



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

**Testimony Before the United States Senate Committee on Health, Education,
Labor and Pensions**

***“Protecting U.S. Biomedical Research:
Efforts to Prevent Undue Foreign Influence”***

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Good morning, Chair Murray, Ranking Member Burr, and distinguished members of the Committee. I am Gary Cantrell, Deputy Inspector General for Investigations with the Department of Health and Human Services (HHS) Office of Inspector General (OIG). I appreciate the opportunity to appear before you to discuss how HHS-OIG is diligently working, in conjunction with our HHS and law enforcement partners, to protect taxpayer-funded medical research.

OIG is responsible for overseeing HHS's \$2.2 trillion in expenditures made in fiscal year 2020, and our work spans the over 100 programs at HHS. We combat fraud, waste, and abuse in those programs; promote their efficiency, economy, and effectiveness; and protect the beneficiaries they serve. To accomplish this, OIG employs tools such as data analysis, audits, evaluations, and investigations. We are a multidisciplinary organization comprised of investigators, auditors, evaluators, analysts, clinicians, and attorneys. We depend on our strong public and private partnerships to ensure coordinated enforcement success.

The Office of Investigations is the law enforcement component of OIG that investigates fraud and abuse against HHS programs. Our special agents have full law enforcement authority and effect a broad range of actions, including the execution of search warrants and arrests. We use traditional as well as state-of-the-art investigative techniques and innovative data analysis to fulfill our mission.

INTRODUCTION

Today, I will cover how OIG enhances the Federal Government's ability to detect, deter, and take enforcement action to ensure the integrity of taxpayer-funded medical research against foreign threats.

To date, the National Institutes of Health (NIH) has referred to OIG for investigation numerous allegations of noncompliance with its terms and conditions for receiving a medical research grant. The allegations primarily deal with the failure of grantee principal investigators to disclose foreign government affiliations. Because most of these referrals are still active, to avoid compromising ongoing investigations, I cannot provide much further specific details at this time. However, I can cover how we generally handle grant fraud allegations related to taxpayer-funded medical research.

Although foreign theft of taxpayer-funded medical research is a high-profile complex issue, the cases under our purview all involve aspects of grant fraud—something which OIG has extensive experience investigating. HHS is the largest grant-making organization and second-largest contracting agency in the Federal Government. It is also the second-largest payer under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. Given this nexus, OIG has made oversight and enforcement of grant fraud and related grant program integrity a priority.

PROACTIVE GRANT FRAUD EDUCATION, WITH ENFORCEMENT WHEN NEEDED

We take a two-pronged approach to preventing and acting against grant fraud. First, OIG works collaboratively to educate key stakeholders—including HHS operating divisions and grant recipient organizations—on ways to detect and prevent grant fraud through proactive training. Second, we take action, when needed, against grant fraud by investigating allegations of criminal misconduct and making appropriate referrals for criminal, civil, or administrative action.

OIG receives allegations of grant fraud or uncovers potential fraud in a variety of ways, including OIG hotline complaints, referrals from HHS operating divisions and law enforcement partners, whistleblower disclosures, and proactive data analysis. Our hotline's mobile compatible web form is specifically designed to easily collect grant and contract fraud complaints from the public and/or HHS employees, and we also have an Operating Division portal that is only available to our HHS operating division partners so they can quickly refer grant and contract related matters to OIG for immediate review.

Upon receiving an allegation pertaining to grant fraud involving NIH or other HHS operating division, OIG evaluates the allegation and determines whether we will open an investigation; refer the matter to another agency with appropriate authorities; or, when appropriate, refer the matter back to the HHS operating division involved for administrative review and potential action.

When evaluating referrals involving allegations of foreign threats to taxpayer-funded medical research, OIG is sensitive to the fact that academic and professional reputations could easily be damaged by erroneous allegations. All complaints are treated with confidentiality and discretion, and we only proceed with investigations when sufficient factual information supports such investigative activity. When OIG identifies a potential violation of civil or criminal law during an investigation, OIG presents the facts to the Department of Justice for prosecutorial consideration.

To protect the integrity of medical research, OIG coordinates with the HHS Office of National Security (ONS). In some instances, OIG works on matters with the Federal Bureau of Investigation's (FBI's) Joint Terrorism Task Forces and National Cyber Investigative Joint Task Force, the Department of Homeland Security, and components at FBI Headquarters and local field offices. When appropriate, we work together with NIH and ONS to develop followup approaches and mitigation strategies for such cases.

