



U.S. Department of Health and Human Services
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**NIH Has Made Strides in
Reviewing Financial
Conflicts of Interest in
Extramural Research,
But Could Do More**

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NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More

What **OIG** Found

The National Institutes of Health (NIH) has made progress in overseeing financial conflicts of interest (FCOIs) that extramural grantee institutions (institutions) report for their research investigators. Over the last decade, NIH has strengthened its reporting requirements and developed an online system for collecting, reviewing, and storing FCOIs that institutions report. These changes have resulted in improvements in how NIH tracks and reviews FCOIs that institutions report.

Because of its improved tracking, NIH is now able to provide the number and types of FCOIs that institutions report. Overall, 3 percent of NIH grants in fiscal year (FY) 2018 had investigators with FCOIs. These grants received \$1 billion in funding during FY 2018, and institutions reported a total of 2,755 FCOIs.

Key Takeaway

NIH has improved its tracking and review of investigators' financial conflicts of interest (FCOIs) over the last decade, and additional actions would further strengthen its oversight of investigators' FCOIs and its monitoring of FCOIs involving foreign interests.

Although NIH has made substantial strides in reviewing each reported FCOI for completeness and compliance, as well as to ensure the reasonableness of institutions' management plans, we found inconsistencies in the depth of its oversight reviews. Across the three NIH Institutes and Centers (ICs) that we reviewed, staff differed in the level of scrutiny they applied to their review of FCOIs. Furthermore, NIH lacks quality assurance procedures in its review process. Specifically, NIH central management and

the three ICs that we reviewed do not perform any systematic analyses or even ad-hoc checks to determine whether staff accurately and consistently review reported FCOIs, and **OIG** found a small number of inconsistencies in the FCOI data that institutions reported, which might highlight the need for more oversight of the review process.

Lastly, NIH was unable to identify FCOIs involving foreign interests because U.S. Department of Health and Human Services' (HHS) regulations do not require institutions to indicate whether an investigator's FCOI involves an entity (e.g., a company, university, or government) that is based outside the United States. NIH has no plans to require institutions to designate—when reporting their investigators' FCOIs—whether those FCOIs involve foreign entities. Instead, NIH is collecting information regarding investigators' foreign associations through a clarification of its requirements for pre-award reporting.

What **OIG** Recommends

NIH has taken many steps within the last decade to improve its tracking and review of investigators' FCOIs, and additional actions would further strengthen the consistency and rigor of its oversight process. We recommend that NIH (1) perform periodic quality assurance reviews of the FCOI information in its online system to ensure the adequacy of its oversight, and (2) use information regarding foreign affiliations and support that it collects during the pre-award reporting process to decide whether to revise its FCOI review process to address concerns regarding foreign threats. NIH concurred with both recommendations.

Why **OIG** Did This Review

NIH awards more than 70 percent of its \$37 billion budget to universities and other grantee institutions. Identifying and managing investigators' FCOIs is critical to safeguarding the integrity of NIH-funded research.

In 2008, **OIG** identified serious gaps in NIH's oversight of investigators' FCOIs. More recently, failures by some investigators to disclose substantial contributions of resources from other organizations—including foreign governments—have raised new concerns about threats to research integrity. This failure highlights (1) the need for institutions to accurately identify and report investigators' FCOIs, and (2) the need for NIH to have robust oversight of institutions' management of these FCOIs.

This report focuses on the need for this robust oversight, follows up on **OIG**'s prior work, and seeks to determine whether NIH has addressed the gaps that **OIG** previously identified in the oversight of investigators' FCOIs. It also provides—for the first time—information about the total number and types of FCOIs that institutions are reporting to NIH. In a separate review, **OIG** examined NIH's policies, procedures, and controls regarding institutions' reporting of investigators' FCOIs.

How **OIG** Did This Review

We collected from NIH the number and type of FCOIs that institutions reported in FY 2018. We sent a questionnaire and conducted an interview with staff from NIH's Office of Extramural Research. We also reviewed guidance and training documents related to investigators' FCOIs. Finally, we interviewed staff at three NIH ICs regarding their procedures for reviewing FCOIs that institutions reported.

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BACKGROUND

Objectives

1. Describe the number and types of financial conflicts of interest (FCOIs) reported in fiscal year (FY) 2018 to the National Institutes of Health (NIH) by extramural grantee institutions.
2. Identify the actions that NIH has taken to track and review FCOIs reported by extramural grantee institutions.
3. Determine whether and how NIH's FCOI review process addresses recent concerns regarding investigators' financial interests with foreign entities.

For FY 2019, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) received \$5 million in congressional appropriations to conduct oversight of NIH grant programs and operations.¹ As indicated by the conference report that accompanied the legislation, "the conferees direct[ed] the OIG to examine NIH's oversight of its grantees' compliance with NIH policies."²

This review is part of a larger body of HHS OIG work focused on oversight of NIH grant programs and operations. Our work will review (1) intellectual property and cybersecurity protections; (2) compliance with Federal requirements and NIH policies for grants and contracts; and (3) integrity of grant application and selection processes. OIG is issuing two reports directly related to FCOIs: one that examines NIH's policies, procedures, and controls regarding institutions' reporting of investigators' FCOIs;³ and this report, which addresses NIH's tracking and review of FCOIs that extramural grantee institutions report.

More than 70 percent of NIH's \$37 billion budget in FY 2018 went toward extramural grants⁴ to support investigators working in universities and other

¹ Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, P.L. No. 115-245 (Sept. 28, 2018).

² Department of Defense for the Fiscal Year Ending September 30, 2019, and for Other Purposes. Conference Report to Accompany H.R. 6157, H.R. Rep. No. 115-952, 2018.

³ OIG, *NIH 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.

⁴ Extramural grants are grants that NIH awards to external organizations, including universities, medical schools, hospitals, and other research facilities.

grantee institutions (hereinafter institutions). These institutions play a key role in protecting the integrity and security of U.S. biomedical research by managing their investigators' FCOIs and reporting them to NIH.

In August 2018, NIH issued a statement that raised concerns about increasing risks to the security of intellectual property in its biomedical research enterprise.⁵ Among NIH's concerns was the failure by some investigators to disclose substantial contributions of resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds. NIH stated that it was addressing these concerns—in part—by taking steps to improve accurate reporting of all sources of research support, financial interests, and affiliations.

A 2008 OIG report identified serious gaps in NIH's oversight of extramural investigators' FCOIs.⁶ In light of NIH's stated concerns about protecting the integrity of U.S. biomedical research, this evaluation follows up on our previous work and describes the FCOIs that institutions reported in FY 2018, as well as how NIH tracks and reviews FCOIs that institutions reported.

