division of Grants Compliance and Oversight (DGCO) monitors grantee compliance with NIH policy and legislative mandates and enhances compliance oversight by grantees.²³ DGCO can use various types of activities to ensure grantee compliance, including:

- Proactive Compliance Site Visits, which assess grantees' understanding of Federal policies and regulations, minimize or eliminate areas of noncompliance, and nurture partnerships between NIH and grantees; and
- Targeted Site Reviews, which focus specifically on assessing grantees' compliance with the FCOI regulations.²⁴

NIH enforcement actions

If a grantee fails to comply with Federal statutes, regulations, or the terms and conditions of an award, NIH may take one or more enforcement actions which include disallowing costs; withholding further awards; or wholly or partly suspending the grant.²⁵ NIH may also terminate the grant in whole or in part.²⁶

NIH's response to concerns regarding foreign influence

NIH is committed to international collaborative research and has highlighted that many recent scientific advancements were predicated upon international collaborations. At the same time, NIH has raised concerns since 2018 about foreign threats to the integrity of medical research and intellectual property in NIH-funded biomedical enterprises. In response, NIH has increased its efforts to strengthen and enforce reporting requirements regarding investigators' foreign financial interests and support, including the following actions:

- In March 2018, NIH issued a notice to clarify that investigators must disclose all financial interests received from a foreign institution of higher education or the government of another country.²⁷

- In July 2019, NIH issued a notice to remind grantees that support includes *all* resources and financial support made available to an investigator from all foreign and domestic entities in support of and/or related to *all* of the investigator's research endeavors, regardless of whether or not those endeavors have monetary value and regardless of whether the endeavors are based at the grantee institution that the investigator identifies for the current grant.²⁸ This notice specifically reminded grantees that they must report investigators' participation in foreign "talents" programs, foreign in-kind resources, and foreign professional affiliations as support.
- In September 2020, NIH notified grantees that, effective November 2020, they are required to submit their publicly assessable FCOI policy to NIH.²⁹ In this notice, NIH stated that a grantee's failure to comply with this requirement by December 1, 2020, may cause NIH to delay issuance of awards, impose specific award conditions, or take other enforcement actions to address compliance.
- In March 2021, NIH issued a notice related to support to remind grantees of disclosure requirements and to introduce new requirements.³⁰ The notice reminds grantees that an item or service given to an investigator with the expectation of an associated time commitment is not a gift and must be reported as support. This notice also reminds grantees that they must establish and maintain effective policies and procedures to ensure that investigators disclose all support. As part of this notice, NIH released an updated Biosketch Format Page and Other Support Format Page that applicants and recipients must use beginning in January 2022.^{31, 32} These updated forms contain specific instructions for investigators to disclose all current positions and scientific appointments both domestic and foreign, as well as in-kind contributions. The updated Other Support Format Page also contains a signature block for investigators to certify the accuracy and completeness of information submitted. In addition, effective January 2022, grantees must submit supporting documentation (e.g., copies of contracts, grants, or other agreements) for all foreign activities and resources reported in the updated Other Support Format Page.

Related OIG work

Over the past decade, OIG has conducted numerous studies and made many recommendations regarding NIH's FCOI policies and procedures. In 2008 and 2009, OIG released reports that found, respectively, (1) that NIH lacked accurate records regarding the number or type of FCOIs reported by grantees; and (2) that vulnerabilities existed in how grantees were identifying, managing, and overseeing investigators' FCOIs.³³ Subsequently, NIH implemented multiple OIG recommendations to improve FCOI policies, and HHS regulations were revised to

strengthen the reporting and management of investigators' FCOIs related to NIH-funded research.³⁴

In FYs 2019, 2020, and 2021, OIG received congressional appropriations to conduct oversight of NIH grant programs and operations, including oversight of foreign threats to research integrity.³⁵ OIG released several reports as part of a body of work focusing on NIH's oversight of grant programs and operations. One 2019 report found that some NIH-funded investigators may not have been aware of their responsibility to report all sources of financial interests and not all grantees had their policies publicly posted, as required.³⁶ In response to a recommendation from this report, NIH implemented procedures to ensure that all grantees have FCOI policies by requiring all NIH-funded grantees to submit their publicly accessible FCOI policy to NIH as of December 2020. NIH also concurred with this report's recommendation to enhance its monitoring of grantees' FCOI policies but has not yet implemented this recommendation. Another 2019 OIG report found that NIH could not—and did not plan to—identify whether investigators' FCOIs involved foreign entities.³⁷ Instead, NIH believed investigator's foreign financial interests are most appropriately captured as part of the support reporting process, rather than as part of the FCOI reporting process.³⁸ Therefore, OIG recommended that NIH use information that it collects regarding investigators' foreign support to decide whether to revise its FCOI review process to address concerns regarding foreign influence. NIH concurred with this recommendation and is working to implement it.

Methodology

Survey of Grantees

We requested and obtained from NIH a list of contact information and funding amounts for grantees that met the following criteria: (1) they were U.S.-based;³⁹ (2) they received NIH funding for FY 2020 as of July 1, 2020; and (3) they were not grantees with only SBIR Program or STTR Program grants (because SBIR Program and STTR Program grants have different reporting requirements). From this list, we excluded five grantees that were no longer operating as of fall 2020 or were part of ongoing OIG audits. Our final list of 773 grantees collectively received \$20.4 billion in NIH funding for FY 2020 as of July 1, 2020. Of these 773 grantees, 244 each received more than \$10 million and collectively accounted for 95 percent of the total funding. We categorized grantees by total funding received into the following two groups:

- (1) 244 grantees with more than \$10 million each in NIH grants (hereafter larger grantees) and
- (2) 529 grantees with less than \$10 million each in NIH grants (hereafter smaller grantees).⁴⁰

We administered either a detailed or shorter survey to all 773 grantees. We sent a detailed survey, which contained closed-ended and open-ended questions and

requested relevant policies and procedures, to a simple random sample of 100 larger grantees.⁴¹ A total of 673 grantees (144 larger grantees and all 529 smaller grantees) received a shorter survey that contained the same closed-ended questions and select open-ended questions, but did not request documentation.

Both versions of the grantee survey asked questions about the extent to which grantees have policies, procedures, and practices in place to ensure that investigators disclose all foreign financial interests and support. We also asked questions about whether and how grantees review investigators' disclosures of foreign financial interests and support prior to reporting this information to NIH, as well as questions about the actions, if any, that grantees take to address instances of nondisclosure by investigators. Only the version of the survey that went to our random sample of 100 larger grantees contained questions about the actions that grantees took when they identified investigators who failed to disclose foreign financial interests and support in the last 2 years.

From October 2020 to January 2021, we administered online surveys to 773 grantees. We received responses from a total of 617 grantees, for an overall response rate of 80 percent.⁴² Of the 617 responding grantees, 207 were larger grantees and 410 were smaller grantees. In addition, some respondents were Department of Veteran Affairs' Nonprofit Corporations. Investigators at these grantees are Federal employees and are not subject to HHS's FCOI regulations. Therefore, eight of these grantees opted to complete only the section of our survey that pertained to support. As a result, our total number of respondents was reduced from 617 to 609 throughout the report for any findings pertaining only to financial interests.

We summarized survey responses and reviewed procedures across grantees to determine whether they complied with Federal requirements and to identify certain best practices and challenges. We counted grantees as having procedures in place for foreign financial interests and support if they had procedures that applied to foreign-only or to both domestic and foreign sources of financial interests and support. In addition, we did not evaluate whether certain practices were more effective than others, but only evaluated whether grantees performed certain practices more often than other practices.

Limitations

We used self-reported data from grantees and did not independently verify the accuracy of the information presented by the grantees. However, when possible, we reviewed responses for consistency and possible data entry errors. We also did not independently verify the grant information that NIH sent to us. Our results apply only to the 617 grantees that responded to our surveys and cannot be generalized to all NIH-funded grantees.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Overall, we found that many grantees failed to meet at least one requirement related to investigators' foreign financial interests or support. In addition, many grantees lacked oversight practices that would help ensure that all materials submitted to NIH are complete and accurate. At the same time, some grantees reported promising practices that, if more widely adopted, present additional opportunities to strengthen oversight of investigators' foreign financial interests and support.