To illustrate the types of grant fraud investigations OIG conducts, I will offer summaries of two recent research integrity investigations.

A professor of internal medicine and researcher who led a team conducting autoimmune research at The Ohio State University and Pennsylvania State University, pled guilty in late 2020 to making false statements to Federal authorities as part of an immunology research grant fraud scheme. As part of his plea, the professor/researcher admitted he lied on applications in order to use approximately

\$4.1 million in NIH grants to develop China's expertise in the areas of rheumatology and immunology. According to his plea, he submitted materially false and misleading statements on NIH grant applications, seeking to hide his participation in a Chinese Talent Plan and his affiliation and collaboration with a Chinese university controlled by the Chinese government. He is now awaiting sentencing.

In late 2019 Van Andel Research Institute (VARI) agreed to pay \$5.5 million to resolve allegations that it violated the False Claims Act by submitting Federal grant applications and progress reports to NIH in which VARI failed to disclose Chinese government grants that funded two VARI researchers. The settlement further resolves allegations that in a Dec. 21, 2018, letter, VARI made certain factual representations to NIH with deliberate ignorance or reckless disregard for the truth regarding the Chinese grants. The Government specifically alleged that between January 2012 and December 2018, one of the researchers received grants and research support from a variety of Chinese sources, including the People's Republic of China's Thousand Talents Program.

As mentioned earlier, OIG's approach to addressing grant fraud includes working collaboratively with stakeholders to increase their ability to detect and prevent grant fraud through proactive training. OIG works with representatives of the Federal law enforcement community and HHS's Office of Research Integrity (ORI) to promote awareness of research misconduct and improve efforts to protect against such conduct. In addition to joint training efforts, ORI notifies OIG when conduct that might be criminal arises in the course of a research misconduct investigation. OIG's work is independent of ORI's, and ORI must refer all credible allegations of criminal conduct they uncover to OIG. In short, OIG's enhanced collaboration with ORI adds a layer of scrutiny to ensure that both ORI and OIG can take appropriate actions to protect U.S. biomedical research investments.

OIG increases HHS employee, contractor, and grantee awareness of how to identify and report allegations pertaining to grant fraud as well as foreign threats to taxpayer-funded medical research through training and presentations. For instance, OIG has provided numerous grant fraud training sessions at NIH Regional Seminars and NIH SBIR and STTR Town Hall meetings.

To educate grant recipient organizations, OIG has partnered with several academic entities to address best practices to ensure Research Integrity Officers and Compliance Officers are informed on the roles, responsibilities, and authorities of OIG. We tailor our efforts for each grant recipient organization to address what best practices are most helpful to serve its unique needs.

RISK MITIGATION THROUGH MINIMIZING VULNERABILITIES

OIG conducts oversight of NIH through audits and evaluations, some of which relate to protecting the integrity of NIH-funded research. Our work is informed by concerns raised by Congress, NIH, and other Federal law enforcement agencies about foreign threats to the integrity of U.S. medical research and intellectual property. OIG has identified the threat

of foreign government action aimed at unduly influencing and capitalizing on medical research programs funded and overseen by the Department as part of the 2020 Top Management Challenges Facing HHS. Furthermore, one of OIG's Top 25 Recommendations to HHS is that NIH should build on its efforts to identify and mitigate potential foreign threats to research integrity.

In fiscal year 2019, OIG began receiving transferred funding of \$5 million for oversight of grant programs and operations of NIH, including NIH efforts to ensure the integrity of its grant application evaluation and selection processes. This funding has been provided in addition to existing resources for NIH oversight, and has continued through fiscal year 2021.¹ As an associated requirement attached to this funding each year, OIG must submit an NIH oversight plan to the Committee on Appropriations of the House of Representatives and the Senate. OIG recently submitted to Congress its fiscal year 2021–2022 NIH Oversight Plan. The fiscal year 2021–2022 plan was developed, as required, in consultation with the Committees on Appropriations in the House of Representatives and the Senate and focuses on four key areas:

- **Cybersecurity protections.** OIG plans to conduct audits related to cybersecurity controls built into NIH's enterprise network and IT contracts.
- **Compliance with requirements for grants, contracts, and other transactions.** Our oversight activities will help ensure NIH-funded research institutions comply with Federal requirements and NIH policies that establish controls for NIH grants, contracts, and other transactions.
- **Integrity and management of grant application and selection processes.** OIG's planned oversight activities will examine NIH's efforts to ensure the integrity and the effective management of its grant application and selection processes.
- **Intellectual property and research integrity.** OIG's oversight will examine NIH's efforts and grantee institutions' implementations of internal controls and effective oversight practices in response to threats, including foreign threats, to intellectual property and research integrity.

