

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**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**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Gloria L. Jarmon
Deputy Inspector General
for Audit Services

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A-03-19-03003

Office of Inspector General

<https://oig.hhs.gov>

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Report in Brief

Date: September 2019

Report No. A-03-19-03003

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

News reports have raised concerns about foreign threats to the United States biomedical research enterprise. In a letter to institutes receiving National Institutes of Health (NIH) funding, the Director of NIH highlighted concerns about diversion of intellectual property; sharing of confidential information from grant applications; and the failure by some NIH-funded researchers to report substantial financial support from other organizations, including foreign governments.

Our objective was to determine whether NIH has policies, procedures, and controls in place for helping to ensure that institutions report all sources of research support, financial interests, and affiliations.

How OIG Did This Review

We reviewed the 2011 financial conflict of interest (FCOI) regulations and the NIH Grants Policy Statement to identify any FCOI requirements with which institutions must comply during the grant period and any NIH oversight responsibilities to monitor institutions during the grant period. We obtained an understanding of NIH's FCOI compliance program and analyzed the results of reviews conducted after the implementation of the 2011 FCOI regulations.

We reviewed institutions that were required to maintain FCOI policies and that received NIH grants in fiscal year 2018 to determine whether they had publicly accessible FCOI policies.

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

What OIG Found

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. Of the 1,875 institutions that received NIH funding in fiscal year 2018 and were required to have FCOI policies, 1,013 did not have FCOI policies posted on their websites. Of the 90 institutions in our sample that had websites but did not have posted FCOI policies, 41 either did not have FCOI policies or did not respond to our requests that they provide policies. Of the 10 institutions in our sample that did not have websites, 3 did not have FCOI policies, and 1 did not respond to our request that it provide its policy. In addition, not all NIH-funded investigators may be aware that they are required to disclose significant financial interests to their institutions, and some institutions stated that they were not aware of their responsibility to create and maintain FCOI policies.

What OIG Recommends and NIH Comments

We recommend that NIH (1) ensure that the 1,013 institutions we identified as not having FCOI policies on their website post those policies as required, (2) enhance its FCOI monitoring program to ensure that institutions resolve identified deficiencies and to review all grantee websites to ensure that FCOI policies are publicly accessible, and (3) implement procedures to ensure that all institutions required to have FCOI policies actually have FCOI policies.

In written comments on our draft report, NIH concurred with our recommendations but stated that we conflated reporting requirements for research support and affiliations with reporting requirements for FCOIs. NIH also noted that the 1,013 institutions we identified that did not have an FCOI policy on their websites account for less than 4 percent of NIH grant awards and less than 5 percent of research funding.

We maintain that the facts of our report are valid; we reviewed NIH policies with regard to significant financial interests resulting from research support and affiliations. Additionally, although the institutions we identified that did not have an FCOI policy posted on a publicly accessible webpage represent only a small percentage of the overall dollar amount, they still represent a risk because the size of an institution or the amount of funding received does not lessen the possibility that an FCOI may go unreported.

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INTRODUCTION

WHY WE DID THIS REVIEW

News reports^{1, 2} have raised concerns about foreign threats to the United States biomedical research enterprise. In an August 20, 2018, letter to institutes receiving National Institutes of Health (NIH) funding, the Director of NIH acknowledged that “threats to the integrity of the U.S. biomedical research exist” and that NIH was concerned about three areas in particular: (1) diversion of intellectual property; (2) sharing of confidential information from grant applications; and (3) the failure by some NIH-funded researchers to report substantial financial support from other organizations, including foreign governments.³ In October 2018, Congress sent a letter to the Director of NIH expressing concern about foreign threats to the integrity of United States biomedical research.⁴ In particular, the letter highlighted concern regarding “cases in which researchers supported by federal grants may have failed to disclose financial contributions from foreign governments.”

For fiscal year (FY) 2019, the 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 (P.L. No. 115-245).⁵ 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.”⁶

This review is part of a larger body of HHS OIG work focused on oversight of NIH grant programs and operations. OIG’s 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 will issue a

¹ Swenson, A. and Bradsher, K. “White House Considers Restricting Chinese Researchers Over Espionage Fears.” Available online at <https://www.nytimes.com/2018/04/30/us/politics/trump-china-researchers-espionage.html>. Accessed on July 15, 2019.

² Cohen, J. “Massive Cyberhack by Iran Allegedly Stole Research from 320 Universities, Governments and Companies.” Available online at <https://www.sciencemag.org/news/2018/03/massive-cyber-hack-iran-allegedly-stole-research-320-universities-governments-and>. Accessed on July 15, 2019.

³ Letter from Francis S. Collins, Director, National Institutes of Health, to NIH Grantee Institutions (August 20, 2018).

⁴ Letter from Senator Charles E. Grassley, Chairman, Committee on the Judiciary, to Francis S. Collins, Director, NIH (October 23, 2018). Available online at [https://www.grassley.senate.gov/sites/default/files/constituents/2018-10-23%20CEG%20to%20NIH%20\(Research%20Threats\).pdf](https://www.grassley.senate.gov/sites/default/files/constituents/2018-10-23%20CEG%20to%20NIH%20(Research%20Threats).pdf). Accessed on July 15, 2019.