FCOIs of NIH-Funded Investigators

The HHS regulations at 42 CFR Part 50, Subpart F establish standards to provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research will be free from bias resulting from investigators' FCOIs.^{7, 8} An FCOI exists when an institution reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of NIH-funded research.⁹

Investigators' Significant Financial Interests

HHS regulations define a significant financial interest as any financial interest of the investigator¹⁰ (and those of the investigator's spouse and dependent children) that reasonably appears to be related to the

⁵ NIH, *Statement on Protecting the Integrity of U.S. Biomedical Research*, August 2018. Accessed at <https://www.nih.gov> on June 6, 2019.

⁶ OIG, *National Institutes of Health: Conflicts of Interest in Extramural Research*, OEI-03-06-00460, January 2008.

⁷ 42 CFR § 50.601.

⁸ These regulations do not apply to Phase I Small Business Innovation Research (SBIR) Program or Small Business Technology Transfer (STTR) Program applications. 76 Fed. Reg. 53256, 53261 (Aug 25, 2011).

⁹ 42 CFR § 50.604(f).

¹⁰ An investigator is defined as 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. See *NIH Grants Policy Statement*, ch. 4.1.10, October 2018.

investigator’s institutional responsibilities.¹¹ Intellectual property rights and interests (e.g., patents and copyrights) may constitute a significant financial interest. Other examples include remuneration (e.g., salary, consulting fees, honoraria, paid authorship) and/or equity interest received from an entity that exceeds \$5,000 in the aggregate in the year prior to disclosure with regard to any publicly traded entity.¹²

Requirements for Reporting Investigators’ FCOIs to NIH

Prior to expending any funds under the NIH-funded research project, institutions must review all investigator disclosures of significant financial interests and determine whether any FCOIs exist.¹³ If an institution determines that an FCOI exists, it must develop and implement a management plan that specifies the actions that have been taken and will be taken to manage the FCOI to protect the design, conduct, and reporting of research from bias.¹⁴ The FCOI and the key elements of the institution’s management plan must be reported to NIH.¹⁵ If an institution identifies any FCOIs after the expenditure of NIH funds has begun, it must report those to NIH within 60 days of identifying the FCOI.¹⁶

Reporting of FCOIs to NIH

HHS revised regulations in 2011 to expand on the information that institutions must report to NIH about FCOIs. Specifically, institutions must include sufficient information to enable NIH to (1) understand the nature and extent of the investigator’s FCOI and (2) assess the appropriateness of the institution’s plan to manage the FCOI to protect the research from bias.¹⁷ After initially reporting an FCOI, an institution must submit annual reports to inform NIH of the status of the FCOI and any changes, if applicable, to the management plan.^{18, 19}

Noncompliance With FCOI Reporting

If an investigator does not disclose a significant financial interest, or an institution does not manage an FCOI in a timely manner, or an investigator does not comply with the management plan, this constitutes

¹¹ 42 CFR § 50.603.

¹² Ibid.

¹³ 42 CFR § 50.605(a)(1).

¹⁴ Ibid.

¹⁵ 42 CFR § 50.605(b)(1).

¹⁶ 42 CFR § 50.605(b)(2).

¹⁷ 42 CFR § 50.605(b)(3).

¹⁸ An institution must submit these annual reports to NIH each year within a competitive segment or until the institution reports that the FCOI no longer exists.

¹⁹ 42 CFR § 50.605(b)(4).

noncompliance with the FCOI regulations.²⁰ Within 120 days of determining noncompliance, the institution must conduct a retrospective review to determine whether the investigator's NIH-funded project conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of the research.²¹ If the institution finds bias, it must submit to NIH a mitigation report that describes the impact that the bias had on the research. The mitigation plan also must detail the institution's plan of action to eliminate or mitigate the effect of the bias.²²

Enforcement Actions

If at any time NIH determines that an institution has failed to comply with the terms and conditions of award—including failure to report or manage an investigator's FCOI—NIH may take one or more enforcement actions.²³ These enforcement actions include disallowing costs, withholding of further awards, suspending the grant (wholly or partially), and terminating the grant.^{24, 25}

Investigators' Foreign Investments

In March 2018, NIH released a Guide Notice that reminds and clarifies for the extramural research community that investigators must disclose all financial interests received from a foreign institution of higher education or a foreign government.²⁶ In December 2018, NIH's ACD [Advisory Committee to the Director] Working Group for Foreign Influences on Research Integrity recommended that NIH implement a broad education campaign to raise awareness about the need to disclose other research support, international affiliations, international collaborations, and foreign financial interests. This group also recommended that NIH consider expanding its current regulatory approach concerning investigators' FCOIs to expressly account for interest in which no financial remuneration is indicated but which overlaps with the scope of the NIH-funded research.²⁷

²⁰ 42 CFR § 50.605(a)(3)(ii)(A).

²¹ Ibid.

²² 42 CFR § 50.605(a)(3)(iii).

²³ 42 CFR § 50.606(a).

²⁴ 42 CFR § 50.606(b).

²⁵ NIH, *NIH Grants Policy Statement*, ch. 8.5.2, October 2018.

²⁶ NIH, *Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests*, NOT-OD-18-160, March 2018. Accessed at <https://grants.nih.gov> on May 28, 2019.

²⁷ NIH Advisory Committee to the Director, *ACD [Advisory Committee to the Director] Working Group for Foreign Influences on Research Integrity*, December 2018. Accessed at <https://acd.od.nih.gov> on December 28, 2018.

NIH's Responsibilities for Tracking and Reviewing Reported FCOIs

NIH awards grants to institutions through its 24 Institutes and Centers (ICs) that have grant-making authority.²⁸ Each IC is responsible for the daily management and oversight of its grants,²⁹ and each has its own grants management office and program office. ICs follow the FCOI regulations, which are outlined in the *NIH Grants Policy Statement*.³⁰ Institutions must follow this policy statement as a term and condition of their respective NIH grant awards. The *NIH Grants Policy Statement* is maintained by NIH's Office of Extramural Research (OER).³¹ OER and ICs share responsibility for ensuring that institutions are reporting and managing investigators' FCOIs according to the regulations.

OER's Responsibilities for Overseeing the FCOI Review Process

Within NIH's Office of the Director, OER supports the entire NIH extramural research community by providing policy, guidance, systems and other support to grant recipients and to the grant-making ICs.³² OER provides leadership and oversight to the extramural research community and NIH extramural staff, including matters relating to FCOIs.³³ OER has established (based on governing regulations) training and guidance regarding the monitoring and reviewing of FCOIs.³⁴

NIH ICs' Responsibilities for Tracking and Reviewing Reported FCOIs

The NIH IC that awards a grant is responsible for the administration and monitoring of grant-supported activities. Within each IC, grants management staff are responsible for the business management aspects of grants, while program office staff are responsible for the programmatic, scientific, and/or technical aspects of grants. Grants management staff and program office staff each play a role in reviewing FCOI reports that institutions submit, as shown in Exhibit 1. Although all ICs adhere to the FCOI regulations, ICs may develop their own internal procedures for reviewing reported FCOIs in addition to those established by OER.

