NIH Has Acted To Protect Confidential Information Handled by Peer Reviewers, But It Could Do More

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Each year the National Institutes of Health (NIH) relies on thousands of peer reviewers to review tens of thousands of extramural grant applications, helping NIH determine the most promising research to fund.

Key Takeaway
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.

What OIG Found
NIH has policies and procedures to protect the confidentiality of the peer review process and takes action against reviewers who disclose information. To prevent disclosures, NIH requires all peer reviewers to sign electronic nondisclosure certifications and trains peer reviewers to keep the information in grant applications private. To detect potential disclosures, NIH relies primarily on peer reviewers to report suspicious activity by other reviewers, but the agency is starting to use technology to detect disclosures. NIH has taken a range of actions against peer reviewers found to have disclosed confidential information, including terminating the reviewer's service or referring the reviewer to law enforcement for investigation.

NIH actively responds to instances of suspected undue foreign influence in peer review, but the agency is in the early stages of addressing this threat systemically. NIH learns of instances of potential undue foreign influence in peer review primarily from its national security partners and from NIH staff. It has responded to these instances on a case-by-case basis. NIH is developing an approach to address foreign-influence concerns systemically—through general oversight—in addition to responding to specific incidents.

What OIG Recommends
NIH is taking steps to address concerns about foreign threats to research integrity, and has an opportunity to more directly address—in a systemic way—concerns about foreign threats to the confidentiality of the peer review process. We recommend that NIH conduct targeted, risk-based oversight of peer reviewers using risk indicators identified from analysis of research integrity threats. In addition, NIH should update its training materials routinely with information about confidentiality breaches and undue foreign influence, and the agency should require all peer reviewers to attend periodic trainings about these risks. NIH should also continue consulting with national security experts about peer review risks and mitigation to inform a risk-based oversight approach. NIH concurred with all four of our recommendations.

Full report can be found at oig.hhs.gov/oei/reports/oei-05-19-00240.asp

Why OIG Did This Review
Congress, NIH, and Federal intelligence agencies have raised concerns about foreign threats to the integrity of U.S. medical research and intellectual property. This includes foreign programs that may unduly influence and capitalize on NIH-funded research. In August 2018, NIH Director Dr. Francis Collins raised concerns that peer reviewers—who have unique access to confidential information in grant applications—were, in some cases, inappropriately sharing this information with foreign entities. Subsequently, Congress appropriated funding for the Office of Inspector General to conduct oversight of NIH grant programs and operations, including examining the effectiveness of NIH's efforts to protect intellectual property derived from NIH-supported research. This study describes and assesses NIH's oversight of peer reviewers' handling of confidential information.

How OIG Did This Review
We interviewed NIH staff at the Office of Extramural Research, the Center for Scientific Review, the Office of Management Assessment, and the Office of Federal Advisory Committee Policy about their roles in setting and implementing policy related to peer reviewers' handling of confidential information. We also reviewed NIH policies, guidance, and training materials related to oversight of peer reviewers. Lastly, we collected information from NIH about its investigations of peer reviewers and about any actions it has taken against reviewers who disclosed confidential information.

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BACKGROUND

Objective
To describe and assess the National Institutes of Health's (NIH) oversight of peer reviewers' handling of confidential information.

Concerns About Foreign Threats to Research Integrity

For fiscal year 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. OIG's work is reviewing (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.

Congress directed OIG to examine—as part of this oversight work—(1) NIH's efforts to ensure the integrity of its grant evaluation and selection processes; and (2) the effectiveness of NIH's and grantee institutions' efforts to protect intellectual property derived from NIH-supported research.[3]

This evaluation and a companion report issued in September 2019 examine NIH's efforts to mitigate risks to research integrity and intellectual property posed by peer reviewers. Specifically, the first evaluation examined NIH's process for vetting prospective peer reviewers and found that NIH focuses its vetting of peer reviewer nominees on scientific skills and preventing undue influence generally, but does not focus its vetting specifically on undue foreign influence.[4] This report focuses on NIH's oversight of peer reviewers' handling of confidential information.