⁵ Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, P.L. No. 115-245, 132 Stat. 2981 (September 28, 2018).

⁶ 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), page 531-532.

companion report that addresses NIH’s policies and procedures related to the tracking and review of financial conflicts of interest (FCOIs) reported by institutions.⁷

OBJECTIVE

Our objective was to determine whether NIH has policies, procedures, and controls in place for helping to ensure that institutions report all sources of research support, financial interests, and affiliations.

BACKGROUND

National Institutes of Health

NIH is the largest source of public funding for medical research in the world. NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and apply that knowledge to enhance health, lengthen life, and reduce illness and disability.

More than 70 percent of the \$37 billion that NIH received from Congress for FY 2018 was awarded in the form of extramural grants to more than 300,000 investigators at more than 2,500 universities, medical schools, and other research institutions. Investigators⁸ may use their grant funds to support a variety of needs, including staffing laboratories, purchasing supplies and equipment, and attending national and international conferences to discuss research findings. To further address their research needs, some investigators who apply for or receive NIH grants may also seek research support from other organizations, including foreign entities.

The universities, medical schools, and other research institutions where the investigators conduct their research are responsible for soliciting and reviewing investigators’ significant financial interests resulting from an investigator’s research support,⁹ financial interests, and affiliations and then determining if those significant financial interests constitute FCOIs.

Research support includes all financial resources—whether Federal, non-Federal, commercial or institutional—available in direct support of an individual’s research endeavors, including, but not limited to, research grants, cooperative agreements, contracts and institutional awards. It

⁷ *NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research But Could Do More* (OEI-03-19-00150), issued September 2019.

⁸ Investigators include project directors, principal investigators, and any other individuals, regardless of title or position, who are responsible for the design, conduct, or reporting of research either funded by the Public Health Service (PHS) or proposed for such funding.

⁹ Throughout this report “research support” is used to refer to “other support” as defined by the NIH Grants Policy Statement.

also includes information on active and pending support and identification of scientific, budgetary, and commitment overlap.

A financial interest is anything of monetary value. A significant financial interest is any financial interest of the investigator, the investigator's spouse, and the investigator's dependent children that appears to be reasonably related to the investigator's "institutional responsibilities."¹⁰ A minimum threshold of \$5,000 for disclosure generally applies to most types of financial interests or to the total combined value of the financial interests.¹¹ Intellectual property rights and interests (e.g., patents and copyrights) may constitute a significant financial interest.¹²

Affiliations occur when one company or person controls or has the power to control another company or person. Institutions may take into account factors such as ownership, management, contractual relationships, and previous relationships with or ties to another concern when determining whether an affiliation exists.¹³

Sources of research support, financial interests, and affiliations may be reported on the grant application, after the grant is awarded but before grant funds are expended, and as they occur during the grant funding period.¹⁴

2011 Financial Conflict of Interest Regulations

In 2011, HHS published a final rule requiring that each institution that applies for or receives research funding from NIH make its FCOI policy available on a publicly accessible website.¹⁵ This final rule built upon a 1995 regulation requiring each institution to maintain an up-to-date, written, enforced FCOI policy.¹⁶ The 2011 FCOI regulations apply to institutions that apply for or seek NIH funding for research. The regulations do not, however, apply to Small Business

¹⁰ The definition of significant financial interest under the 1995 regulations was linked to an investigator's project responsibilities. The 2011 FCOI regulations broadened the definition of significant financial interest to include an investigator's institutional responsibilities (76 Fed. Reg. 53256, 53263).

¹¹ 42 CFR § 50.603.

¹² 42 CFR § 50.603.

¹³ At NIH, the term "affiliate" has the meaning set forth in 13 CFR section 121.103(a)(2). See <https://grants.nih.gov/grants/glossary.htm#Affiliate> for NIH's use of the term.

¹⁴ 42 CFR § 50.605(b). Sources of research support, financial interests, and affiliations may be reported during the grant's funding period for various reasons. For example, a new investigator may join the research group after grant funds have been expended.

¹⁵ 42 CFR § 50.604(a).

¹⁶ 76 Fed. Reg. 53256, 53267 (Aug. 25, 2011).

Innovation Research (SBIR)/Small Business Technology Transfer Research (STTR) Phase I applications and Federal interagency agreements.

The requirement to post FCOI policies on a publicly accessible website was part of an HHS effort to update the standards for ensuring that there is a reasonable expectation that the design, conduct, and reporting of research is free from bias resulting from investigator FCOIs.¹⁷ In that spirit, the resulting 2011 FCOI regulations were designed to increase accountability, add transparency, enhance regulatory compliance, promote effective institutional management of FCOIs, and strengthen compliance oversight.¹⁸ NIH is responsible for overseeing institutional compliance with the 2011 FCOI regulations.¹⁹

NIH Financial Conflict of Interest Reporting

An FCOI exists when the institution reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.²⁰ An investigator's research support, financial interests, or affiliations may result in a significant financial interest.