²⁸ NIH, *About the Office of Extramural Research (OER) at NIH*. Accessed at <https://grants.nih.gov> on January 11, 2019.

²⁹ NIH, *NIH Grants Policy Statement*, ch. 1.2, October 2018.

³⁰ NIH, *NIH Grants Policy Statement*, ch. 4.1.10, October 2018.

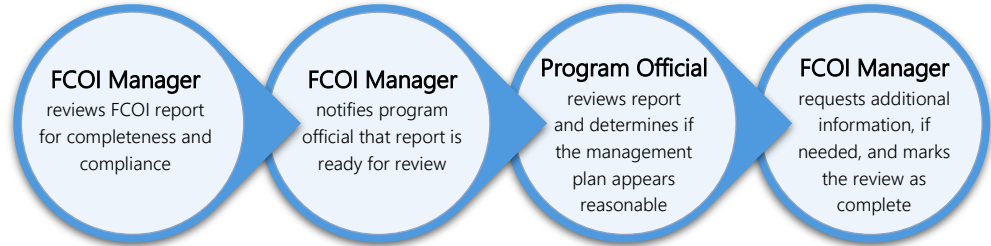
³¹ NIH, *Office of Policy for Extramural Research Administration (OPERA)*. Accessed at <https://grants.nih.gov> on January 11, 2019.

³² NIH, *About the Office of Extramural Research (OER) at NIH*. Accessed at <https://grants.nih.gov> on January 11, 2019.

³³ Within OER's Office of Policy for Extramural Research Administration, the Division of Grants Compliance and Oversight is the focal point to advance external institutions' compliance with policy and legislative mandates. NIH, *Office of Policy for Extramural Research Administration (OPERA)*. Accessed at <https://grants.nih.gov> on January 11, 2019.

³⁴ NIH, *Financial Conflict of Interest*. Accessed at <https://grants.nih.gov> on May 28, 2019.

Exhibit 1: NIH Staff Roles and Responsibilities for Reviewing FCOIs, as Outlined in NIH Guidance



Source: NIH, *OER Training for NIH Program and Grants Management Staff*, April 2014, and NIH, *Q&As: Implementation of the 2011 Revised Financial Conflict of Interest Regulation*, p. 5.

Role of Grants Management Staff. Within ICs, grants management staff—typically, FCOI Managers—are responsible for tracking the receipt of FCOIs that institutions report.³⁵ According to NIH training documents, once an institution reports an FCOI, an FCOI Manager is responsible for checking the report for completeness and compliance. Following this review, the FCOI Manager notifies the program official that the report is ready for their review. Each IC also has a Chief Grants Management Officer (CGMO), who is responsible for the business and fiscal management of an IC’s grant portfolio.³⁶

Role of Program Official Staff. Program officials are responsible for reviewing a reported FCOI and determining whether the institution’s management plan appears reasonable to protect the research from bias given the nature of the significant financial interest and the role of the investigator.³⁷ If a program official determines that additional information is needed from the institution, the program official notifies the FCOI Manager, who then submits a request for additional information to the institution. NIH recommends that program officials complete their review within 30 days.

Related Office of Inspector General Work

Previous OIG studies examined NIH’s policies and procedures with regard to extramural investigators’ FCOIs. In a 2008 report, OIG found that NIH could not provide an accurate count of the FCOIs that institutions reported during FYs 2004 through 2006. OIG also found that NIH was not aware of the

³⁵ NIH, *OER Training for NIH Program and Grants Management Staff*, April 2014.

³⁶ Within each IC, there also is an individual who serves as the FCOI Liaison. This individual serves as a consultant if an FCOI Manager or program office staff have questions regarding a FCOI report or issue. The FCOI Liaison also coordinates with OER to resolve specific FCOI questions or concerns, if necessary. The roles of CGMO, FCOI Manager, and FCOI Liaison may be held by one or more individuals.

³⁷ NIH, *OER Training for NIH Program and Grants Management Staff*, April 2014.

types of significant financial interests that existed among extramural investigators or how FCOIs were being managed by the institutions.³⁸ In 2009, OIG reported that vulnerabilities existed in how institutions identified, managed, and monitored investigators' FCOIs.³⁹ The findings of these studies raised serious concerns about NIH's oversight of institutions and how well these institutions were reporting and managing FCOIs. On the basis of these findings, subsequent recommendations, and other information, HHS revised the FCOI regulations to enhance oversight and accountability. NIH developed a tracking system and monitoring system and it updated and developed procedures to more accurately track the FCOIs that institutions report.

This report is the first OIG evaluation regarding NIH oversight of FCOIs that institutions report since NIH revised its reporting requirements for institutions in 2011.

Methodology

We collected several types of information from OER. OER provided aggregated counts of the number and types of FCOIs that institutions reported in FY 2018, as well as the total number of grants, institutions, and grant dollars awarded in FY 2018. We calculated the percentage of grants with an associated FCOI that was reported in FY 2018 and the percentage of institutions that reported at least one FCOI. We also sent a questionnaire to OER requesting detailed information about the role that OER plays in the review and monitoring of FCOIs. We then conducted a followup interview to clarify and obtain more details on OER's written responses. We also reviewed OER's guidance, training, and procedural documents pertaining to the tracking and reviewing of reported FCOIs.

In addition, we conducted interviews with staff from three of the ICs to determine the roles of OER and IC staffs in reviewing and monitoring reported FCOIs. We selected these ICs based on their size and the number of FCOIs that their institutions reported in FY 2018. We also reviewed IC-specific documents, where applicable.

Lastly, we analyzed information on reported FCOIs from NIH's online system to determine the average number of days that staff took to review a reported FCOI, as well as whether inconsistencies were present in the data.

Appendix A contains a detailed description of our methodology.

³⁸ OIG, [National Institutes of Health: Conflicts of Interest in Extramural Research](#), OEI-03-06-00460, January 2008.

³⁹ OIG, [How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health](#), OEI-03-07-00700, November 2009.

Limitations

Although each of the 25 ICs⁴⁰ must adhere to NIH-wide policies and procedures for reviewing FCOIs, ICs may develop their own procedural documents to effectuate NIH-wide policies and procedures. We interviewed three ICs and collected IC-specific procedural documents from these ICs only. Also, this evaluation focused on how NIH reviewed the FCOIs that institutions reported; we did not determine whether institutions reported all FCOIs that they were required to report. Another OIG report examines NIH's policies, procedures, and controls regarding institutions' reporting of investigators' FCOIs.⁴¹ While we collected information about how NIH assesses the sufficiency of institutions' plans for managing the FCOIs that they report, we did not independently assess the adequacy of institutions' management plans.