NIH recognizes that threats to the security of intellectual property and the integrity of peer review are increasing. In his August 2018 statement on protecting the integrity of U.S. biomedical research, NIH Director Dr. Francis Collins expressed concern about the inappropriate sharing of confidential information by peer reviewers with others, including foreign entities.[5] At the same time, Dr. Collins wrote to NIH grantee institutions to alert them to these foreign threats, noting that "foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers."[6] As an example of these programs, NIH's Advisory Committee to the Director warned NIH of China's Thousand Talents plan, which is intended to attract talented scientists while facilitating access to intellectual

property (see the box on this page).[7] In both his statement on the integrity of biomedical research and his letter to grantee institutions, Dr. Collins stated that in response to these increasing risks, NIH would work with other government agencies, institutions, and organizations to identify robust methods to protect the integrity of peer review.

Additionally, congressional committees have expressed concerns and requested information about potential threats to the integrity of taxpayer-funded research, including the theft of intellectual property and its diversion to foreign entities.[8, 9] In a June 2019 Senate hearing, NIH Principal Deputy Director Dr. Lawrence Tabak testified that NIH was "aware that a few foreign governments have initiated systematic programs to capitalize on the collaborative nature of biomedical research and unduly influence U.S.-based researchers."[10]

NIH also has raised concerns about possible unintended consequences that foreign threats may have on scientific collaborations. Specifically, NIH staff have stated concerns about protecting relationships with foreign scientists because of the perception of racial/ethnic profiling and stigmatization.[11] NIH further indicated that it seeks to mitigate risks to intellectual property security while continuing its tradition of international collaboration.[12]

China's Thousand Talents Plan

China's central government announced the Thousand Talents plan in 2008. One aspect of the plan provides financial incentives for Chinese scientists living abroad to return to China.[13] According to NIH, access to foreign intellectual property is key to a scientist's selection for the Thousand Talents program. In a 2018 meeting of NIH's Advisory Committee to the Director, NIH identified several concerns related to talent recruitment programs such as the Thousand Talents plan:

- undisclosed foreign financial conflicts;
- undisclosed conflicts of commitment; and
- peer review violations, including the inappropriate sharing of confidential information.[14]

The peer review process is central to the integrity of evaluating and selecting grants. According to NIH policy, the peer review process is intended "to ensure that applications for funding submitted to NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias."[15] However, as Dr. Collins' statement suggested, peer reviewers also present a potential risk to intellectual property or other confidential information contained in grant applications if they inappropriately share that information.[16]

Because peer reviewers review research-grant applications submitted to NIH, they have a unique opportunity to access confidential information in the applications. Accordingly, NIH policy seeks to ensure that peer reviewers do not inappropriately disclose or divert confidential information, including information related to intellectual property.[17]

NIH Efforts To Address Concerns About Foreign Threats to Research Integrity

In response to concerns about foreign threats to research integrity, NIH has taken steps to protect the integrity of the grantmaking and peer review process. To raise awareness of confidentiality in peer review, NIH has communicated with its staff, the research community, and grantee institutions, some of which have proactively raised concerns with NIH.[18] NIH convened a new working group for the Advisory Committee to the Director to explore additional steps to protect the integrity of peer review. The working group released its findings and recommendations in December 2018.[19] NIH also has conducted a fraud risk assessment of its extramural grant program to identify strengths and weaknesses. Additionally, NIH is working with law enforcement and national security partners—Federal agencies inside HHS (e.g., the HHS Office of National Security and OIG), as well as outside agencies (e.g., the Federal Bureau of Investigation (FBI))—to identify and follow up on scientists of possible concern among NIH grantees.[20] NIH staff reported that the agency will not invite individuals to serve as peer reviewers if it has "strong evidence" that an individual is linked to China's Thousand Talents program. Furthermore, NIH has worked to improve the security of the electronic systems that researchers use to submit grant applications and that peer reviewers use to access these applications.[21]