NIH is not required to proactively ensure that investigators disclose all sources of research support, financial interests, and affiliations. Instead, it provides oversight of institutions' compliance with the relevant regulations, policies and procedures. On its policy and compliance webpage,²¹ NIH notes that:

The NIH is committed to preserving the public's trust that the research supported by us is conducted without bias and with the highest scientific and ethical standards. We believe that strengthening the existing regulations on managing financial conflicts of interest is key to assuring the public that NIH and the institutions we support are taking a rigorous approach to managing the essential relationships between the government, federally-funded research institutions, and the private sector.

¹⁷ 42 CFR § 50.601.

¹⁸ NIH, "Frequently Asked Questions: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR part 50, subpart F) applicable to grants and cooperative agreements (2011 Revised Regulations)," (October 22, 2015). Available online at https://grants.nih.gov/grants/policy/coi/coi_faqs.htm. Accessed on July 15, 2019.

¹⁹ 76 Fed. Reg. 53256 (Aug. 25, 2011).

²⁰ 42 CFR § 50.604(f).

²¹ NIH, "Financial Conflict of Interest." Available online at <https://grants.nih.gov/grants/policy/coi/index.htm>. Accessed on July 15, 2019.

Institutions are responsible for soliciting and reviewing disclosures of significant financial interests from each investigator who is planning to participate in or is participating in NIH-funded research.²² Institutions also are responsible for reporting to NIH any significant financial interests that constitute an FCOI.²³

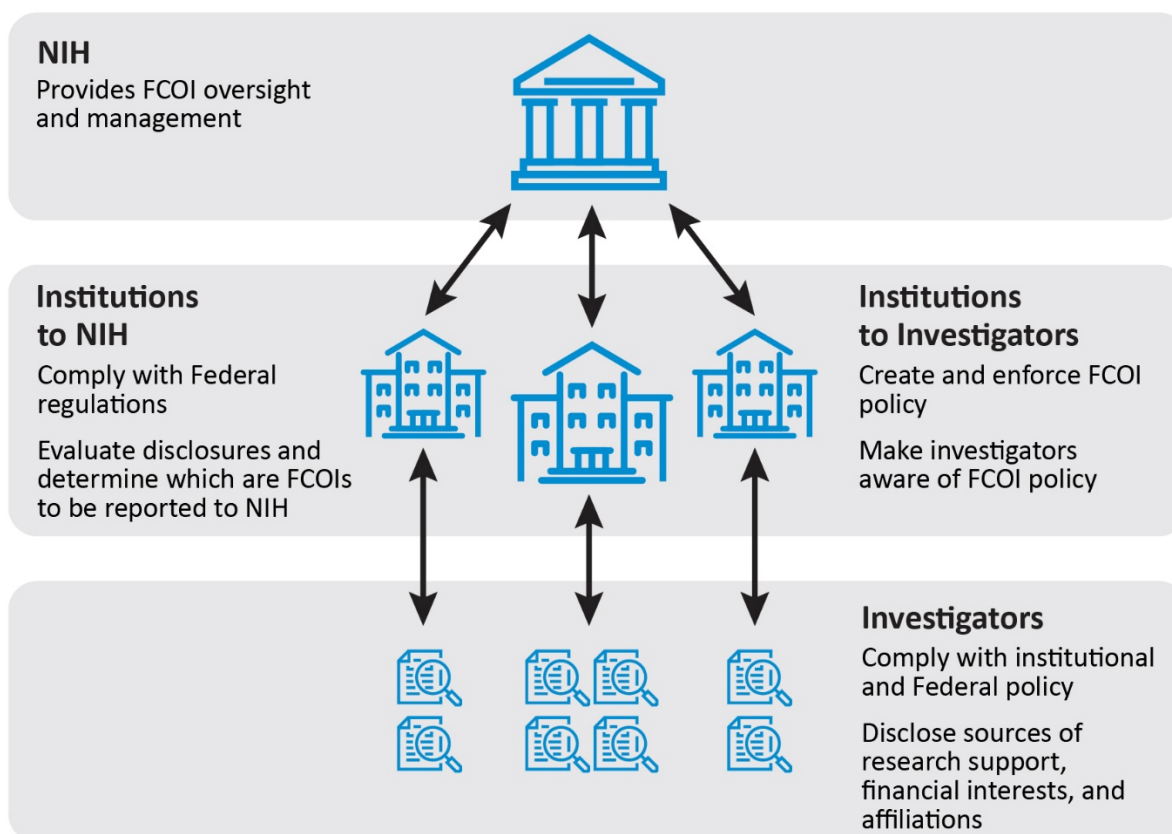
Investigators are required to disclose any significant financial interests to the official at their institution who is responsible for reviewing such disclosures.²⁴ The institutional official then determines whether the investigator's significant financial interest is related to his or her institutional responsibilities and if so, whether the significant financial interest constitutes an FCOI. Because an investigator's research support, financial interests, and affiliations may constitute a significant financial interest, they must be disclosed to the institution. (See Figure 1 on the following page.)