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.

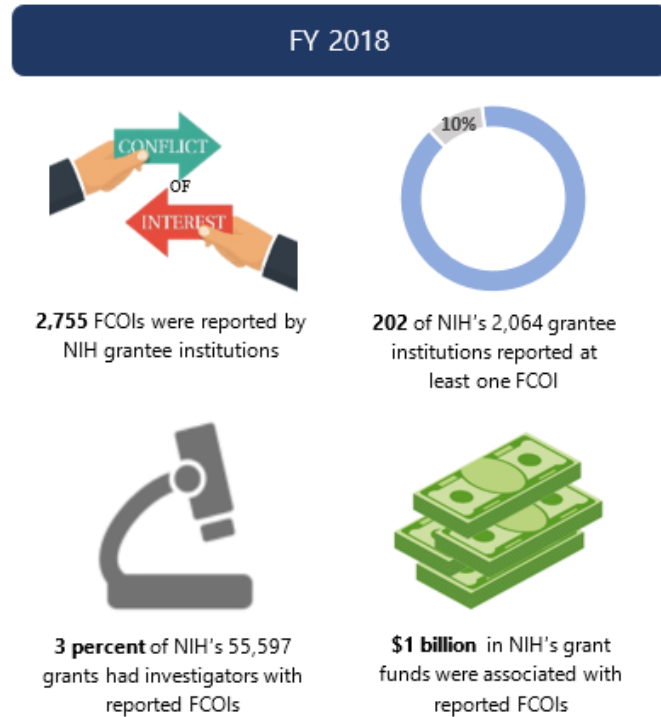
⁴⁰ There are 24 ICs that have grant-making authority. In addition, awards also are made on behalf of NIH's Office of the Director. In this report, we refer collectively to these 24 ICs and the Office of the Director as 25 ICs.

⁴¹ OIG, *NIH 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.

Landscape of Reported FCOIs in FY 2018

In FY 2018, only a small percentage of NIH's extramural grants had investigators with reported FCOIs, as shown in Exhibit 2.

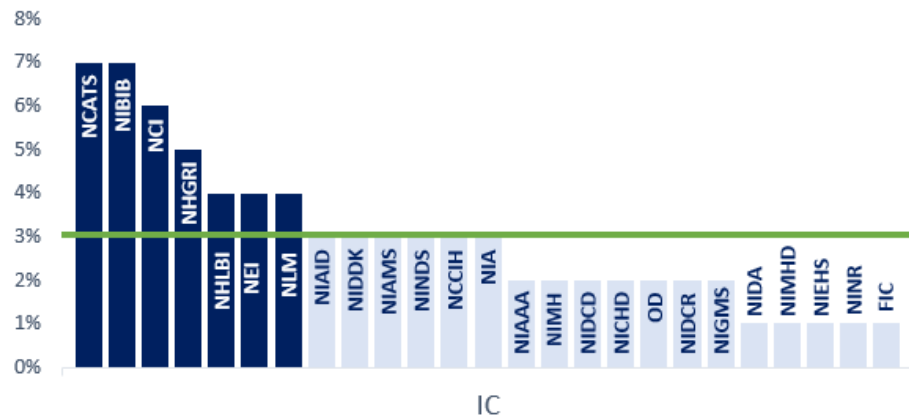
Exhibit 2: Landscape of FCOIs reported to NIH in FY 2018



Source: OIG analysis of FCOIs reported to NIH in FY 2018.

There was variability across ICs in the proportion of NIH-funded grants that had investigators with reported FCOIs, but no IC had more than 7 percent. For most ICs (18 of 25), 3 percent or fewer of their grants involved investigators with reported FCOIs, as shown in Exhibit 3.

Exhibit 3: For most ICs, 3 percent or fewer of the IC's grants had investigators with reported FCOIs



Source: OIG analysis of FCOIs reported to NIH in FY 2018. Appendix B provides the name of each IC and the detailed summary counts of reported FCOIs and grant awards for each IC.

Institutions reported equity interest as the most common significant financial interest associated with FCOIs that investigators disclosed.⁴² In total, 49 percent of reported significant financial interests entailed the investigator holding equity (e.g., stock, stock options, or other ownership interests) in either nonpublicly or publicly traded entities, as shown in Exhibit 4. Appendix C presents the overall counts and percentages of all types of significant financial interests associated with the FCOIs reported in FY 2018.

Exhibit 4: Almost half of the significant financial interests associated with FCOIs were equity interests held by investigators

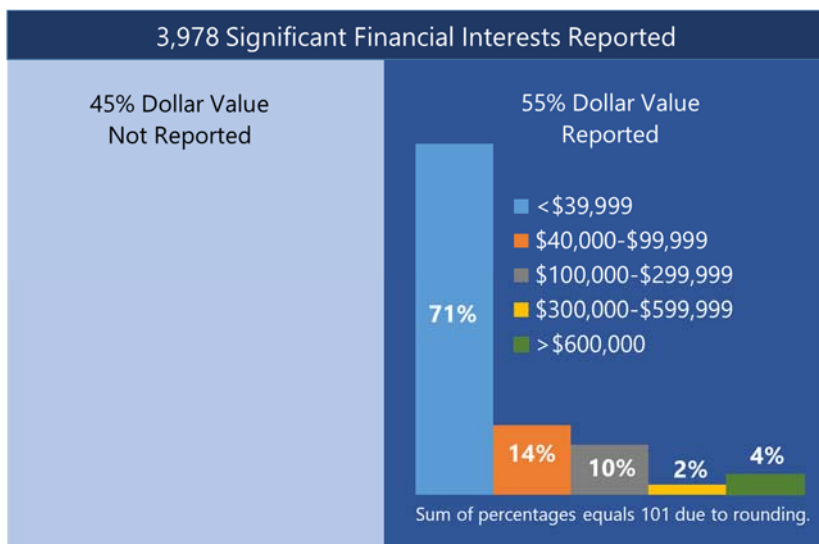


Source: OIG analysis of FCOIs reported to NIH in FY 2018.

¹Payment for services may include consulting fees, honoraria, and paid authorship.

²Examples of other financial interests included being an advisory board member or being the owner or cofounder of a company.

Exhibit 5: Institutions could not readily determine the dollar value for nearly half of significant financial interests



Source: OIG analysis of FCOIs reported to NIH in FY 2018.