NIH's Peer Review Process

Each year, NIH receives more than 80,000 extramural grant applications from outside researchers and organizations and evaluates them using a two-level review process.[22] For about 75 percent of those applications, NIH's Center for Scientific Review (CSR) manages the first level of peer review. For the remaining applications, NIH's institutes and centers (ICs) manage the first level of review. An Advisory Council or Board at each IC conducts the second level of review.[23] The director of each IC or a designated individual makes the final funding decision.[24] In fiscal year 2018, NIH awarded $31.5 billion in extramural funding.[25]

At CSR, peer reviewers who serve on study sections (also known as scientific review groups) conduct the first level of review of grant applications. During this review, peer reviewers evaluate proposed projects based on their scientific and technical merit.[26] Each study section includes between 12 and 25 peer reviewers, all of whom are recognized as experts in their fields. Study sections usually hold three meetings per year, during which peer reviewers discuss multiple grant applications on the same scientific topic and give each application a preliminary score based on the proposed

project's likelihood of creating "a major scientific impact."[27] Study sections are grouped by topic into Integrated Review Groups.

NIH engages both temporary and appointed peer reviewers to review grant applications. Temporary reviewers join study section meetings on a one-off basis when there is a need for their area of expertise. By contrast, appointed reviewers serve 4-year terms and are expected to attend all meetings of their respective study sections.[28] Both temporary and appointed peer reviewers typically have received NIH grants in the past or have active grants, although this is not a requirement. NIH staff reported that the agency's oversight of peer reviewers does not vary with respect to peer reviewers' status as temporary or appointed. NIH considers both temporary and appointed peer reviewers to be professional service consultants.[29]

Nearly all of CSR's peer reviewers work at research institutions located in the United States, according to NIH. Reviewers include both U.S. citizens and foreign nationals. CSR vets all of these reviewers in the same way.

Peer Review Integrity

NIH seeks to ensure that its approximately 27,000 peer reviewers review grant applications in a manner free from inappropriate influence. NIH identifies the following core values for its peer reviewers: (1) expert assessment, (2) transparency, (3) impartiality, (4) fairness, (5) confidentiality, (6) security (added in 2018), (7) integrity, and (8) efficiency.[30] NIH vets peer reviewer nominees for their alignment with these values, focusing on nominees' scientific expertise and ability to effectively use that expertise in a peer review setting. OIG evaluated NIH's vetting of peer reviewer nominees in a previous report.[31]

NIH also conducts ongoing oversight of peer reviewers to verify that reviewers uphold NIH's core values throughout the terms of their participation. Scientific Review Officers (SROs) convene study section meetings and train peer reviewers on NIH policies regarding peer review integrity, including confidentiality and conflict-of-interest rules. NIH also collaborates with grantee institutions and other Federal agencies to respond to peer review integrity issues. (See the box on the next page for more information about NIH offices involved in peer review oversight.)

Additionally, before and after each meeting of a study section, peer reviewers must examine the grant applications they are reviewing and self-assess for conflicts of interest. Conflicts of interest could include, among other things, working at the same institution as the applicant or collaborating with any person listed in a major role on the application. Following their self-assessment, reviewers must electronically sign a conflict-of-interest certification through NIH's online peer review system. Reviewers who do not sign the certification cannot submit critiques or scores for grant applications. If reviewers identify conflicts with any applications, they are to notify their SROs and recuse themselves from

discussing those applications. In some instances, reviewers are not permitted to attend the study section meeting at all—for instance, if they are named on a grant application in a major professional role or if they would receive a direct financial benefit if an application were funded.[32]