²² 42 CFR § 50.604(d).

²³ 42 CFR § 50.605(b).

²⁴ 42 CFR § 50.604(e)(1).

Figure 1: Financial Conflicts of Interest Responsibilities (or Requirements) for NIH, Institutions, and Investigators



On March 30, 2018, NIH released a guide notice,²⁵ *Financial Conflict of Interest: Investigator Disclosure of Foreign Financial Interests*,²⁶ to remind the NIH extramural research community that it is critically important that investigators understand the applicability of the 2011 FCOI regulations, including that compliance with the regulations is a condition of funding. Additionally, NIH specifically highlighted the requirement to disclose foreign financial interests related to foreign universities.

NIH Division of Grants Compliance and Oversight

The NIH Division of Grants Compliance and Oversight (DGCO) monitors external compliance with NIH policy and legislative mandates and enhances compliance oversight by recipient institutions. DGCO also ensures and evaluates the management of extramural resources.

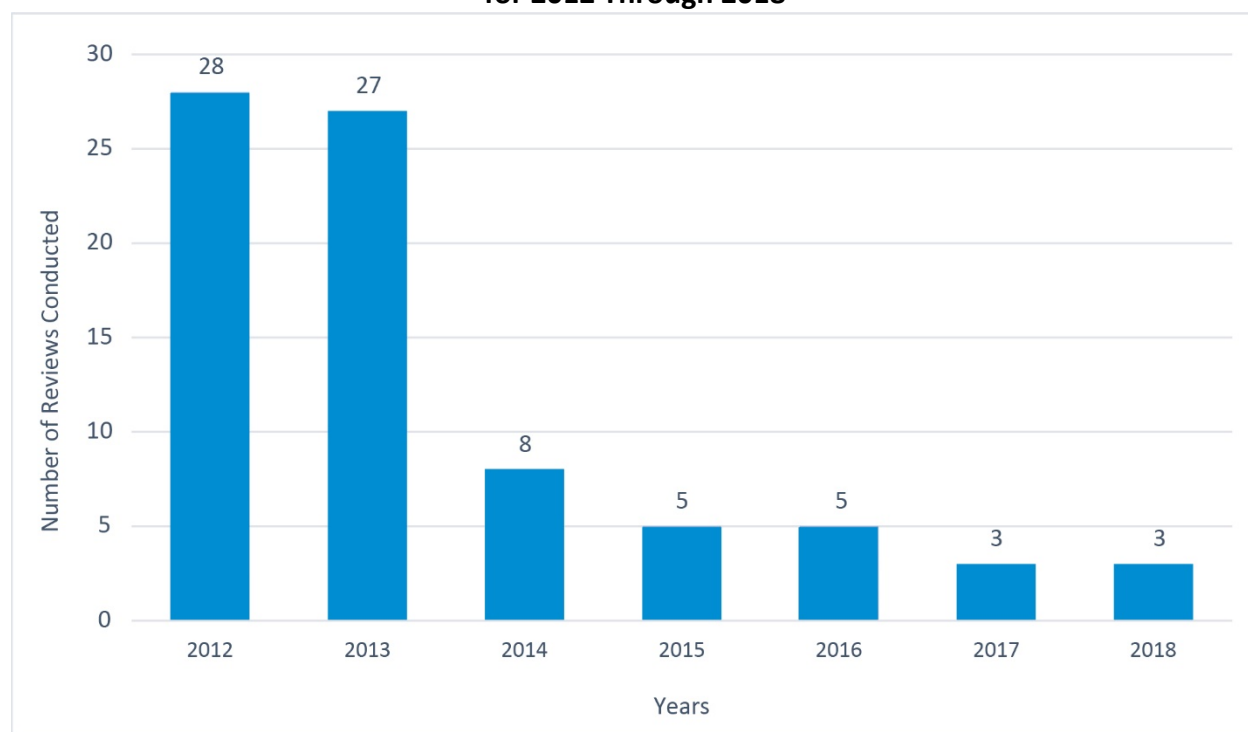
²⁵ Guide notices are released on the NIH Guide for Grants and Contracts page of NIH's website. Compliance with guide notices is a term and condition of awards. Each year, NIH incorporates the essential features of these notices into the annual update of the *NIH Grants Policy Statement*.

²⁶ *Financial Conflict of Interest: Investigator Disclosure of Foreign Financial Interests* (NOT-OD-18-160), March 30, 2018.

In 2012, DGCO established the Proactive FCOI Compliance Oversight Program (FCOI compliance program) as a component of NIH's oversight responsibilities to assess institutional implementation of the 2011 FCOI regulations and ensure grantee compliance.²⁷ Under the FCOI compliance program, DGCO assists institutions with developing and implementing their FCOI policies by reviewing and providing feedback on institutions' publicly accessible FCOI policies.