NONCOMPLIANCE WITH FEDERAL REQUIREMENTS

The security and integrity of NIH-funded research relies, in part, on grantees' oversight of their investigators' foreign financial interests and support. HHS established specific requirements to ensure that NIH-funded grantees are providing adequate oversight, including that grantees must (1) require their investigators to disclose all required types of foreign financial interests and support; (2) train investigators about their responsibility to disclose foreign financial interests; and (3) perform reviews to determine whether investigators' foreign financial interests are conflicts that could bias their research. Grantees' lack of compliance with these Federal requirements may leave NIH-funded research vulnerable to foreign influence.

More than two-thirds of grantees failed to require investigators to disclose at least one required type of foreign financial interest or support

Sixty-nine percent of the NIH-funded grantees in our review (428 of 617) did not require their investigators to disclose at least 1 required type of foreign financial interest or support.⁴³ This is despite NIH emphasizing the importance of accurate reporting of all sources of financial interests and support. Among the 428 grantees that were noncompliant with at least 1 disclosure requirement, three-quarters were smaller grantees, i.e., those with less than \$10 million in grant funding.⁴⁴ Appendix A contains detailed information on the percentage of grantees that do not require investigator disclosure for each type of foreign financial interest and support. By and large, when grantees did not require disclosure of foreign financial interests and support, they also did not require disclosure of the same types of financial interests and support received from domestic entities.

Almost half of grantees did not comply with disclosure requirements for nonpublicly traded equity interests from foreign entities

For Federal FCOI purposes, investigators must disclose to grantees *all* of their equity interests (e.g., stock, stock option, or other ownership interests) in nonpublicly traded entities; however, 45 percent of grantees (277 of 609) were not compliant with this disclosure requirement for equity interests in nonpublicly traded foreign entities. Further, 80 of these noncompliant grantees did not require any disclosure of equity interests from nonpublicly traded foreign entities.

Grantees' lack of compliance may stem—in part—from differences in requirements across other Federal entities that grant research awards. For example, NIH makes a distinction between publicly and nonpublicly traded equity interests—requiring disclosure of *all* nonpublicly traded equity interests, but requiring disclosure of publicly traded equity interests that, when combined with other remuneration, exceed a dollar threshold.⁴⁵ In contrast, the National Science Foundation does not make a distinction between publicly versus nonpublicly traded entities.⁴⁶ Among the 277 grantees that did not require investigators to disclose *all* nonpublicly traded equity interests from foreign entities, 191 *did* require this disclosure at a dollar threshold that was the same as their requirement for publicly traded equity interests from foreign entities. Across all grantees, 59 percent reported that a lack of consistency in requirements across Federal entities was a challenge related to identifying investigators' foreign financial interests. In addition, 60 percent of grantees reported this was a challenge related to identifying investigators' support.

Despite NIH's 2019 reminder, grantees often did not require investigators to disclose in-kind resources, professional affiliations, or participation in foreign "talents" programs

Nearly half of grantees (273 of 617) reported in October 2020 through January 2021 that they did not require their investigators to disclose at least 1 of the 3 types of foreign support that NIH requires to be reported. Of the 273 grantees, 96 did not require investigators to disclose any of these 3 types of foreign support. In July 2019, NIH specifically clarified that grantees must report investigators' participation in foreign "talents" programs (e.g., China's Thousand Talents Plan), foreign in-kind resources (e.g., laboratory space, equipment, or employees), and foreign professional affiliations (e.g., positions and scientific appointments). Notably, just over a third of the 273 grantees mentioned above reported that staying up to date with changes in NIH guidance and/or requirements was a challenge with regard to identifying investigators' foreign support.

Since January 2021, NIH has made further efforts to clarify the requirements for these three types of foreign support, including updating the Biosketch Format Page and Other Support Format Page used to disclose this information.

Grantees that receive only R13 grants may be unaware that they must adhere to Federal requirements regarding investigators' disclosure of foreign financial interests and support

R13-only grantee:
"It would be helpful to provide guidance for how this applies to these [R13] grants as compared to other grant types."

Across all grantees in our review that received only R13 grants, almost all (26 of 28) did not require their investigators to disclose at least 1 NIH-required type of foreign financial interest or support.⁴⁷ R13 grants specifically support high-quality conferences and scientific meetings that are relevant to NIH's mission and to public health. Grantees that receive only R13 grants (hereafter R13-only grantees) are subject to Federal requirements for reporting investigators' financial interests and support. Appendix A contains detailed information on the percentage of R13-only grantees that do not require investigator disclosure for each type of foreign financial interest and support. Some R13-only grantees were unaware that these requirements apply to R13 awards. For example, one R13-only grantee incorrectly stated that the survey questions were not applicable because the grantee did not receive research funding. Another R13-only grantee was unclear of how an "investigator" is defined for R13 grants.

Some grantees did not comply with Federal requirements to train investigators regarding disclosure of foreign financial interests

Nearly a quarter of grantees were not in compliance with Federal requirements to train investigators about their responsibility to disclose foreign financial interests. Specifically, 23 percent of grantees (140 out of 609) did not require investigators to complete all NIH-required training, and over half of these (81 out of 140) also did not require or offer any other training regarding disclosure of foreign financial interests. HHS regulations require grantees to ensure that investigators complete FCOI training that includes training regarding the disclosure of financial interests prior to engaging in NIH-funded research and at least every 4 years thereafter. Some grantees may also offer voluntary trainings (e.g., presentations, online resources, or education materials) to investigators about disclosing their foreign financial interests. Of the 81 grantees that did not require all NIH-required training and did not require or offer other training, almost all were smaller grantees. For most of the 140 grantees, if they did not require trainings for foreign financial interests, they also did not require them for domestic financial interests.

Overall, 18 percent of grantees did not require investigators to complete the initial training and 20 percent did not require investigators to complete the recurring training. Furthermore, almost all (24 out of 28) of the R13-only grantees in our review did not require all NIH-required trainings regarding disclosure of foreign financial interests, and 21 also did not require other training or offer other training to their investigators.

Ten percent of grantees did not perform required reviews to determine whether investigators' foreign financial interests were conflicts that could bias their research

One in 10 grantees did not conduct a required review of investigators' foreign financial interests to protect NIH-funded research from potential bias. Prior to expending funds under an NIH grant, grantees must review all investigator disclosures of financial interests and determine whether an FCOI exists.⁴⁸ However, 10 percent of grantees (61 of 609) reported that they did not review each foreign financial interest to identify whether it is a potential FCOI. Of the noncompliant grantees, 93 percent were smaller grantees.

ADDITIONAL OPPORTUNITIES TO STRENGTHEN OVERSIGHT

In addition to complying with NIH's specific oversight requirements, grantees have general responsibilities for overseeing the disclosure and management of investigators' foreign financial interests and support. We found that many grantees could strengthen their oversight practices to better ensure that all materials submitted to NIH are complete and accurate. At the same time, there are certain promising practices that—although they are not required—may present opportunities for grantees to strengthen their oversight.

Most grantees lacked written guidance and/or training for investigators about disclosing foreign support

Seventy-four percent of grantees (455 of 617) lacked written guidance and/or did not require their investigators to complete training regarding the disclosure of foreign support. This is despite Federal requirements for grantees to have policies and procedures—including written policies and training—to manage funds and activities.⁴⁹ Although HHS has specific requirements for grantees to maintain written FCOI policies and provide investigators with training about disclosure of *financial interests*, it does not have the same specific requirements for *support*. Overall, 35 percent of grantees did not issue written guidance and 71 percent of grantees did not require investigators to complete training regarding disclosure of their foreign support. Further, 41 percent of grantees did not offer voluntary trainings, such as presentations, online resources, or education materials. Overall, a quarter of grantees (156 of 617) had no written guidance, did not require trainings, and did not offer voluntary trainings regarding the disclosure of foreign support.

Fourteen percent of grantees did not issue written guidance regarding requirements for investigators' disclosure of foreign financial interests

Fourteen percent of grantees (84 of 609) did not choose to issue written guidance about their requirements for investigators' disclosure of foreign financial interests. Most of these grantees were smaller grantees (76 of 84). Of the R13-only grantees in our review, most (20 of 28) did not choose to issue written guidance. Overall, when grantees did not issue written guidance regarding disclosure requirements for foreign financial interests, most (81 percent) also did not do so for domestic financial interests.