> ### NIH Offices Involved in Peer Review
> Several NIH offices participate in the management and oversight of the peer review process.
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> The **Center for Scientific Review (CSR)** receives all grant applications submitted to NIH and determines whether the first round of review will be conducted by CSR or by an IC. CSR reviews about 75 percent of the applications; ICs review the rest.
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> The **Office of Extramural Research (OER)** oversees the integrity of the extramural peer review process and writes policies governing peer review operations, including the nondisclosure and conflict-of-interest certifications that peer reviewers must sign.[33] OER is further charged with following up on most allegations of peer-review violations.[34]
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> The **Office of Management Assessment** advises NIH on matters relating to program integrity and risk management and is NIH's central liaison to OIG and the FBI. The Office of Management Assessment conducts internal risk assessments and investigates misconduct allegations, including those involving peer reviewers.[35, 36]

Related Work

OIG has conducted two previous evaluations related to NIH's peer review process. Most recently, in 2019, OIG evaluated the strengths and limitations of CSR's initial vetting of peer reviewer nominees. OIG found that CSR focused its vetting on nominees' scientific credentials and preventing undue influence generally, but did not specifically focus on preventing undue foreign influence. OIG recommended that NIH, in consultation with national security experts, update its guidance on vetting peer reviewer nominees to identify potential foreign threats to research integrity and develop a risk-based approach for identifying nominees who warrant additional vetting. NIH concurred with both recommendations.[37] Also, in 2017, in response to a congressional request, OIG found that NIH's National Institute of Environmental Health Sciences (NIEHS) met the requirements of the peer review processes for funding on research related to bisphenol-A (BPA). However, we also found that for 14 percent of grants for BPA-related research—versus 4 percent of grants for research on other topics—NIH used its funding discretion to fund grant applications that had less favorable scores than competing applications. OIG concluded that although NIEHS has discretion to fund grant applications with less favorable scores ahead of competing applications with higher scores, NIEHS's application of its

discretion frequently or disproportionately in one research area may invite scrutiny to its funding decisions.[38]

Additionally, OIG has examined NIH's oversight of extramural researchers' financial conflicts of interest. OIG found that over the last decade, NIH has improved its tracking and review of researchers' financial conflicts, but that additional actions would further strengthen its oversight of researchers' conflicts and its monitoring of conflicts involving foreign interests.[39] OIG recommended that NIH perform quality assurance reviews of the financial-conflict information and consider revising its financial-conflict review process to address concerns regarding foreign threats. NIH concurred with both recommendations. In a related report, OIG found that NIH has limited policies, procedures, and controls in place to help ensure that research institutions report all sources of support, financial interests, and affiliations. OIG recommended that NIH enhance its financial-conflict monitoring to ensure that policies are publicly available and that it implement procedures to ensure that research institutions have financial-conflict policies.[40] NIH also concurred with these recommendations.

OIG is continuing to conduct oversight of NIH. Ongoing OIG work includes examining NIH's process for assessing and overseeing risks associated with grant applications and recipients; conducting an inventory of NIH's information technology resources; and determining whether NIH's internal controls effectively prevent duplication of grant funding.

Methodology

Scope

This report focuses on NIH's oversight policies and procedures in 2019 related to protecting the confidentiality of grant applications handled by peer reviewers serving on study sections organized by CSR. These study sections review about 75 percent of all NIH grant applications. This report does not include first-level reviews that are organized by individual ICs (e.g., the National Cancer Institute) rather than by CSR; special emphasis panels; or the second level of grant application review. Scientific and disease experts who are appointed as Special Government Employees largely conduct the second level of review. This report also does not cover the initial screening of peer reviewer nominees, as that is addressed in another OIG report.

Data Collection

We requested from NIH its policies, procedures, and training materials governing and related to peer reviewer oversight in 2019. Some of the procedures were specific to CSR, and some policies—like those from OER— applied to all of NIH. We collected information regarding peer review policies and procedures already in effect, as well as policies and procedures that NIH plans to implement shortly.