NIH's FCOI compliance program seeks to address compliance with the 2011 FCOI regulations by providing oversight of institutions' implementation and maintenance of FCOI policies and procedures. The objective of the initial phase of the FCOI compliance program was to review publicly accessible FCOI policies for a sample of NIH institutions. If there were deficiency areas, NIH expected the institutions to formally address and resolve all identified issues. The number of reviews conducted under the FCOI compliance program significantly decreased from 28 reviews in FY 2013 to only 3 reviews in FY 2018. See Figure 2 for the number of reviews conducted under the FCOI compliance program from 2012 through 2018.

Figure 2: NIH Financial Conflict of Interest Compliance Program Reviews for 2012 Through 2018



HOW WE CONDUCTED THIS REVIEW

To determine whether NIH has policies, procedures, and controls in place to help ensure that institutions report all sources of research support, financial interests, and affiliations, we

²⁷ *Proactive Compliance Oversight Program-Financial Conflict of Interest Requirements for NIH-Supported Institutions* (NOT-OD-12-159), September 21, 2012.

reviewed the 2011 FCOI regulations to understand NIH's responsibilities and the NIH Grants Policy Statement to identify (1) any FCOI requirements with which institutions must comply during the grant period and (2) any NIH oversight responsibilities to monitor institutions during the grant period. We also obtained an understanding of NIH's FCOI compliance program and analyzed the results of reviews conducted in the 7-year period following the implementation of the 2011 FCOI regulations.

To determine whether institutions were aware of their obligations under the 2011 FCOI regulations, we reviewed a list of 1,875 institutions that received grants from NIH in FY 2018 and were required to maintain FCOI policies²⁸ and determined whether each had a web presence. We judgmentally sampled 90 institutions that had a web presence but did not make their FCOI policy available on a publicly accessible website and requested that they provide their FCOI policies. We also judgmentally sampled 10 institutions that did not have a web presence and requested that they provide their FCOI policies within 5 business days, as required by the 2011 FCOI regulations.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

See Appendix A for the details of our audit scope and methodology.

FINDING

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. Although no Federal regulation requires NIH to proactively ensure that each investigator has disclosed all sources of research support, financial interests, and affiliations, NIH is responsible for overseeing institutional compliance with the regulations. The NIH Grants Policy Statement section 4.1.10, is a basis for NIH's policies and procedures that require institutions to disclose all sources of research support, financial interests, and affiliations. NIH also issues policy notices throughout the year, which are then incorporated into the grants policy statement on an annual basis.

Not all NIH-funded investigators may be aware that they are required to disclose significant financial interests with regard to research support, financial interests, and affiliations. Of the 1,875 institutions that received NIH funding in FY 2018 and were required to have FCOI policies, 1,013 did not have FCOI policies posted on their websites. Of the 90 institutions in our sample of institutions that had websites but did not have publicly accessible FCOI policies, 41 either did not have FCOI policies or did not respond to our requests that they provide their policies. In

²⁸ We received a listing of FY 2018 organizations from NIH that excluded SBIR and STTR Phase 1 recipients and interagency agreements.

addition, of the 10 institutions in our sample that did not have websites, 3 did not have FCOI policies, and 1 did not respond to our request that it provide its policy.

Although NIH has conducted outreach and provided technical assistance regarding FCOI policy requirements, some institutions stated that they were not aware of their responsibility to create and maintain FCOI policies.

FEDERAL REQUIREMENTS

Federal regulations establish standards that provide a reasonable expectation that the design, conduct, and reporting of NIH research will be free from bias resulting from investigators' FCOIs (42 CFR part 50, subpart F). NIH is responsible for overseeing institutional compliance with the regulations, and in accordance with NIH policies documented in NIH's Grants Policy Statement, section 4.1.10, NIH requires recipients and investigators to comply with the requirements at 42 CFR part 50, subpart F.

The responsibility for ensuring investigators disclose significant financial interests rests with the institutions (42 CFR part 50, subpart F). To help mitigate the risk that FCOIs will not be reported and to ensure that investigators are aware that they must disclose significant financial interests, institutions are required to implement and maintain FCOI policies and provide FCOI training to investigators receiving NIH research funding (42 CFR § 50.604(b)).

Federal regulations require each grantee institution to maintain an up-to-date, written, enforced policy on FCOI and make that policy available on a publicly accessible website (42 CFR § 50.604(a)). If the institution does not have a presence on a publicly accessible website, the institution must make its written FCOI policy available to any requestor within 5 business days of a request (42 CFR § 50.604(a)). The grant announcement or agency-specific instructions inform institutions of this requirement, and institutions agree to follow it upon signing the grant application.

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

NIH policies, procedures, and controls for helping to ensure that institutions report all sources of research support, financial interests, and affiliations mainly consist of NIH's Grants Policy Statement, section 4.1.10, NIH's FCOI compliance program, and the FCOI page of the NIH website. NIH's Grants Policy Statement mirrors the 2011 regulations. NIH's FCOI compliance program was set up to assess institutional implementation and compliance with the 2011 FCOI regulations. However, it does not have procedures and controls in place for following up on identified deficiencies in an institution's FCOI policy or for verifying that all institutions have FCOI policies. The FCOI webpage provides FCOI training and resources, including an FCOI policy development checklist that covers all the requirements institutions must implement to be in compliance with the 2011 FCOI regulations. However, we found that several institutions did not know the FCOI page existed and were therefore not aware of the resources available.