Institutions reported that they could not readily determine the dollar value for nearly half of the significant financial interests that they reported in FY 2018, as shown in Exhibit 5. Although this occurred mainly when institutions reported equity interests in nonpublicly traded companies, some included financial interests for which a dollar value likely *could* be determined—such as salary, travel reimbursement, and payment for services. Among the significant financial interests with a reported dollar value, 71 percent were valued in the range of \$0 to \$39,999.⁴³

⁴² In NIH’s online system, an investigator may have one FCOI that includes multiple types of significant financial interests received from the same entity. The 2,755 reported FCOIs were associated with 3,978 significant financial interests.

⁴³ In NIH’s online system, institutions must select a dollar-value range (e.g., \$0-\$39,999) or a statement that a value cannot be readily determined for each significant financial interest reported.

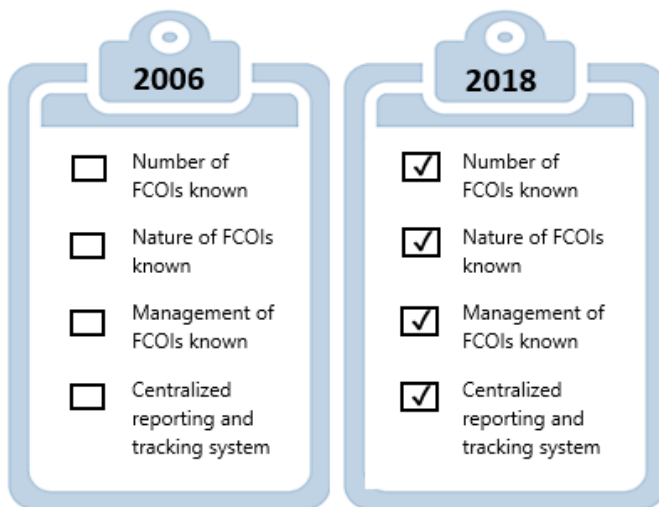
Findings

NIH has improved the process for reporting and tracking FCOIs over the last decade

NIH can now readily determine the number and types of FCOIs reported because it expanded its reporting requirements and developed an online tracking system

In contrast to what we found in our 2008 report—that NIH was unable to provide the number or types of FCOIs associated with its extramural grants—NIH is now able to provide the total number of FCOIs that institutions report as well as a detailed count of the types of significant financial interests associated with these FCOIs, as shown in Exhibit 6.

Exhibit 6: NIH has improved its tracking of FCOIs in the decade since OIG’s last review



Source: OIG analysis of FCOIs reported to NIH between FYs 2004 through 2006 and in FY 2018.

To accomplish these improvements, HHS revised regulations requiring institutions to report to NIH additional information regarding the nature and extent of investigators’ FCOIs.⁴⁴ NIH now requires institutions to submit FCOI reports electronically, instead of through paper submissions to the awarding IC. To streamline and track the reporting of FCOIs, NIH implemented an online reporting, tracking, and monitoring system—the electronic Research Administration (eRA) Commons FCOI Module. In addition to streamlining the process that institutions use to report FCOIs, the FCOI Module also has made FCOI information readily available for NIH review. The FCOI Module provides NIH staff with the ability to access, review, and perform searches of reported FCOIs.

NIH now has information regarding how institutions are managing investigators’ FCOIs

NIH now requires institutions to report the key elements of their plan to manage FCOIs, which should ensure a reasonable expectation that the research is free from bias. As OIG reported in 2008, for 89 percent of FCOIs that institutions reported between FYs 2004 through 2006, the institutions did not explain how they were managing the FCOIs. Since 2012, HHS regulations have required institutions to include—when reporting an investigator’s FCOI(s) to NIH—information about the key elements of their plan to manage the FCOI(s). These key elements include the following: the role of the conflicted investigator in the research, details of the management plan, how the management plan will safeguard research objectivity, confirmation of the

⁴⁴ 42 CFR § 50.605(b)(3).

NIH has made strides in its review of reported FCOIs, but it could do more to ensure the adequacy and consistency of its reviews

investigator’s agreement to the management plan, and how the institution will monitor the management plan to ensure investigator compliance.

NIH reviewed each reported FCOI—the vast majority within the recommended timeframe

NIH has improved its process for reviewing investigators’ FCOIs. Following publication of OIG’s 2008 report, NIH’s OER developed written guidance that outlines the responsibilities for staff reviewing FCOIs, as well as the actions that staff should take once an institution submits an FCOI report in the FCOI Module. NIH now has a process to review each reported FCOI for completeness and compliance as well as to ensure the reasonableness of institutions’ management plans. This differs from what OIG found in 2008—that NIH relied on institutions’ assurances that they were following the FCOI regulations, rather than directly overseeing or reviewing institutions’ management of the FCOIs they reported.

For 87 percent of FCOIs reported in FY 2018, program officials completed their reviews within 30 days—the recommended timeline established for reviewers. However, for 13 percent of reported FCOIs, NIH staff completed their reviews after 30 days, with the longest period of review lasting 260 days.

Not all ICs opted to develop internal written guidance to assist staff in their reviews of FCOIs, and NIH staff differed in the depth of their reviews

Fifteen of the 25 ICs reported having written procedures to supplement the guidance from OER. The documents shared by the three ICs we reviewed differed in their level of detail and instruction. Only one of the three guidance documents provided IC staff with specific criteria aimed at standardizing the review of FCOIs. For example, this guidance included questions for program officials to consider during their review to identify concerns in one or more high-risk areas, such as clinical trials. This guidance also suggested that reviewers use any other information to help determine if more information is needed to understand whether the reported FCOI may adversely impact the research.

Program officials across the three ICs that we reviewed differed in their respective approaches and the level of scrutiny they applied when assessing whether institutions’ plans to manage FCOIs were reasonable. For example, program officials in two of the ICs use external resources—such as investigators’ publications, Google Patents, or the United States Patent and Trademark Office website—to assist in their review of institutions’ reported information and to strengthen their oversight of FCOI reports. The program official at the third IC reported not seeking out any additional information other than what the institution had reported in the FCOI Module.

Program officials also reported wide-ranging review times, with two ICs’ program officials generally spending 5 to 30 minutes per review and the other

IC's staff spending several hours. They reported that the length of review can depend on the complexity of the review as well as whether they are reviewing an initial report or an annual report, with annual reports needing less time for review. Program officials must rely heavily on their scientific knowledge and expertise when assessing whether a management plan appears reasonable to protect the research from bias. Given the unique nature of each research project, and any significant financial interest associated with it, some differences in the scope of review are to be expected. However, the program officials who reported using external sources in their reviews reported that they spent more time conducting their reviews.