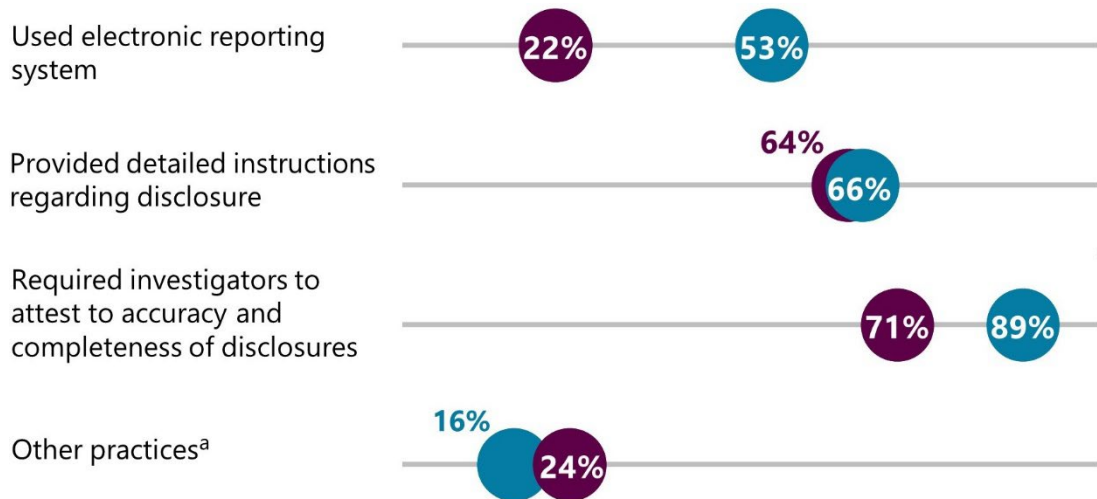
Grantees did not always implement practices that could strengthen their identification of investigators' foreign financial interests and support

In addition to having the required procedures for investigators' disclosures of foreign financial interests and support, some grantees used such practices as requiring investigator attestation, using electronic reporting systems, and providing detailed instructions to investigators. However, 82 grantees (13 percent) did not choose to use any of these practices to ensure that investigators disclosed foreign support, and 51 grantees (8 percent) did not use any of these practices to ensure disclosure of foreign financial interests.

Only a few grantees reported having specific or additional practices related to foreign (versus domestic) financial interests and support. For example, one grantee asked investigators additional questions related to foreign funding or relationships on disclosure forms. Another grantee reported that it conducted internet searches for information about foreign affiliations that may be tied to financial interests from foreign entities.

Grantees did not always use the same practices for disclosures of support as they used for disclosures of financial interests, as shown in Exhibit 3. For example, half of grantees used an electronic reporting system (e.g., an online reporting tool or specific software) for investigators' disclosure of foreign financial interests compared to nearly a quarter that did so for foreign support. These electronic systems have the potential to improve the efficiency and completeness of investigators' disclosures. As one grantee explained, its system can create support documentation from known grants and proposals, which the investigator and grantee then reviews and updates to ensure that all known support is listed.

Exhibit 3. With regard to ensuring that investigators disclose all required information, grantees used certain practices more often for foreign financial interests than for support.



Source: OIG analysis of 617 NIH grantees’ responses to survey administered from October 2020 to January 2021.

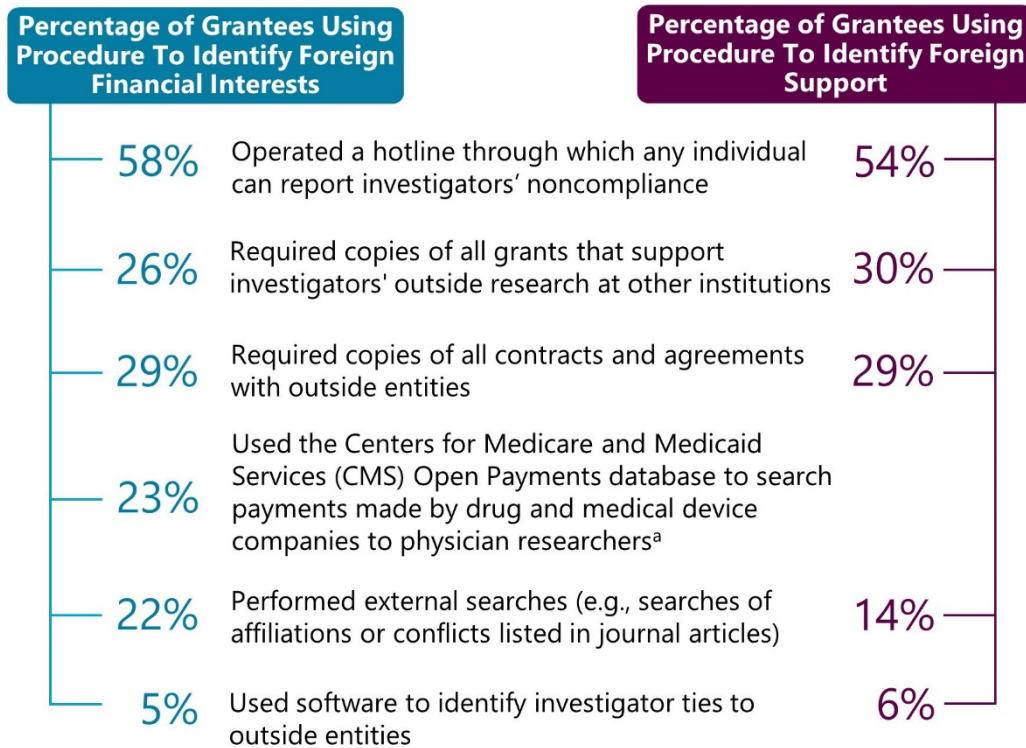
^a Some examples of other practices included providing individualized guidance to investigators who have questions or concerns about the support-related section of the application; surveying investigators just prior to issuing an award to determine whether all support has been disclosed; and providing investigators with a customized report that is populated with previously self-reported information and then working with the investigator to review or update the information.

Most grantees took at least one step beyond relying on investigators’ disclosures to identify investigators’ foreign financial interests and support, but many could do more

Although 79 percent of grantees had at least 1 procedure to identify foreign financial interests and/or support beyond relying on investigators’ disclosure, many grantees could be doing more. Aside from operating a hotline, less than a third of grantees had any other types of procedures in place, as shown in Exhibit 4. Overall, 21 percent of grantees did not take any steps to identify investigators’ foreign financial interests and support that went beyond relying on investigators’ disclosures.

Just 29 percent of grantees required—as a way to identify foreign financial interests and support—that their investigators provide copies of all contracts and agreements with outside entities. Many grantees may need to change their procedures to comply with new requirements to submit certain documentation when reporting investigators’ foreign support. These requirements—which became effective May 25, 2021—require grantees to provide NIH with copies of investigators’ contracts, grants, or any other agreements related to foreign appointments or foreign employment when reporting these types of other support to NIH.⁵⁰ As of January 2021, less than a third of grantees required investigators to submit copies of all grants from outside entities for their disclosures of foreign support, and just a quarter of grantees required this for disclosures of foreign financial interests.

Exhibit 4. With regard to identifying investigators’ foreign financial interests or support, some grantees implemented practices beyond relying on investigators’ disclosure.



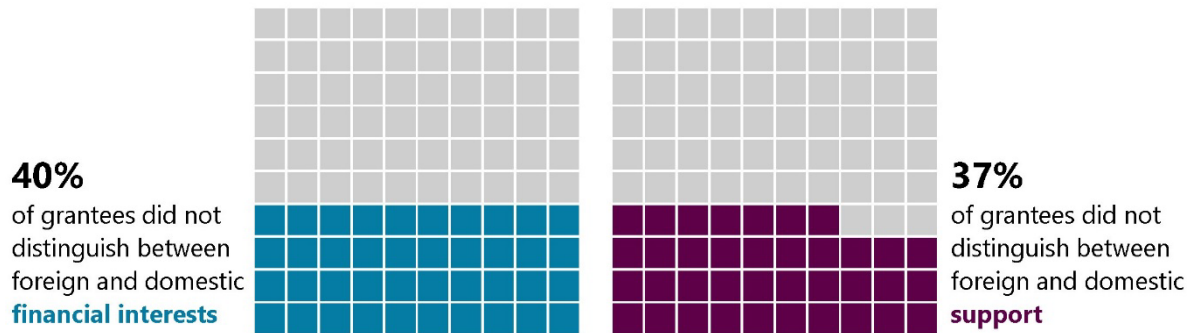
Source: OIG analysis of 617 NIH grantees’ responses to survey administered from October 2020 to January 2021.

^a This question was asked only with regard to financial interests, not with regard to support.