Federal regulations do not require NIH to ensure that investigators disclose all sources of research support, financial interests, and affiliations. Instead, Federal regulations place the responsibility of reporting FCOIs on grantee institutions. NIH stated that its communications to institutions regarding compliance with Federal regulations surrounding FCOI policies, reporting, and monitoring are consistent with the 2011 FCOI regulations. The regulations allow NIH to inquire, at any time before, during, or after the award, about any investigator's disclosure of financial interests and the institution's review of the investigator's disclosure,²⁹ but the regulations require the institutions, not NIH, to determine which significant financial interests are considered FCOIs and to report them accordingly.

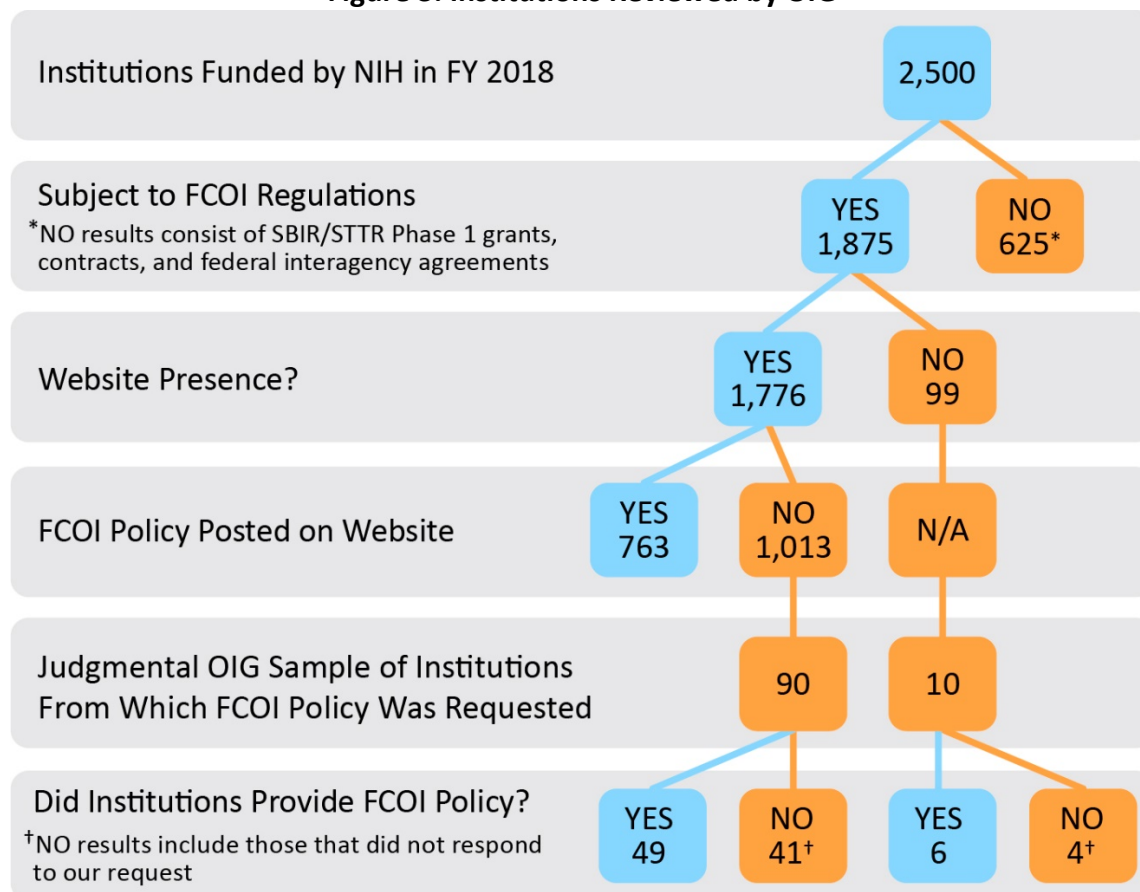
Each institution is required to maintain an up-to-date, written, enforced policy on FCOIs. This policy must be available on a publicly accessible website, and the institution must inform each investigator of the FCOI policy. Institutions must solicit and review disclosures of significant financial interests from each investigator who is planning to participate in, or is participating in, the NIH-funded research. If an institution determines that an FCOI exists, the institution must provide to NIH an FCOI report describing the investigator's FCOI and ensure that it has implemented a plan to manage the investigator's FCOI. The institution must provide the FCOI report to NIH before the institution expends any NIH-funded research project funds under a new award.

In addition, we determined that 1,013 of the 1,776 institutions with a web presence did not have FCOI policies posted on their websites as required by 42 CFR § 50.604(a). Of the 90 institutions in our sample that did not have publicly accessible FCOI policies on their websites, we were able to obtain FCOI policies from 49 institutions. The remaining 41 institutions either did not have FCOI policies or did not provide their FCOI policies upon our request. Of these 41 institutions, 10 stated that they did not have FCOI policies, 5 provided an FCOI policy that was created after our request, 12 provided policies on topics other than FCOI, and 14 did not respond to our phone calls and emails.