Although program officials differed in their review approaches, all mentioned that they pay particular attention to the management of an FCOI if human subjects are involved in the research. For example, one program official stated that if human subjects or a clinical trial is involved, program officials "put more effort" to ensure that essential information is not missing from the FCOI report.

NIH staff seldom requested additional information from institutions to assist in their review of FCOIs. In FY 2018, NIH staff requested additional information for 76 of the 2,755 reported FCOIs. NIH staff at the three ICs reviewed confirmed that they also rarely requested additional information during their reviews of reported FCOIs. Although NIH has not taken any enforcement actions regarding missing or late information, NIH has delayed grant awards while awaiting responses to requests for additional information. NIH was unable to provide the number of grants for which awards were delayed.

NIH provides mentorship and support to staff who review FCOIs, but it does not conduct quality assurance of reviewers' oversight of FCOIs

Program officials are supported in their role as reviewers through general guidance available from OER as well as through informal on-the-job mentorship within the IC. New program officials undergo training (known as the Core Curriculum) that includes information about institutions' requirements for reporting FCOIs and NIH's responsibilities for reviewing the FCOIs that institutions report. Program officials also may access pertinent webinars and other guidance materials through OER's website. Additionally, staff from two ICs mentioned that newer staff have access to ongoing mentorship and training from seasoned program officials.

NIH staff do not perform any quality assurance to ensure the adequacy or consistency of program officials' reviews of FCOIs. Neither OER nor IC management staff perform any systematic analyses or ad-hoc checks to determine whether NIH staff accurately and consistently review the FCOIs that institutions report. OER staff reported that they had a process in place to provide oversight of ICs' reviews of reported FCOIs and proactively provide guidance to ICs, but that they no longer have sufficient staff to continue this

oversight. With this being the case, OER now relies on IC staff to seek guidance when needed and does not conduct regular oversight of the ICs. Similarly, none of the three ICs we reviewed perform quality checks to ensure the thoroughness or consistency of review by program officials. Staff members from one IC stated that while they do not conduct quality checks, the IC provides newer program officials more guidance during their first few reviews. Staff from another IC stated that ensuring consistency is more of an informal process, with program officials seeking guidance or advice from other staff when necessary.

Some FCOIs in the FCOI Module contained inconsistencies that may indicate noncompliance with the FCOI regulations. OIG conducted a cursory quality check of the FCOI Module that uncovered inconsistencies in a small number of the 2,755 reported FCOIs. Within the FCOI Module, there were 43 reported FCOIs for which institutions indicated noncompliance with the FCOI regulations.⁴⁵ In these cases, institutions were required to complete a retrospective review within 120 days to determine whether the FCOI biased the research. However, for 25 of these 43 cases, the institution indicated that it did not complete a retrospective review.⁴⁶ Although 6 of these 25 cases specifically noted that the retrospective review was underway, this was not the case for the other 19. It is not known whether these institutions completed the required retrospective reviews, and NIH does not require institutions to update the FCOI Module once they complete the retrospective review.⁴⁷ In addition, NIH does not instruct its staff to follow up with institutions to ensure that these retrospective reviews have been completed.

Only one of the three ICs we reviewed had any of these inconsistencies. This IC had one of the largest numbers of inconsistencies across all ICs, and the FCOI Manager indicated that this IC passes the FCOI report to the program official without checking the report for completeness and compliance. In contrast, the FCOI Managers at the other two ICs reported that they did a review for completeness and compliance review prior to sending the report to the program official.

⁴⁵ Noncompliance can include a failure by the investigator to disclose a significant financial interest that the institution determines to be an FCOI; a failure by the institution to review or manage an FCOI; or a failure by the investigator to comply with the management plan. 42 CFR § 50.605(a)(3).

⁴⁶ For these 25 cases, we reviewed the description of the noncompliance that the institution provided in the FCOI Module. The description provided for 23 of these cases appeared to indicate that a retrospective review would be required. In two cases, there was either no descriptive information or too little information to make a determination.

⁴⁷ The FCOI regulation does not require institutions to report to NIH when a retrospective review is completed or on the results of the retrospective review unless bias is found or when additional information is discovered during the retrospective review that was not previously reported.

NIH cannot identify—and does not plan to identify—whether FCOIs involve foreign entities, but is identifying foreign affiliations through a clarification of its pre-award reporting requirements

NIH was unable to provide OIG with the number of FCOIs reported in FY 2018 that involved a significant financial interest in a foreign entity (e.g., the investigator with the FCOI was conducting research in the United States but had a significant financial interest in a foreign entity). Although NIH released a notice in March 2018⁴⁸ to remind the NIH extramural research community that investigators must disclose all financial interests received from a foreign institution of higher education or the government of another country, NIH has no mechanism within the FCOI Module to identify foreign entities.

The HHS regulations on FCOIs do not require institutions to designate whether FCOIs involve foreign entities, and NIH reported that it has no plans to expand these regulations to include such a requirement. Instead, NIH released a notice in July 2019 that clarifies its policy regarding other support, including foreign affiliations.^{49, 50} Specifically, NIH clarifies that institutions are required to provide information during the pre-award process about investigators' other active and pending support—regardless of whether or not that support has monetary value—from all foreign and domestic entities. NIH believes that collecting information regarding an investigator's foreign interests is most appropriately captured as part of the pre-award reporting process rather than as part of the FCOI reporting process.

⁴⁸ NIH, *Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests*, NOT-OD-18-160, March 2018. Accessed at <https://grants.nih.gov> on June 3, 2019.

⁴⁹ Other support includes information on all resources—whether Federal, non-Federal, commercial or institutional—available in direct support of an investigator's project. *NIH Grants Policy Statement*, ch. 2.5.1, October 2018.

⁵⁰ 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> on July 16, 2019.

CONCLUSION AND RECOMMENDATIONS

Congress and NIH have raised concerns about threats to research integrity, including foreign threats. We found that, overall, NIH has made progress in overseeing extramural investigators' FCOIs—but has made no changes to its FCOI review process in light of recent concerns about foreign threats. Since our previous report in 2008, NIH has expanded and standardized the collection of investigators' FCOIs. In addition, NIH now reviews all reported FCOIs. However, NIH staff have approached these reviews with different levels of scrutiny, and NIH management does not conduct quality assurance reviews. Furthermore, NIH was unable to identify whether any of the reported FCOIs involved foreign entities. As such, additional actions would enhance the consistency and rigor of NIH's oversight of investigators' FCOIs. Therefore, OIG recommends that:

NIH should perform periodic quality assurance reviews of information in the FCOI module to ensure the adequacy of oversight regarding FCOIs

Given the variability across ICs in their approaches to, and scrutiny of, the information in the FCOI Module, NIH would be well-served to heighten its oversight. Conducting quality assurance reviews could identify shortfalls in ICs' approaches and opportunities to add consistency to their review of reported FCOIs. For example, OER staff could perform an annual review of a subset of all reported FCOIs from each IC (or from selected ICs) to ensure that IC staff are adequately reviewing FCOI information that institutions report. In addition, ICs could implement periodic quality checks of the FCOI reviews that their staff perform. These reviews could identify any data inconsistencies that might indicate institution noncompliance with requirements for reporting and managing FCOIs.