More than a third of grantees did not distinguish whether the sources of investigators’ financial interests or support were foreign or domestic entities

Thirty-seven percent of grantees reported that when they identified their investigators’ support, they did not distinguish whether the source of support was a foreign entity. Furthermore, 40 percent of grantees did not capture this information for investigators’ financial interests, as shown in Exhibit 5. In 2019, OIG found that NIH could not identify whether investigators’ financial conflicts involved foreign interests using the information that grantees reported to NIH about FCOIs.⁵¹ At that time, NIH believed that this information was most appropriately captured in the information that grantees report to NIH regarding investigators’ support. However, from October 2020 through January 2021, many grantees reported that they were not capturing data that would enable them to report to NIH whether the sources of investigators’ financial interests or support were foreign entities.

Exhibit 5. Many grantees did not distinguish whether the sources of investigators' financial interests and support were foreign or domestic entities.



Source: OIG analysis of 617 NIH grantees' responses to survey administered from October 2020 to January 2021.

Among grantees that *did* distinguish whether the source of an investigator's financial interest or support is a foreign entity, their most common method was to require the investigator to provide an address for the entity. Some grantees also reported having a checkbox on the form used by investigators to distinguish whether the source is a foreign entity. Appendix B lists the other ways that grantees identify whether financial interests and support involve foreign entities.

Some grantees did not implement certain practices that could strengthen their review of investigators' foreign financial interests and support

Grantees must have internal controls related to ensuring compliance with all Federal requirements, yet some grantees did not perform certain reviews that could help strengthen their internal controls. Most grantees followed up with the investigator for more information or clarification as needed. However, some grantees did not perform any *other* types of reviews or checks of investigators' disclosures prior to reporting this information to NIH. (Exhibit 6 shows the types of reviews or checks that grantees performed before reporting information to NIH.) For example, more than one-third of grantees did not compare the disclosed financial interest information to the investigator's external contracts or agreements. Similarly, 40 percent of grantees did not compare the disclosed financial interest information to information identified in external searches (e.g., general web searches or searches of affiliations and/or conflicts listed in journal articles). Furthermore, 36 grantees—or 6 percent of all grantees—reported that they did not perform any review of investigators' disclosures of foreign interests and support prior to reporting this information to NIH.

Exhibit 6. Some grantees did not perform certain types of reviews of investigators’ foreign financial interests and support prior to submitting this information to NIH.

Type of Review	Percentage of Grantees That Performed This Review:	
	Financial Interests	Support
Follow up with the investigator for more information or clarification, as needed	90%	86%
Review investigators’ support to identify whether it may cause scientific, budgetary, or commitment overlap to investigators’ research	NA	80%
Identify gaps or inconsistencies in the disclosed information without performing comparisons to external information	67%	62%
Compare disclosed information to investigators’ contracts, agreements, and intellectual property rights	64%	54%
Compare disclosed information to other external disclosures (e.g., financial interest or support disclosures; Biographical Sketch; routing and approval forms; or other Just-in-Time approvals)	60%	62%
Compare disclosed information to information identified in external searches (e.g., general web searches or affiliations/conflicts listed in journal articles)	52%	38%
Compare disclosed information to information in grant documents for outside research at other institutions	48%	45%
Contact entities with which an investigator reports an agreement, contract, or grant to confirm the nature of the entity’s relationship with the investigator	42%	35%
Use translation services to review documents or online content that is not in English	40%	35%
Operate a centralized electronic system that integrates information across offices or departments within the grantee institution for ease of review and comparison	31%	24%
Verify disclosed information (e.g., physical address and website) against a list of international organizations/entities maintained by the grantee	18%	18%

Source: OIG analysis of 617 NIH grantees’ responses to survey administered from October 2020 to January 2021.

Notably, 54 percent of grantees indicated that a challenge they face is a lack of guidance from NIH on methods they could use to verify information disclosed by investigators when reviewing investigators’ disclosures of foreign financial interests. Similarly, 57 percent of grantees reported this same challenge with regard to reviewing investigators’ disclosures of foreign support. One grantee expressed a desire for NIH to provide further guidance, saying: “Provide guidance on what constitutes ‘due diligence’ [so that grantees have a better understanding of how much review is needed] to prove a person’s disclosures are accurate and complete.”

Almost all grantees reported that they had the ability to take action if an investigator failed to disclose foreign financial interests or support

Almost all grantees (578 of 617) reported that they had at least 1 kind of action available to them under their institutions’ policies and procedures that they could take if an investigator failed to disclose either foreign financial interests or support. Across grantees, the most common actions were to follow up with the investigator to request additional information/clarification and to report the incident to NIH, as shown in

Exhibit 7. However, some grantees reported that they did not have the ability to take certain actions if an investigator failed to disclose information. For example, 30 percent of grantees stated that they would not have the ability to postpone a promotion if an investigator failed to disclose a foreign financial interest.

Exhibit 7. Grantees reported a variety of actions they could take if investigators failed to disclose foreign financial interests or support.

Type of Action	Percentage of Grantees That Could Take This Action:	
	Financial Interests	Support
Follow up with investigator	95%	95%
Report incident to NIH or other Federal entity	92%	92%
Review previously undisclosed support for possible scientific, budgetary, or commitment overlap with the investigators' research	NA	90%
Require investigator to take training	91%	89%
Determine whether the integrity of the research was impacted by the nondisclosed support	NA	88%
Complete a retrospective review to determine whether any NIH-funded research was biased in its design, conduct, or reporting	89%	NA
Suspend investigator from research project	88%	87%
Bar investigator from submitting additional grant applications	86%	84%
Determine whether information about the research was inappropriately shared with outside entities	80%	78%
Formally counsel investigator regarding the breach of policies	82%	77%
Suspend investigator from employment	74%	72%
Terminate investigator	73%	70%
Postpone promotion of investigator (including tenure track)	70%	67%

Source: OIG analysis of 617 NIH grantees' responses to survey administered from October 2020 to January 2021.

In general, the actions that grantees could take in instances of nondisclosure were the same for both foreign and domestic financial interests or support. Some grantees reported that they could take specific actions that applied only to nondisclosures of foreign financial interests or support, such as escalating their actions more quickly for nondisclosures of foreign financial interests and support compared to those from domestic entities.

Fifteen percent of 565 responding grantees⁵² identified investigators who failed to disclose foreign financial interests in the 2 years prior to the survey, and 18 percent of 575 responding grantees identified investigators who failed to disclose foreign support during that time period. Among grantees that reported investigator nondisclosures, a small number of larger grantees that received the detailed survey described the actions they took in response to these nondisclosures. These actions included following up with investigators to request additional information or clarification, suspending investigators from the research project, and postponing an investigator's promotion (including tenure track).

CONCLUSION AND RECOMMENDATIONS

NIH is committed to international collaborative research, but at the same time, it has raised concerns about foreign threats to the integrity of medical research and intellectual property in NIH-funded biomedical enterprises. Research integrity and security relies, in part, on NIH-funded grantees' oversight of their investigators' relevant foreign financial interests and support. However, some grantees reported gaps in their procedures for identifying and reviewing these financial interests and support, and some of these gaps resulted in noncompliance with Federal requirements. In general, these gaps also applied to grantees' procedures regarding investigators' domestic financial interests and support. These gaps were more frequent among smaller grantees, i.e., those that (as of July 1, 2020) received less than \$10 million in NIH funding. Furthermore, some grantees that received only R13 grants—i.e., grants for conferences—were unaware that they must adhere to Federal requirements regarding investigators' disclosure of foreign financial interests and support.

The gaps identified in this evaluation—including that more than two-thirds of grantees did not require their investigators to disclose all foreign financial interests and support—highlight the need to strengthen grantees' oversight of investigators' disclosures. The lack of full disclosure of investigators' foreign financial interests and support limits grantees' and NIH's ability to perform reviews and ensure protection from potential undue foreign influence. Opportunities also exist for the use and sharing of best practices across grantees. Although some grantees implemented practices that may strengthen their ability to identify investigators' foreign financial interests and support, more grantees could benefit from adapting these types of practices. This could further mitigate the risk of undue foreign influence and ensure more uniform and robust review practices across grantees.

Since the time of our review, NIH has taken steps that may address some of the gaps identified in this review. These steps include further clarifying requirements for disclosing investigators' support, requiring investigators to certify to the accuracy of their disclosures of support, requiring grantees to submit supporting documentation for investigators' foreign activities, and requiring grantees to submit their FCOI policies to NIH. These are important steps toward promoting research integrity and security. We recommend that NIH take additional steps to ensure grantees' compliance with existing Federal requirements, to develop new requirements to strengthen grantee oversight, and to support the sharing of promising practices implemented by grantees.