We also interviewed staff at CSR and OER about how they oversee peer reviewers. We interviewed five SROs; four Integrated Review Group Chiefs; the Research Integrity Officers at CSR and OER; and staff from the Office of the Director of CSR. We interviewed SROs because they train peer reviewers, conduct study section meetings, and may identify suspicious activities by peer reviewers. We interviewed Integrated Review Group Chiefs because they also may identify reviewers' suspicious activities. Additionally, we interviewed NIH staff at OER, the Office of Management Assessment, and the Office of Federal Advisory Committee Policy about their roles in setting and implementing policy regarding the oversight of peer reviewers.

Lastly, we collected information from NIH about its investigations of peer reviewers known or alleged to have disclosed confidential information from grant applications, as well as any enforcement actions that the agency has taken against peer reviewers who were found to have disclosed confidential information in grant applications.

Data Analysis
We analyzed the documents and interviews to identify NIH's approach to overseeing peer reviewers and the extent to which NIH considered undue foreign influence during its oversight.

Limitations
Our analysis relied on interviews, self-reported data, and documents provided by NIH staff. We did not independently verify the data we received. We also did not verify staff's compliance with NIH oversight policies.

Standards

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

FINDINGS

NIH protects the confidentiality of the peer review process through efforts to prevent disclosures, identify potential breaches, and take action against reviewers who disclose confidential information

This report focuses on peer reviewers serving in study sections organized by NIH's CSR, which manages the first-level review process for 75 percent of NIH grants. The rules that govern CSR study sections are formulated and/or executed by both CSR and NIH's OER. Although these rules may also apply to reviews conducted by study sections that are organized by NIH ICs, we limited this study to focus on policies and procedures that apply only to CSR.

NIH has policies and procedures to prevent peer reviewers in CSR-organized study sections from breaching confidentiality, to detect breaches of confidentiality when they do occur, and to enforce consequences against violators. Peer reviewers who breach confidentiality by disclosing information from grant applications or associated materials—all of which is confidential—violate NIH's core values of peer review integrity.

NIH works to prevent breaches of confidentiality in the peer review process by requiring nondisclosure certifications, training reviewers to protect grant application information, and implementing technological safeguards

NIH tries to prevent breaches of confidentiality by peer reviewers in three main ways. First, NIH requires peer reviewers to electronically sign nondisclosure certifications before they can access application materials. Second, NIH provides training for peer reviewers to inform them of their responsibilities to protect information and report suspicious activity by other reviewers. Third, NIH has introduced technological safeguards to increase the security of peer review systems.

Nondisclosure certifications. NIH requires reviewers to certify prior to each study section meeting that they agree not to disclose grant applications; meeting materials; or information discussed in the meeting, all of which is confidential.[41, 42] When signing NIH's nondisclosure certification, reviewers must certify that they will not disclose confidential information, give nondesignated individuals access to materials, or use any information contained in an application for personal gain.[43]

Training and guidance. NIH provides training and guidance to peer reviewers regarding their responsibilities for maintaining confidentiality. Prior to each meeting, SROs hold teleconferences with peer reviewers about maintaining confidentiality and upholding other core values of review integrity. These teleconferences are mandatory for new reviewers; existing reviewers are not required to attend. In the teleconferences, SROs inform reviewers that they cannot share review materials, discussions, or scores and cannot discuss applications in the SRO's absence.[44] At the start of each

study section meeting, SROs remind reviewers of these policies in their opening remarks.

NIH also created several informational documents on confidentiality and nondisclosure for peer reviewers, including a Guide Notice that outlines reviewers' responsibilities.[45] The Guide Notice reiterates peer reviewers' responsibility to maintain confidentiality and articulates the consequences that reviewers may face if they breach confidentiality. NIH instructs SROs to provide peer reviewers with a link to this Guide Notice if reviewers contact SROs with questions or concerns regarding the confidentiality of peer review.

Finally, NIH reported that it is developing two new trainings for peer reviewers—including one that will be publicly available on NIH's website—to help raise awareness about the confidentiality of grant applications that peer reviewers handle. These trainings will include examples of breaches of the peer-review process's integrity—including the disclosure of confidential information—that range from the low-level to the egregious.