Since the beginning of fiscal year 2019, utilizing both this supplemental funding as well as our permanent funding streams, OIG has completed nine related reviews focused on NIH. In addition, OIG has eight related ongoing reviews that have started since the beginning of fiscal year 2020. This work includes, but is not limited to:

- *Assessments of NIH's vetting and oversight of its peer reviewers.* OIG assessed NIH's vetting and oversight of the 27,000 peer reviewers who review grant applications for NIH each year. Peer reviewers have access to confidential information in grant applications. NIH has raised concerns about some peer reviewers inappropriately disclosing confidential information, including to foreign entities.

¹ The Consolidated Appropriations Act, 2021 (Public Law No. 116-260).

We found that NIH focuses its vetting of peer reviewer nominees on scientific skills and preventing undue influence generally, but it has not focused its vetting specifically on undue foreign influence. We recommended that NIH: (1) update its guidance on vetting peer reviewer nominees to identify potential foreign threats to research integrity, in consultation with national security experts as needed, and (2) work with HHS Office of National Security to develop a risk-based approach for identifying nominees who warrant additional vetting. NIH agreed with both recommendations.

With respect to NIH oversight of peer reviewers, we found that NIH enforces policies and procedures that protect confidential information in grant applications handled by peer reviewers, but it could do more to address the risk that undue foreign influence poses to maintaining confidentiality. We recommended that NIH: (1) conduct targeted, risk-based oversight of peer reviewers using analysis of information about threats to research integrity; (2) update its training materials routinely to include information about breaches of peer reviewer confidentiality and possible undue foreign influence; (3) require all peer reviewers to attend periodic trainings about peer review integrity; and (4) consult with Federal law enforcement and national security experts to determine what additional steps it might take to identify and address potential risks to the confidentiality of the peer review process, including possible undue foreign influence. NIH agreed with all of these recommendations and has implemented the fourth one.

- *NIH oversight of financial conflicts of interest and other support.*
OIG has also examined how NIH ensures that grantee institutions report all sources of research support, financial interests, and affiliations, as well as how NIH reviews financial conflicts of interests that are reported to them. With respect to required reporting, we 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 financial conflict of interest (FCOI) policies, 1,013 did not have FCOI policies posted on their websites. We recommended 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. NIH concurred with all of our recommendations. Although NIH has made progress with implementing these recommendations, they all remain unimplemented.

In addition, we found that NIH has improved its tracking and review of investigators' financial conflicts of interest (FCOIs) over the last decade. However, it could improve the consistency and quality assurance over these reviews. Further, NIH has no mechanism to identify FCOIs that involve foreign entities and is not planning to expand its FCOI reporting requirements to include such a designation. We

recommended that NIH: (1) perform periodic quality assurance reviews of information to ensure the adequacy of oversight of reported FCOIs; and (2) use information regarding foreign affiliations and support collected during the pre-award process to decide whether to revise its FCOI review process to address concerns regarding foreign influence. NIH agreed with both recommendations and has implemented the first one.

In the second half of fiscal year 2021, OIG plans to begin another four reviews, and our work plan will be updated as individual report designs are finalized. We would be more than happy to brief the Members of this Committee and staff on this work on an ongoing basis.

CONCLUSION

OIG is committed to working collaboratively to address foreign threats to taxpayer-funded medical research through preventive efforts to mitigate risk and minimize vulnerabilities in HHS programs and conducting enforcement actions whenever necessary. In cooperation with our HHS and law enforcement partners, OIG will continue to leverage our grant fraud investigative work and capabilities to maximize our efforts in this area as authorities, resources, and funding allow.

Thank you for your ongoing leadership in this area and for affording me the opportunity to discuss this important topic with you.