We recommend that NIH:

Ensure that grantees comply with Federal requirements to train investigators regarding disclosure of significant financial interests

We found that despite Federal requirements, not all grantees required investigators to complete training regarding disclosure of significant financial interests. To ensure maximum transparency in disclosure of all investigators' foreign financial interests, NIH should ensure that grantees are complying with all Federal requirements regarding investigator training, as outlined in the *NIH Grants Policy Statement*. Specifically, NIH should ensure that grantees consistently train their investigators regarding disclosure of significant financial interests. Methods that NIH could use to ensure that grantees comply with the training requirement include, but are not limited to:

- reviewing grantees' training requirements during site visits;
- requiring investigators to annually certify that they have fulfilled the training requirements and comply with the terms of their awards; and
- surveying grantees periodically about their training procedures.

Ensure that grantees conduct the required review of investigators' significant financial interests to determine whether conflicts exist

We found that despite Federal requirements, not all grantees were reviewing all significant financial interests once investigators had disclosed them. To ensure maximum transparency in disclosure of all investigators' foreign FCOIs, NIH should ensure that grantees are performing all required actions, as outlined in the *NIH Grants Policy Statement*. Specifically, NIH should ensure that grantees consistently review all disclosed significant financial interests to identify whether a potential FCOI exists. Methods that NIH could use to ensure that grantees consistently review all disclosed significant financial interests include, but are not limited to:

- advising grantees during site visits on their reviewing procedures;
- issuing reminders to grantees regarding their responsibility to review all significant financial interests that their investigators disclose; and
- targeting additional outreach to smaller grantees to confirm that they understand this requirement.

Specifically require grantees to provide trainings and maintain a written policy regarding investigators' disclosure of other support

Grantees must have policies and procedures to manage funds and activities. For financial interests, there also are specific requirements for investigator training and maintaining a written policy. In the absence of these specific requirements for other support, we found that most grantees did not require investigators to complete training regarding the disclosure of their foreign support, and some grantees did not issue written guidance about their requirements for investigators to disclose foreign support. To help ensure that investigators receive written guidance and training, NIH should update the *NIH Grants Policy Statement* to specifically require grantees to:

- ensure that investigators complete training regarding the disclosure of other support prior to engaging in NIH-funded research and at least every 4 years thereafter; and
- establish and maintain a written policy on other support that includes investigators' responsibilities to disclose information about other support.

Modify reporting mechanisms to require grantees to report whether investigators' significant financial interests and other support involve foreign entities

A 2019 OIG report found that NIH could not identify—and did not plan to identify—whether investigators' FCOIs involve foreign entities. At that time, NIH believed that collecting information regarding an investigator's foreign interests was most appropriately captured as part of the other support reporting process rather than as part of the FCOI reporting process. However, this evaluation found that more than a third of grantees did not distinguish investigators' foreign sources of financial interests and support from their domestic sources of financial interests and support. To increase transparency of the sources of investigators' financial interests and support, NIH should require grantees to identify which financial interests and support are from a foreign source.⁵³

To do this, NIH may consider:

- modifying the eRA Commons FCOI Module, Biosketch Format Page, and/or Other Support Format Page to require grantees to report whether investigators' significant financial interests and other support involve foreign entities; or
- implementing a new reporting mechanism that will allow grantees to indicate whether disclosed financial interests and support are from foreign sources.

Conduct outreach to grantees with R13 conference grants to clarify requirements regarding the disclosure and review of investigators' significant financial interests and other support

Grantees that received only R13 grants—i.e., grants for conferences—had a higher noncompliance rate for requirements for reporting investigators' financial interests and support. These grantees also expressed confusion about the applicability of Federal requirements to R13 grants. NIH should conduct outreach to all grantees with R13 grants to ensure that they are aware that these grants are subject to these requirements for reporting investigators' financial interests and support. As part of this outreach, NIH should clarify how grantees should define an "investigator" for the purposes of R13 grants. In addition to contacting grantees that have R13 grants, NIH could dedicate a section on its website outlining requirements for R13 grants or communicate these requirements to grantees (e.g., through email, blog posts, newsletters, etc.).

Clarify whether and how grantees should verify investigators' significant financial interests and other support prior to submitting information to NIH

Grantees must have internal controls related to ensuring compliance with all Federal requirements. However, we found that many grantees did not perform reviews that could help strengthen their internal controls. Also, some grantees indicated that a lack of guidance from NIH on methods they could use to verify the information disclosed by investigators was a challenge. Therefore, NIH should develop more detailed guidance for grantees about reviewing investigators' disclosures prior to submitting information to NIH. For example, NIH may consider developing a checklist that outlines when grantees should perform a review and provides suggested methods that grantees may use in performing these reviews.

Establish a method for grantees to share their best practices for identifying and reviewing investigators' foreign significant financial interests and other support

Not all grantees are leveraging practices that could reduce vulnerabilities related to foreign influence. Several grantees indicated that it would be helpful if NIH disseminated best practices implemented at other grantee institutions. To encourage grantees to learn about and potentially adopt best practices and strategies that have worked for their peers, NIH should establish a method such as an interactive virtual webinar that is held at least once per year. The method that NIH establishes should promote grantees sharing their best practices for (1) ensuring that investigators

disclose all foreign significant financial interests and other support; and (2) reviewing disclosed information prior to submitting it to NIH.

OIG RESPONSE TO AGENCY COMMENTS

NIH concurred with all recommendations and has planned actions for implementation.

In response to our first recommendation, NIH plans to take several actions to ensure that grantees comply with Federal requirements to train investigators regarding disclosure of significant financial interests. These actions include issuing a notice that reminds grantees about the FCOI training requirements for investigators; updating webpages and communications to grantees with additional information and reminders about the FCOI training requirement; and enhancing the eRA Commons FCOI Module to require grantees to certify their compliance with FCOI training requirements.

In response to our second recommendation, NIH plans to issue a notice that reminds grantees that they are required to review investigators' significant financial interests to determine whether an FCOI exists. NIH also plans to enhance the eRA Commons FCOI Module to require grantees to certify their compliance with this requirement.

In response to our third recommendation, NIH highlighted a January 2022 memorandum issued by the National Science and Technology Council. The memorandum requires certain grant recipients to certify their implementation of a research security program, which may include other support disclosure training. NIH also stated that it will provide necessary extramural training and training for NIH staff on disclosure of other support. OIG continues to recommend that in addition to these actions, NIH update the *NIH Grants Policy Statement* to specifically require grantees to complete training regarding the disclosure of other support and to establish a written policy that outlines investigators' responsibilities to disclose other support.

In response to our fourth recommendation, NIH will look into modifying reporting mechanisms to require grantees to report whether investigators' significant financial interests and other support involve foreign entities. NIH will also issue a notice that reminds grantees about their responsibility to disclose all foreign financial interests.

In response to our fifth recommendation, NIH plans to clarify disclosure and review requirements for recipients of R13 conference grants by issuing a notice to grantees.

In response to our sixth recommendation, NIH will work with grantees to ensure that they understand how significant financial interests and other support disclosures are verified. OIG suggests that NIH provide grantees with guidance that could include specific instructions about how grantees could perform additional reviews when verifying information related to foreign financial interests and support.

In response to our seventh recommendation, NIH will take actions to facilitate grantees sharing their best practices for identifying and reviewing investigators' foreign significant financial interests and other support. These actions will include providing the venue for the first forum for grantees to share FCOI and other support best practices at its 2022 Regional Seminar and dedicating a session of the seminar to discuss this topic.

OIG believes NIH's planned actions will implement these recommendations and improve grantee oversight of foreign significant financial interests and other support.

Appendix C provides the full text of NIH's comments.

APPENDICES

Appendix A: Percentage of Grantees Not In Compliance With NIH’s Disclosure Requirements For Investigators’ Foreign Financial Interests or Support

The *NIH Grants Policy Statement* and HHS regulations specify the types of information that investigators must disclose to grantees and which information grantees must then report to NIH. The exhibits below show the overall percentage of grantees not in compliance with these disclosure requirements for financial interests or support from foreign entities.

Among the 617 grantees that responded to our survey, 28 received only R13 conference grants (i.e., they were R13-only grantees) in FY 2020 as of July 1, 2020. R13 grants support high-quality conferences and scientific meetings that are relevant to NIH's mission and to the public health. Although grantees that receive this type of grant are subject to Federal requirements for reporting investigators’ financial interests and support, most of the R13-only grantees that responded to our survey failed to meet at least one of the Federal disclosure requirements. Additionally, some R13-only grantees were unaware that these requirements apply to them. The tables below show the percentage of R13-only grantees that were not in compliance with Federal disclosure requirements.