Of the 10 institutions in our sample that did not have a web presence, 6 had FCOI policies and provided them within the required timeframe. However, three institutions did not have FCOI policies, and one institution did not respond. See Figure 3 on the following page for a summary of what we found.

²⁹ 42 CFR § 50.606(b).

Figure 3: Institutions Reviewed by OIG



Some of the institutions we contacted stated that they were unaware that they were responsible for creating and maintaining FCOI policies. If an institution does not have an FCOI policy, the potential exists that investigators will not know that they have to disclose FCOIs and, as a result, FCOIs will not be reported according to the regulations. If FCOIs are not reported, NIH cannot appropriately oversee and monitor them.

NIH officials described their compliance program as a proactive review to assess institutional implementation and compliance with the 2011 FCOI regulations. For selected institutions, NIH provides a comprehensive list of any deficiencies in their FCOI policies and offers technical guidance and constructive feedback in addressing deficiencies. While NIH states that it expects institutions to formally address and resolve all identified issues, it does not currently conduct follow-up reviews. In addition, the number of proactive NIH reviews has significantly decreased from 28 reviews (FY 2013) to 3 reviews (FY 2018). While NIH is not required to conduct these reviews or follow up on the ones that it does perform, we maintain that the proactive reviews and follow-up would be an effective means of ensuring institutional compliance with the requirements.

While NIH cannot ensure that all FCOIs are reported, not verifying that an institution addresses identified deficiencies in its FCOI policy and that each institution has an FCOI policy increases the risk that FCOIs will not be reported.

RECOMMENDATIONS

We recommend that the National Institutes of Health:

- ensure that the 1,013 institutions identified by this review as not having FCOI policies on their website post these policies as required,
- enhance its FCOI monitoring program to (1) ensure that institutions resolve identified deficiencies and (2) review all grantee websites to ensure that FCOI policies are publicly accessible, and
- implement procedures to ensure that all institutions that are required to have FCOI policies have FCOI policies.

NATIONAL INSTITUTES OF HEALTH COMMENTS

In written comments on our draft report, NIH concurred with our recommendations and described corrective actions it plans to take to address them. Even though NIH concurred with our recommendations, it stated that we conflated reporting requirements for research support and affiliations with reporting requirements for FCOIs. NIH also stated that we did not review any requirements related to research support and affiliations and that this may have led to an inaccurate conclusion that NIH has limited policies, procedures, and controls to help ensure that institutions report FCOIs. NIH stated that it has extensive FCOI resources on its website.

Although NIH agreed with the facts in our draft report, it pointed out that even though they made up 54 percent of our sample, the 1,013 institutions we identified that did not have an FCOI policy posted on their website account for less than 4 percent of NIH grant awards and less than 5 percent of research funding. NIH stated that of the 55,981 awards that NIH issued in 2018 to 1,875 institutions, 53,840 (96.2 percent) were issued to institutions that made their FCOI policy publicly available on their websites. Similarly, of \$27.3 billion research funds issued to the 1,875 institutions, \$26 billion (95.4 percent) was awarded to institutions that posted their FCOI policy on their websites.

NIH also provided technical comments, which we addressed as appropriate. NIH's comments, excluding the technical comments, are included as Appendix B.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing NIH's comments, we maintain that the facts of our report are valid. The scope of our review included NIH's policies related to oversight of investigator disclosure of sources of research support, financial interests, and affiliations specifically as they pertain to FCOIs. We reviewed NIH's policies, procedures, and controls with regard to significant financial interests

resulting from research support and affiliations and reached the conclusion that NIH policies, procedures, and controls are limited.

We agree that NIH has extensive FCOI resources on its website and stated in our report that the FCOI webpage provides FCOI training and resources, including an FCOI policy development checklist that covers all the requirements institutions must implement to be in compliance with the 2011 FCOI regulations. However, we found that several institutions did not know the FCOI page existed and were therefore not aware of the resources available.

While it is accurate that over 95 percent of the \$27.3 billion in research funds was awarded to institutions that were covered by FCOI policies, we determined that 1,013 institutions representing \$1.2 billion in research funding did not have an FCOI policy posted on a publicly accessible webpage as required by the regulations. Although these institutions represent only a small percentage of the overall dollar amount funded by NIH in 2018, they are required by 42 CFR § 50.604(a) to maintain an up-to-date, written, enforced FCOI policy on a publicly accessible website. Furthermore, the low dollar amount of these grants relative to the overall dollar amount of research funds awarded does not lessen the possibility that an investigator at a smaller institution may have an FCOI to report and therefore does not mitigate the necessity of smaller institutions having FCOI policies. Not having an FCOI policy in place may increase the risk of unreported FCOIs, which may compromise the research projects funded by NIH. When we presented our finding to NIH officials, they acknowledged this risk.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed NIH's policies related to oversight of grantee disclosure of sources of research support, financial interests, and affiliations specifically as they pertained to FCOI. Our review covered 1,875 institutions that received grants from NIH in FY 2018 and were required to maintain FCOI policies. We did not review SBIR and STTR Phase 1 grants because these are exempt from the elements of the FCOI criteria that we reviewed.