NIH also should consider following up with institutions that report noncompliance within the FCOI Module but do not indicate that they completed a retrospective review. Although an institution is not required to report its findings of a retrospective review to NIH unless it finds bias, NIH should have a mechanism in place to ensure that institutions are completing required retrospective reviews.

NIH should use information regarding foreign affiliations and support that it collects during the pre-award process to decide whether to revise its FCOI review process to address concerns regarding foreign influence

NIH released a notice in July 2019 that reminds institutions about the need to report investigators' foreign affiliations during the pre-award process. NIH should use this information on investigators' foreign affiliations to

evaluate whether the requirements regarding investigators' FCOIs also need to be updated to fully address concerns about investigators' foreign affiliations. If NIH decides that revisions are needed, it should consider modifying the FCOI Module to require institutions to report whether investigators' significant financial interests involve foreign entities. Such a modification would remedy this potential gap in information and increase transparency for the parties involved, which may help safeguard against potential risks to the security of intellectual property and the integrity of NIH-funded research.

AGENCY COMMENTS AND OIG RESPONSE

NIH concurred with both of our recommendations but did not provide details of its implementation plans. Rather, NIH stated that it will provide detailed corrective action plans in 6 months when it submits its final management decision to the OIG.

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

APPENDIX A: Detailed Methodology

FCOI Data from OER

From OER, we requested aggregated counts of the number and types of FCOIs that institutions reported in FY 2018, as well as the total number of grants, institutions, and grant dollars awarded in FY 2018.⁵¹ In addition, we requested the following information about the reported FCOIs:

- the number of institutions that reported at least one FCOI;
- the number of grants for which institutions reported at least one FCOI;
- the number of reported FCOIs for which NIH staff requested additional information from institutions and the number of reported FCOIs that were revised as a result of this additional information;
- the number of reported FCOIs submitted between October 1, 2014, and September 30, 2018, for which institutions performed retrospective reviews because of noncompliance with reporting requirements, and, of these, how many had a finding of bias;
- the number of reported FCOIs that involved a significant financial interest in a foreign entity;
- the number of reported FCOIs that NIH reviewed; and
- the number of grants for which NIH took enforcement actions as a result of its review of FCOIs.

From these aggregated counts, we calculated the percentage of grants that had an associated FCOI reported in FY 2018 and the percentage of institutions that reported at least one FCOI. We performed these calculations for reported FCOIs overall and by IC. We also calculated the percentage of total grant dollars associated with reported FCOIs and summarized the types of significant financial interests reported as FCOIs.

Data from NIH's Online System. NIH provided OIG with access to NIH's online system that contains reported FCOIs. We used data from this system to analyze the range and average number of days between the date an institution reported an FCOI (i.e., the submission date) and the date NIH staff completed their review (i.e., the completion date) for FCOIs reported in FY 2018.

⁵¹ We excluded FCOIs that were reported for research on Phase I SBIR/STTR Program grants, as these are not required to be reported. If an FCOI was initially reported and then updated or revised within FY 2018, we requested that OER count only the most recent submission.

We also reviewed the FY 2018 data to determine whether there were instances in which institutions indicated that there was noncompliance with reporting requirements but did not indicate that they completed a retrospective review. For these cases, we reviewed the description of the noncompliance that the institution provided in the FCOI Module, and we (1) assessed whether the noncompliance would have required a retrospective review, and (2) determined whether the institution reported that a retrospective review was in progress.

OER Questionnaire, Interview, and Supporting Documents

We sent a questionnaire to OER requesting detailed information about the role that OER plays in the review and monitoring of FCOIs. We then conducted a followup interview to clarify and obtain more details on OER's written responses.

We also reviewed OER's guidance, training, and procedural documents pertaining to the tracking and reviewing of reported FCOIs. OER also provided a list of the ICs that have their own written policies and procedures regarding FCOIs.

Interviews With Select ICs

We selected three ICs to review based on their size and the number of FCOIs that their institutions reported in FY 2018. To do this, we divided the ICs into thirds (i.e., top third, middle third, and bottom third) according to the total dollars that each awarded to institutions in FY 2018. After excluding the National Cancer Institute (NCI) and the National Eye Institute (NEI), we determined which ICs in each third had the highest number of reported FCOIs in FY 2018.⁵² These were the National Heart, Lung, and Blood Institute (NHLBI); the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS); and the National Institute of Biomedical Imaging and Bioengineering (NIBIB).

We conducted interviews with staff from each of the three ICs and summarized their responses regarding the roles of grants management staff and program official staff in reviewing FCOIs; how staff review FCOIs and management plans; the training and guidance that ICs provide to staff; how ICs consult with OER staff; and any challenges that staff face in reviewing reported FCOIs. We also reviewed IC-specific documents, where applicable. Appendix D provides staffing information for NHLBI, NIAMS, and NIBIB.

⁵² We excluded NCI and NEI because of other ongoing OIG work involving these ICs.

APPENDIX B: Detailed Summary Counts, by Institute and Center

Exhibit B-1: FCOI reports and award information by NIH Institute and Center (IC) for FY 2018

NIH IC	Total FY 2018 award funding	Number of grants ¹	Number of institutions	Number of reported FCOIs	Number of institutions reporting at least one FCOI	Number of unique grants associated with reported FCOIs
National Cancer Institute (NCI)	\$4,027,936,852	7,059	548	676	96	409
National Institute of General Medical Sciences (NIGMS)	\$2,719,507,073	6,670	602	167	48	113
National Heart, Lung, and Blood Institute (NHLBI)	\$2,770,124,029	5,547	460	344	75	213
National Institute of Allergy and Infectious Diseases (NIAID)	\$3,927,572,369	5,483	572	301	67	191
National Institute of Neurological Disorders and Stroke (NINDS)	\$1,764,232,217	4,274	382	167	57	122
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	\$1,674,298,120	4,064	380	211	52	135
National Institute on Aging (NIA)	\$2,083,959,712	3,284	409	134	42	89
National Institute of Mental Health (NIMH)	\$1,461,046,514	3,131	358	86	34	74
National Institute of Child Health and Human Development (NICHD)	\$1,153,533,942	2,591	395	71	36	53
National Institute on Drug Abuse (NIDA)	\$1,019,028,868	2,155	331	50	20	32
National Eye Institute (NEI)	\$610,056,340	1,625	237	125	29	59
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	\$501,409,156	1,415	224	69	28	44