Exhibit A-1. Percentage of Grantees Not in Compliance With Federal Disclosure Requirements For Investigators’ Foreign Financial Interests

Type of Foreign Financial Interest	Percentage of Grantees That Did Not Require Investigators To Disclose Information	
	Total Grantees	R13-Only Grantees
Any equity interest in nonpublicly traded foreign entities ¹	45%	79%
Equity interest in publicly traded foreign entities that exceeds \$5,000	14%	75%
Salaries from foreign entities that exceed \$5,000	13%	75%
Sponsored or reimbursed travel paid for by foreign entities	13%	75%
Payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship) from foreign entities that exceed \$5,000	11%	64%
Intellectual property rights and interests (e.g., patents and copyrights) from foreign entities	6%	74%

Source: OIG analysis of 617 NIH grantees’ responses to survey administered from October 2020 to January 2021.

¹ Among the 277 grantees that did not require investigators to disclose *all* nonpublicly traded equity interests from foreign entities, 197 (71 percent) *did* require disclosure of nonpublicly traded equity interests from foreign entities that met a dollar threshold. Of these 197 grantees, 191 required this disclosure at a dollar threshold that was the same as their requirement for publicly traded equity interests from foreign entities.

Exhibit A-2. Percentage of Grantees Not in Compliance With Federal Disclosure Requirements For Investigators' Foreign Support

Type of Foreign Support	Percentage of Grantees That Did <u>Not</u> Require Investigators To Disclose Information	
	Total Grantees	R13-Only Grantees
Participation in foreign "talents" or similar types of programs	36%	68%
In-kind resources (e.g., office or laboratory space, equipment, supplies, employees, students, and visiting scholars) from foreign entities	31%	68%
Items or funds given with conditions attached or deliverables expected in return from foreign entities	25%	71%
Professional affiliations (e.g., positions and scientific appointments) with foreign entities	21%	50%
Financial support through pending grants from foreign entities	14%	57%
Financial support through cooperative agreements from foreign entities	11%	61%
Financial support through contracts from foreign entities	11%	61%
Financial support through active grants from foreign entities	10%	50%

Source: OIG analysis of 617 NIH grantees' responses to survey administered from October 2020 to January 2021.

Appendix B: Methods Grantees Used To Distinguish Whether the Source of an Investigator’s Financial Interest or Support Was a Foreign Entity

Exhibit B-1. Methods To Distinguish Whether the Source of a **Financial Interest** or **Support** Is a Foreign Entity

Method	Percentage of Grantees That Used This Method:	
	Financial Interests	Support
Require investigator to provide the address of the source	24%	25%
Use other method(s) to distinguish whether the source is from a foreign entity ¹	21%	25%
Have a checkbox on the form used by investigators to distinguish whether the source is a foreign entity	20%	18%
Compare the name of the source to a list of international entities	12%	17%
Require investigators to complete a separate form for reporting financial interests/support from foreign entities versus from domestic entities	5%	6%

Source: OIG analysis of 617 NIH grantees’ responses to survey administered from October 2020 to January 2021.

¹ Examples of other methods include using a single form for reporting all support but requiring investigators to identify whether the support is domestic or foreign through the use of "Domestic" and "Foreign" subcategories; conducting individualized followup with the investigator concerning the nature of the financial interest and other relevant information; and conducting online searches of disclosed entities to identify potential foreign affiliations.

Appendix C: Agency Comments

Following this page are the official comments from NIH.



DATE: April 20, 2022

TO: Suzanne Murrin
Deputy Inspector General for Inspection and Evaluations, HHS

FROM: Acting Principal Deputy Director, National Institutes of Health

SUBJECT: NIH Comments on Draft Report, “*Opportunities Exist To Strengthen NIH Grantees’ Oversight of Investigators’ Foreign Significant Financial Interests and Other Support*” (OEI-03-20-00210)

Attached are the National Institutes of Health’s (NIH) comments on the draft Office of Inspector General’s (OIG) report, “*Opportunities Exist To Strengthen NIH Grantees’ Oversight of Investigators’ Foreign Significant Financial Interests and Other Support*” (OEI-03-20-00210).

NIH appreciates the review conducted by OIG and the opportunity to provide the comments on this draft report. If you have questions or concerns, please contact Tiffany Brown in the Office of Management Assessment at 301-496-2464.

/s/ Tara A. Schwetz, Ph.D.

Tara A. Schwetz, Ph.D.

Attachments

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH (NIH) ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT ENTITLED: “OPPORTUNITIES EXIST TO STRENGTHEN NIH GRANTEE’S OVERSIGHT OF INVESTIGATORS’ FOREIGN SIGNIFICANT FINANCIAL INTERESTS AND OTHER SUPPORT” (OEI-03-20-00210)

The National Institutes of Health (NIH) appreciates the review conducted by the Office of Inspector General (OIG) and the opportunity to provide clarifications on this draft report. NIH respectfully submits the following general comments.

OIG Recommendation 1:

We recommend that the National Institutes of Health ensure that grantees comply with Federal requirements to train investigators regarding disclosure of significant financial interests.

NIH Response:

NIH concurs with OIG's finding and corresponding recommendation to ensure that grantees comply with Federal requirements to train investigators regarding disclosure of significant financial interests.

In addition to the extensive training and resources NIH has provided to its grant recipients on the requirements of the Financial Conflict of Interest (FCOI) regulation, including the requirements and responsibilities surrounding the disclosure and review of significant financial interests and investigator training, the NIH will take the following actions to address this recommendation:

- During FY 2022, NIH will publish a Guide Notice in the NIH Guide for Grants and Contracts to remind the extramural community about the FCOI training requirements for Investigators. The Guide Notice will also alert the community to the training resources NIH has made available on its [FCOI webpage](#). The [FCOI tutorial](#) slide set on the FCOI webpage satisfies the requirement that institutions train Investigators about the FCOI regulation, including financial disclosure requirements.
- During FY 2022, NIH anticipates that it will begin to develop the requirements for Phase II enhancements to the eRA Commons Institution Profile (IPF) Module as announced in NIH Guide Notice [NOT-OD-21-002](#), Required Submission of Financial Conflict of Interest Policy into the eRA Commons IPF Module, dated September 30, 2020. We anticipate that the enhancements will require institutions to submit a compliance certification that their FCOI policy implements the identified FCOI requirements, including Investigator training and disclosure requirements.
- During FY 2022, NIH will update the FCOI webpage to include additional outreach resources that address Investigator training requirements, including presentations and webcasts.
- NIH will continue to provide FCOI training for the extramural community as part of NIH’s outreach program.
- During FY 2022, NIH will publish a blog to remind NIH applicants and recipients about FCOI requirements, including the applicability of the FCOI regulation, the requirement to have a written, enforced policy on FCOI, the requirement to submit a FCOI policy to the NIH via the eRA Commons IPF Module per the NIH Guide Notice NOT-OD-21-002, and to provide FCOI training to Investigators. The blog will also remind the extramural

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH (NIH) ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT ENTITLED: “OPPORTUNITIES EXIST TO STRENGTHEN NIH GRANTEE’S OVERSIGHT OF INVESTIGATORS’ FOREIGN SIGNIFICANT FINANCIAL INTERESTS AND OTHER SUPPORT” (OEI-03-20-00210)

community about the need to submit other support information consistent with NIH policy requirements.

- During FY 2022, NIH will update its Foreign Grant and SBIR/STTR Webpages to include information about FCOI requirements, including the requirement to train Investigators on the FCOI regulation and the Investigator’s responsibility to disclose their significant financial interests.
- During FY 2022, NIH will update its “Welcome Wagon” letter for new recipient organizations to include information about the requirement to submit FCOI policy in the eRA Commons IPF Module and to inform institutions of the resources available on the NIH FCOI webpage, including a training module (FCOI Tutorial) for Investigators.
- During FY 2022, NIH will send a letter to the SBIR/STTR community to remind them about the applicability of the FCOI regulation, the need to submit their institution’s FCOI policy in the eRA Commons IPF Module, and the requirement to provide FCOI training to Investigators, among other things.

OIG Recommendation 2:

We recommend that the National Institutes of Health ensure that grantees conduct the required review of investigators’ significant financial interests to determine whether conflicts exist.