We conducted our review from February through June 2019.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- discussed the 2011 FCOI regulations with NIH personnel;
- reviewed all NIH policies related to oversight of institutions' compliance with the 2011 FCOI regulations;
- downloaded NIH's Awards by Location list of institutions and NIH's ExPORTER database of institutions for FY 2018;
- requested from NIH a list of all FY 2018 institutions that were subject to the 2011 FCOI regulations;
- reconciled the list of FY 2018 institutions provided by NIH to the lists we downloaded;
- reviewed 1,875 institutions to determine whether each had a web presence and a publicly accessible FCOI policy;
- selected a judgmental sample of 90 institutions that had a web presence but did not make their FCOI policy available on a publicly accessible website and contacted them to request their FCOI policies;
- selected a judgmental sample of 10 institutions that did not have a web presence and requested that they provide their FCOI policies within 5 business days as required by the 2011 FCOI regulations; and
- discussed the results of our review with NIH officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain

sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: NATIONAL INSTITUTES OF HEALTH COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: September 3, 2019

TO: Gloria Jarmon
Deputy Inspector General for Audit Services, HHS

FROM: Director, NIH

SUBJECT: NIH Comments on Draft Report, *The National Institutions 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)

Attached are the National Institutes of Health's comments on the draft Office of Inspector General (OIG) report, *The National Institutions 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).

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: “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)

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.

Generally, NIH found that the OIG conflated the requirements of the Financial Conflict of Interest (FCOI) regulation with NIH policy requirements related to reporting other sources of support and affiliations. NIH made extensive technical comments to address this misunderstanding of the FCOI regulatory requirements.

NIH notes that the title of this OIG report includes reporting of all sources of research support and affiliations although the OIG did not review or discuss with NIH any requirements related to those two policy areas. NIH is concerned that this may have led to an inaccurate conclusion that NIH has limited policies, procedures, and controls in place to help ensure that institutions report FCOIs. To the contrary, NIH has extensive FCOI resources on its websites to help ensure that grant recipients report FCOIs including FAQs, reporting guidance, a checklist for FCOI policy development, presentations on FCOI requirements with case studies, a checklist to assist institutions with their FCOI policy development, and an email mailbox dedicated to questions concerning FCOI. NIH also has controls in place over FCOI reporting including an FCOI Module and tools to remind recipients when FCOI reports are due.

NIH also reviewed the data that the OIG used to reach their conclusions and on which to base their findings. The OIG identified 1,013 institutions that did not have a FCOI policy posted on their websites. Although these institutions make up 54% of the sample, they account for less than 4% of NIH grant awards and less than 5% of research funding. Thus, institutions without posted FCOI policies generally receive few grants and little funding each. Nearly all (184 of 188) institutions that are in the top 10% of NIH funding have FCOI policies posted on their website. Thus, of the 55,981 awards that NIH issued in 2018 to the 1,875 institutions, 53,840 (or 96.2%) were issued to an institution that made its FCOI policy publicly available on its website. Similarly, of \$27.289 billion research funds issued to the 1,875 institutions, \$26.021 billion (or 95.4%) were awarded to an institution that posted its FCOI policy on its website. Compared to institutions that had posted FCOI policies, institutions that did not post an FCOI policy on their website received far fewer awards (median number of awards 1.0, IQR 1.0-2.0 vs 7.0, IQR 2.0-43.5) and far fewer funds (median \$million 0.75, IQR 0.44-1.14 vs 3.92, IQR 0.87-22.98).

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: “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)

OIG Recommendation 1:

OIG recommends that NIH ensure that the 1,013 institutions identified by this review as not having FCOI policies on their website post these policies as required.

NIH Response:

NIH concurs with the OIG's recommendation that NIH ensure that the 1,013 institutions that did not have FCOI policies on their website post these policies, or make them publicly available, as required. NIH will provide a detailed corrective action plan in our six-month response to the OIG.

OIG Recommendation 2:

OIG recommends that NIH ensure its FCOI monitoring program to

- (1) ensure that institutions resolve identified deficiencies and
- (2) review all grantee websites to ensure that FCOI policies are publicly accessible

NIH Response:

NIH concurs with the OIG's recommendations that NIH ensure its FCOI monitoring program require institutions to resolve identified policy deficiencies and that NIH review all grantee websites to ensure that FCOI policies are publicly accessible. NIH will provide a detailed corrective action plan in our six-month response to the OIG.

OIG Recommendation 3:

OIG recommends that NIH implement procedures to ensure that all institutions that are required to have FCOI policies have FCOI policies.

NIH Response:

NIH concurs with the OIG's recommendation that NIH ensure that all institutions that are required to have FCOI policies have FCOI policies. NIH will provide a detailed corrective action plan in our six-month response to the OIG.