continued on next page

**Exhibit B-1: FCOI reports and award information by NIH Institute and Center (IC) for FY 2018
(continued)**

NIH IC	Total FY 2018 award funding	Number of grants ¹	Number of institutions	Number of reported FCOIs	Number of institutions reporting at least one FCOI	Number of unique grants associated with reported FCOIs
National Institute on Alcohol Abuse and Alcoholism (NIAAA)	\$384,117,862	1,146	236	44	10	28
National Institute on Deafness and Other Communication Disorders (NIDCD)	\$380,070,366	1,134	212	28	14	25
National Institute of Environmental Health Sciences (NIEHS)	\$568,885,087	1,117	242	17	13	14
National Institute of Biomedical Imaging and Bioengineering (NIBIB)	\$371,512,799	982	209	112	35	64
National Institute of Dental and Craniofacial Research (NIDCR)	\$333,455,993	876	186	29	12	16
Office of the Director (OD)	\$828,877,926	601	193	16	8	11
National Human Genome Research Institute (NHGRI)	\$457,249,652	531	135	29	14	26
National Institute on Minority Health and Health Disparities (NIMHD)	\$263,237,403	431	183	10	5	6
National Institute of Nursing Research (NINR)	\$132,081,511	344	109	5	3	3
National Center for Advancing Translational Sciences (NCATS)	\$596,068,934	331	107	42	18	22
John E. Fogarty International Center (FIC)	\$80,666,953	320	140	2	2	2
National Center for Complementary and Integrative Health (NCCIH)	\$126,819,616	292	128	13	6	8
National Library of Medicine (NLM)	\$84,165,571	194	87	7	7	7
TOTAL	\$28,319,914,865	55,597	2,064²	2,755	202²	1,766

Source: OIG analysis of FCOIs reported to NIH in FY 2018 and *NIH Awards by Location and Organization* from the NIH Research Portfolio Online Report Tools (RePORT).

¹ Excluding Phase 1 Small Business Innovation Research (SBIR) Program or Small Business Technology Transfer (STBT) Program applications.

² The total provided is the unique number of institutions and not the aggregated total of numbers provided in each row.

APPENDIX C: Significant Financial Interests That Institutions Reported in 2018

Exhibit C-1: Type, number, and value of significant financial interests that institutions reported to NIH in FY 2018

Significant Financial Interest (SFI) Type								
Value of significant financial interest	Equity interest in nonpublicly traded entity ¹	Equity interest in publicly traded entity ¹	Intellectual property rights ²	Investments ³	Other	Payment for services ⁴	Reimbursed or sponsored travel	Salary not from the awardee institution
\$0-\$39,999	402	41	132	16	284	625	25	38
\$40,000-\$99,999	53	15	16	1	18	180	0	20
\$100,000-\$149,999	15	4	2	0	10	57	0	8
\$150,000-\$199,999	6	4	1	0	5	35	0	4
\$200,000-\$249,999	8	8	0	0	3	6	0	5
\$250,000-\$299,999	6	0	7	0	0	7	0	8
\$300,000-\$349,999	4	1	1	0	2	2	0	3
\$350,000-\$399,999	3	2	2	0	2	0	0	2
\$400,000-\$449,000	0	0	2	0	0	0	0	1
\$450,000-\$499,999	2	0	0	0	0	0	0	1
\$500,000-\$549,999	6	0	1	0	5	1	0	0
\$550,000-\$599,999	1	1	0	0	0	0	0	1
>\$600,000	32	39	3	0	0	4	0	0
Value cannot be readily determined	1,286	29	165	40	210	42	6	1
TOTAL	1,824	144	332	57	539	959	31	92

Source: OIG analysis of FCOIs reported to NIH in FY 2018.

¹ Examples include stock, stock options, or other ownership interest.

² Examples include royalties, patents, and copyrights.

³ Examples include mutual funds and retirement accounts controlled by the investigator.

⁴ Examples include consulting fees, honoraria, and paid authorship.

APPENDIX D: Staff Information for Three Select Institutes and Centers (ICs)

Exhibit D-1: Number of grants management and program office staff at NIBIB, NIAMS, and NHLBI

NIH IC	Number of FCOI Managers	Number of FCOI Liaisons	Number of Program Officials	Number of Grants Management Specialists (GMSs)	Number of Grants Management Officers (GMOs)	Number of Chief Grants Management Officers (CGMOs)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)	1	1	14	1	7	1
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	1	1	17	10	6	1
National Heart, Lung, and Blood Institute (NHLBI)	4	4	131	9	22	1

Source: OIG analysis of IC staffing information provided by NIH, 2019.

APPENDIX E: Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: September 3, 2019

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

FROM: Director, NIH

SUBJECT: NIH Comments on Draft Report, *NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More* (OEI-03-19-00150)

Attached are the National Institutes of Health's comments on the draft Office of Inspector General (OIG) report, *NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More* (OEI-03-19-00150).

The NIH appreciates the review conducted by the OIG and the opportunity to provide clarifications on this draft report. If you have questions or concerns, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

/s/ Francis S. Collins, M.D., Ph.D.

Francis S. Collins, M.D., Ph.D.

Attachments
Technical Comments
General Comments

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: “NIH HAS MADE STRIDES IN REVIEWING FINANCIAL CONFLICTS OF INTEREST IN EXTRAMURAL RESEARCH, BUT COULD DO MORE” (A-03-19-00150)

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

OIG Recommendation 1:

NIH should perform periodic quality assurance reviews of information in the FCOI module to ensure the adequacy of oversight regarding financial conflicts.

NIH Response:

NIH concurs with OIG's the OIG's recommendation that NIH should perform periodic quality assurance reviews of information in the FCOI Module to ensure adequacy of oversight regarding financial conflicts. NIH will provide a detailed corrective action plan in our six-month response to the OIG.

OIG Recommendation 2:

NIH should use information regarding foreign affiliation and support that it collects during the pre-award process to decide whether to revise its financial-conflict review process to address concerns regarding foreign influence.

NIH Response:

NIH concurs with the OIG's recommendation that NIH should use information collected during the pre-award process to decide whether to revise its financial conflict of interest review process to address concerns regarding foreign influence. NIH will provide a detailed corrective action plan in our six-month response to the OIG.

ACKNOWLEDGMENTS

Maria S. Johnson served as the team leader for this study. Others in the Office of Evaluation and Inspections who conducted the study include Karolina Hill, Anjali Bushan, and Robert Kirkner. Office of Evaluation and Inspections staff who provided support include Clarence Arnold, Christine Moritz, and Melicia Seay.

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.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

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