NIH Response:

NIH concurs with OIG's finding and corresponding recommendation to ensure grantees conduct the required review of investigators’ significant financial interests to determine whether conflicts exist.

- During FY 2022, NIH will include in the above-referenced Guide Notice a reminder that institutions are required to review investigators’ significant financial interests to determine whether a FCOI exists.
- During FY 2022, NIH anticipates that it will begin to develop the requirements for Phase II enhancements that we anticipate will require institutions to certify that they are in compliance with all identified FCOI requirements, including the requirement that institutions review Investigators’ SFIs to determine FCOIs.
- The above-referenced letter to the SBIR/STTR community will also include information on the requirement to review investigator’s SFIs to determine FCOIs.

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH (NIH) ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT ENTITLED: “OPPORTUNITIES EXIST TO STRENGTHEN NIH GRANTEE’S OVERSIGHT OF INVESTIGATORS’ FOREIGN SIGNIFICANT FINANCIAL INTERESTS AND OTHER SUPPORT” (OEI-03-20-00210)

OIG Recommendation 3:

We recommend that the National Institutes of Health specifically require grantees to provide training and written policy regarding investigators’ disclosure of other support.

NIH Response:

NIH concurs with OIG's finding and corresponding recommendation to require grantees to provide trainings and written policy regarding investigators’ disclosure of other support.

- The “Guidance for Implementing National Security Presidential Memorandum 33 (NSPM-33) on National Security Strategy for United States Government-Supported Research and Development” published by National Science and Technology Council in January 2022, requires recipients that are awarded more than \$50 million/year to certify their implementation of a “research security program,” which may include other support disclosure training.
- NIH will continue to work with our Federal partners to provide necessary extramural training and training for NIH staff on disclosure of other support.

OIG Recommendation 4:

We recommend that the National Institutes of Health modify reporting mechanisms to require grantees to report whether investigators’ significant financial interests and other support involve foreign entities.

NIH Response:

NIH concurs with OIG's finding and corresponding recommendation to modify reporting mechanisms.

- Beginning in FY 2022, NIH will look into modifying reporting mechanisms to require grantees to report whether investigator’s significant financial interests and other support involve foreign entities.
- The Guide Notice referenced above will also include a FCOI reminder that Investigators are required to disclose all foreign financial interests. The Guide Notice will also include another support reminder that investigators must disclose all resources made available to them in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant, which includes resources and/or financial support from all foreign and domestic entities.

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH (NIH) ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT ENTITLED: “OPPORTUNITIES EXIST TO STRENGTHEN NIH GRANTEE’S OVERSIGHT OF INVESTIGATORS’ FOREIGN SIGNIFICANT FINANCIAL INTERESTS AND OTHER SUPPORT” (OEI-03-20-00210)

OIG Recommendation 5:

We recommend that the National Institutes of Health conduct outreach to grantees with R13 conference grants to clarify requirements regarding the disclosure and review of investigators’ significant financial interests and other support.

NIH Response:

NIH concurs with OIG's finding and corresponding recommendation to provide guidance to recipients of NIH conference grants regarding the disclosure and review of investigators’ significant financial interests and other support.

During FY 2022, NIH will develop a Guide Notice to be published in the NIH Guide to Grants and Contracts providing guidance for recipients of NIH conference grants on the disclosure and review of investigators’ significant financial interest and other support.

OIG Recommendation 6:

We recommend that the National Institutes of Health clarify whether and how grantees should verify investigators’ foreign significant financial interests and other support prior to submitting this information to NIH.

NIH Response:

NIH concurs that grantees should verify investigators’ foreign significant financial interests and other support prior to submitting this information to NIH.

Investigators make their disclosures to their institutions which, in turn, report to NIH. It is the recipient institution that is responsible for ensuring that the information submitted to NIH is complete and accurate. Therefore, NIH will work with grantees to ensure that they understand how foreign significant financial interests and other support disclosures are verified.

OIG Recommendation 7:

We recommend that the National Institutes of Health establish a method for grantees to share their best practices for identifying and reviewing investigators’ foreign significant financial interests and other support.

NIH Response:

NIH concurs with the OIG’s finding that opportunities exist for the sharing of best practices across grantees that could strengthen their identification of investigators’ foreign financial interests and support.

NIH believes that the recipient community should establish a collaborative forum for recipients to discuss best practices and strategies for identifying and reviewing investigators significant financial interests and other support.

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH (NIH) ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT ENTITLED: “OPPORTUNITIES EXIST TO STRENGTHEN NIH GRANTEE’S OVERSIGHT OF INVESTIGATORS’ FOREIGN SIGNIFICANT FINANCIAL INTERESTS AND OTHER SUPPORT” (OEI-03-20-00210)

Each year, the Office of Extramural Research sponsors the NIH Regional Seminars on Program Funding and Grants Administration. These seminars are intended to help demystify the application and review process, clarify Federal regulations and policies, and highlight current areas of special interest or concern. The seminars serve the NIH mission of providing education and training for the next generation of biomedical and behavioral scientists. NIH policy, grants management, review and program staff provide a broad array of expertise and encourage personal interaction between themselves and seminar participants. There were over 24,000 registered attendees for the 2021 NIH Virtual Seminar on Program Funding and Grants Administration from all 50 states, including Washington, D.C., and Puerto Rico, as well as 118 foreign countries. Approximately 58% of the attendees had Administrators/Financial roles in their institutions (e.g., Office of Sponsored Programs, Departmental Administrators) and approximately 26% had Research-Related roles (e.g., Principal Investigators, Research Trainees). Attendees represented non-profits, small businesses, hospitals, foreign organizations, and institutions of higher education, among others.

NIH supports the formation of a forum for institutions that receive Federal funding to share FCOI and other support best practices and recognizes the need to engage a broad representation of the appropriate level of institutional officials in such discussions to ensure that best practices are duly considered within the institutional framework, including how they can be implemented. NIH will provide the venue for the first forum for grant recipients to share FCOI and other support best practices at its 2022 Regional Seminar. We envision dedicating a session to this discussion to be led by a representative(s) from a grantee institution with NIH participation.

There are professional organizations, such as the Federal Demonstration Partnership, composed of officials from institutions that receive Federal funds and Federal agency representatives that would provide an appropriate venue for recipients to work collaboratively with Federal agency officials to develop and share best practices.

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This report was prepared under the direction of Linda Ragone, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Joanna Bisgaier, Deputy Regional Inspector General.

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To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

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ABOUT THE OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

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ENDNOTES

¹ In this report, we use the term “investigator” to refer to all individuals required to submit information to grantees relating to significant financial interests and/or other support. The requirement to disclose significant financial interests applies to the Program Director/Principal Investigator and any other person—regardless of title or position—who is responsible for the design, conduct, or reporting of research that NIH funds. The requirement to disclose other support applies to all individuals designated as senior/key personnel—those devoting measurable effort to a project.

² NIH, *Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interest and Foreign Components*, NOT-OD-19-114, July 2019. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html> on June 23, 2021.

³ Department of Justice, *Department of Justice Reaches Million-Dollar Settlement with Van Andel Research Institute to Resolve Allegations of Undisclosed Foreign Ties to NIH Grants*, September 2021. Accessed at [Department Of Justice Reaches Million-Dollar Settlement With Van Andel Research Institute To Resolve Allegations Of Undisclosed Foreign Ties To Nih Grants | USAO-WDMI | Department of Justice](https://www.justice.gov/opa/pr/2021/09/21-doj-09-21-21-0001) on January 21, 2022.

⁴ Established by the Chinese government in 2008, the Thousand Talents Plan (also referred to as the Thousand Talents Program) incentivizes individuals engaged in research and development in the United States to transmit the knowledge and research they gain in the U.S. to China in exchange for salaries, research funding, laboratory space, and other incentives. See United States Senate, Permanent Subcommittee on Investigations Staff Report, *Threats to the U.S. Research Enterprise: China's Talent Recruitment Plans*, p. 2. Accessed at <https://www.hsgac.senate.gov/imo/media/doc/2019-11-18%20PSI%20Staff%20Report%20-%20China's%20Talent%20Recruitment%20Plans%20Updated2.pdf> on August 16, 2021.

⁵ NIH, *Statement on Protecting the Integrity of U.S. Biomedical Research*, August 2018. Accessed at <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research> on June 6, 2021.

⁶ Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, P.L. No. 115-245; Further Consolidated Appropriations Act, 2020, P.L. No. 116-94; Consolidated Appropriations Act, 2021, P.L. No. 116-260.

⁷ Investigators must disclose salary and payments (not otherwise identified as salary) received in the prior 12 months from a publicly traded entity as well as any equity interest (as of the date of disclosure) in a publicly traded entity when the total value—when aggregated—exceeds \$5,000. Investigators also must disclose this information for salary, payments, and interests received from a nonpublicly traded entity. However, the \$5,000 threshold applies only to the aggregated value of salary and payments received from a nonpublicly traded entity; investigators must also disclose all equity interests in a nonpublicly traded entity—regardless of value. In addition, investigators must disclose any reimbursed or sponsored travel related to their institutional responsibilities, with some exceptions (42 CFR § 50.603).

⁸ 42 CFR § 50.605(a)(1).

⁹ 42 CFR § 50.605(b)(1) and (b)(3)(viii)(C).

¹⁰ The FCOI module in eRA Commons is an online interface that allows NIH-funded grantees to report the existence of any identified FCOI to NIH, as required by the Federal regulations.

¹¹ NIH, *Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interest and Foreign Components*, NOT-OD-19-114, July 2019. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html> on June 23, 2021. NIH, *NIH Grants Policy Statement*, section 2.5.1, October 2018. Accessed at https://grants.nih.gov/grants/policy/nihgps/nih_gps_2018.pdf on January 24, 2022. We are citing the *NIH Grants Policy Statement* issued in October 2018 because our review focused on grantees that received NIH funding for FY 2020, and this version of the

NIH GPS was in effect during the first part of the FY 2020 award period. In March 2021, NIH issued a notice that reminded grantees that an item or service given to an investigator with the expectation of an associated time commitment is not a gift and must be reported as support. See NIH, *Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or After May 25, 2021*, NOT-OD-21-073, March 2021. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html> on August 24, 2021.

¹² Investigators use the Biosketch Format Page and the Other Support Format Page as templates, which then are used as attachments in grant applications and progress reports. The Biosketch Format Page contains biographical information (e.g., education and training, current position, personal statement, and other positions or scientific appointments). The Other Support Format Page contains information about all resources made available to a researcher in support of and/or related to all of their research endeavors. Both format pages were updated as of March 2021, and grantees must use the updated format pages beginning January 2022.

¹³ NIH, *NIH Grants Policy Statement*, section 2.5.1, October 2018. Accessed at https://grants.nih.gov/grants/policy/nihgps/nih_gps_2018.pdf on January 24, 2022.

¹⁴ NIH, *Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interest and Foreign Components*, NOT-OD-19-114, July 2019. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html> on June 23, 2021.

¹⁵ 42 CFR § 50.602. NIH, *NIH Grants Policy Statement*, section 2.5.1, October 2018. Accessed at https://grants.nih.gov/grants/policy/nihgps/nih_gps_2018.pdf on January 24, 2022.

¹⁶ NIH, *Types of Grant Programs*. Accessed at https://grants.nih.gov/grants/funding/funding_program.htm on October 28, 2021.

¹⁷ 42 CFR § 50.602 and § 50.603.

¹⁸ NIH, *Clarifying Long-Standing NIH Policies on Disclosing Other Support*, July 2019. Accessed at <https://nexus.od.nih.gov/all/2019/07/11/clarifying-long-standing-nih-policies-on-disclosing-other-support/> on August 24, 2021.

¹⁹ 45 CFR Part 75. NIH, *NIH Grants Policy Statement*, sections 8.3 and 2.5.1, October 2018. Accessed at https://grants.nih.gov/grants/policy/nihgps/nih_gps_2018.pdf on January 24, 2022.

²⁰ 42 CFR § 50.604(a).

²¹ 42 CFR § 50.604(b).

²² 42 CFR § 50.604(f)-(h).

²³ NIH, *Grants Compliance & Oversight*. Accessed at <https://grants.nih.gov/policy/compliance.htm#activities> on November 3, 2021.

²⁴ Ibid.

²⁵ 42 CFR § 75.371.

²⁶ 42 CFR § 75.371-.372.

²⁷ NIH, *Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests*, NOT-OD-18-160, March 2018. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html> on April 25, 2022.

²⁸ NIH, *Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interest and Foreign Components*, NOT-OD-19-114, July 2019. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html> on June 23, 2021.

²⁹ NIH, *Required Submission of Financial Conflict of Interest Policy into the eRA Commons Institution Profile (IPF) Module*, NOT-OD-21-002, September 2020. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-002.html> on August 24, 2021.

³⁰ NIH, *Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or After May 25, 2021*, NOT-OD-21-073, March 2021. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html> on August 24, 2021.

³¹ Ibid.

³² NIH expects applicants and grantees to use the updated Biosketch Format Page and Other Support Format Page for applications, Just-in-Time (JIT) Reports, and Research Performance Progress Reports (RPPRs) as of May 25, 2021 but does not require these format pages until January 25, 2022. See NIH, *Implementation of Changes to the Biographical Sketch and Other Support Format Page*, NOT-OD-21-110, April 2021. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-110.html> on August 24, 2021.

³³ OIG, *National Institutes of Health: Conflicts of Interest in Extramural Research*, OEI-03-06-00460, January 2008; OIG, *How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health*, OEI-03-07-00700, November 2009.

³⁴ HHS, *Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors, Final Rule*, 76 Fed. Reg. 53256 (August 25, 2011). These amendments to the regulations at 42 CFR Part 50, Subpart F, apply to institutions applying for or receiving Public Health Service funding, which includes funding from NIH.

³⁵ Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, P.L. No. 115-245; Further Consolidated Appropriations Act, 2020, P.L. No. 116-94; Consolidated Appropriations Act, 2021, P.L. No. 116-260.

³⁶ OIG, *The National Institutes of Health Has Limited Policies, Procedures, and Controls in Place for Helping to Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations*, A-03-19-03003, September 2019.

³⁷ OIG, *NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More*, OEI-03-19-00150, September 2019.

³⁸ Ibid.

³⁹ We removed eight grantees from the list that NIH provided that were not U.S.-based.

⁴⁰ None of the grantees received exactly \$10 million in NIH funding for FY 2020 as of July 1, 2020.

⁴¹ We randomly selected these 100 grantees from a sampling frame of 233 larger grantees—the 244 larger grantees excluding 11 grantees included in Government Accountability Office (GAO) work. We removed these 11 grantees from the sampling frame so as not to overburden them with a detailed survey and documentation request, but we kept them in our overall grantee population. See GAO, *Federal Research, Agencies Need to Enhance Policies to Address Foreign Influence*, GAO-21-130, December 2020. Accessed at <https://www.gao.gov/assets/gao-21-130.pdf> on January 26, 2022.

⁴² Among larger grantees, the response rate was 79 percent for the detailed survey compared to 89 percent for the short survey.

⁴³ There were eight grantees that did not answer survey questions regarding financial interests because their investigators are Federal employees and are not subject to HHS's FCOI regulations. Therefore, we asked these eight grantees to complete only the section of our survey that pertained to other support. As a result, our total number of respondents was reduced from 617 to 609 throughout the report for any calculations pertaining only to financial interests.

⁴⁴ These grantees received less than \$10 million in NIH funding for FY 2020 as of July 1, 2020.

⁴⁵ 42 CFR § 50.603.

⁴⁶ The National Science Foundation, *Proposal and Award Policies and Procedures Guide*, NSF 20-1, June 2020. Accessed at https://www.nsf.gov/pubs/policydocs/pappg20_1/nsf20_1.pdf on July 19, 2021.

⁴⁷ To identify grantees in our review that received only R13 conference grants in FY 2020 as of July 1, 2020, we used data from the FY 2020 RePORTER Project Data file. Accessed at https://exporter.nih.gov/ExPORTER_Catalog.aspx on January 13, 2021.

⁴⁸ 42 CFR § 50.605(a)(1).

⁴⁹ 45 CFR Part 75; NIH. *NIH Grants Policy Statement*, sections 8.3 and 2.5.1, October 2018. Accessed at https://grants.nih.gov/grants/policy/nihgps/nih_gps_2018.pdf on January 24, 2022.

⁵⁰ NIH, *Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or After May 25, 2021*, NOT-OD-21-073, March 2021. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html> on August 24, 2021.

⁵¹ OIG, *NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More*, OEI-03-19-00150, September 2019.

⁵² Grantees had the option to skip the questions about whether, in the last 2 years, they had identified any investigator(s) who failed to disclose support or financial interests from a foreign entity and the followup questions regarding what actions were taken in response to the nondisclosure.

⁵³ OIG, *NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More*, OEI-03-19-00150, September 2019.