Technological safeguards. To protect the confidentiality of grant applications that peer reviewers handle, NIH has implemented several technological safeguards and is in the process of implementing at least one additional safeguard. Currently, through its online peer review system, NIH blocks access to grant application materials for reviewers who have not electronically signed the nondisclosure certification. The agency also blocks reviewers' access to any grant application with which reviewers electronically reported a conflict. NIH reports that in the future, it will also require reviewers to use two-factor authentication—i.e., to provide two pieces of information, such as a passcode and a verification code—to access grant application materials through the peer review system.

NIH relies primarily on peer reviewers to identify and report potential breaches of confidentiality by other reviewers, but the agency is starting to employ technology to identify possible breaches

NIH relies on peer reviewers to monitor each other because it would be difficult for the agency to directly oversee all of the thousands of reviewers whom it engages each year. Additionally, NIH staff indicated that the agency relies on peer reviewers to monitor each other, stating that reviewers have a vested interest in ensuring that the review process is fair and in keeping application materials private because reviewers themselves generally have received NIH grants in the past or have active grants. Although NIH relies primarily on reviewers to report each other, it has also started to employ technological tools to identify possible breaches.

Reporting suspicious activity. Peer reviewers are uniquely positioned to identify suspicious or inappropriate behavior by other reviewers because they work closely with one another during study section meetings and may

know each other through their professional and scientific networks. However, NIH's trainings for peer reviewers do not currently include examples of suspicious or inappropriate behavior. (NIH reported that it plans to add case studies to future peer reviewer trainings.) NIH staff stated that instead, they encourage reviewers to report any suspicious activity, including possible breaches of confidentiality, by emphasizing a culture of "If you see something, say something." SROs reinforce this message to peer reviewers during their pre-meeting teleconferences and in their opening remarks for each study section meeting. NIH encourages peer reviewers to report suspicious behavior to any NIH staff members involved in peer review, including reviewers' own SROs, an Integrated Review Group Chief, or a Research Integrity Officer.

NIH also trains SROs and Integrated Review Group Chiefs to report any suspicious activities by peer reviewers to a Research Integrity Officer. SROs typically monitor reviewers' behavior in study section meetings. In some cases, Integrated Review Group Chiefs also may attend these meetings to watch reviewers' behavior.

NIH provides SROs with examples rather than clear definitions of "suspicious" or "inappropriate" activity or behavior that may indicate a breach of confidentiality by peer reviewers. NIH staff reported that such a definition would include a long list of the many ways in which peer reviewers have breached confidentiality, and said that NIH cannot anticipate every possible way in which a reviewer could disclose confidential information. NIH staff said that instead, the agency attempts to raise awareness that any suspicious activity should be reported. For instance, in its trainings for SROs, NIH provides examples of inappropriate behavior by peer reviewers so that SROs may watch for these behaviors.

NIH evaluates allegations before taking action against accused reviewers. According to NIH, when a peer reviewer reports suspicious activity, NIH staff report the allegation to a Research Integrity Officer. The Research Integrity Officer gathers evidence from the accuser, which may include emails, voicemails, and text messages. Research Integrity Officers store these allegations and supporting information in a case management system. When allegations involve violations of peer review integrity, NIH may request that the accused reviewer's institution gather evidence (e.g., searching his or her work emails).

Technological tool. To supplement its reliance on peer reviewers, NIH is expanding a technological tool—namely, its Forensics Dashboard—to help identify breaches of peer review integrity, including peer reviewers' disclosure of confidential information. NIH is further developing the Dashboard to facilitate fact-finding within the agency. The Dashboard allows NIH staff to retrieve information from NIH's computer systems, such as the identities of reviewers who downloaded grant applications and other related documents, like scores and meeting notes, and the dates and times

they did so. For example, NIH staff can view system logs in the Dashboard to quickly identify which reviewers accessed confidential information from a study section at the time of the breach. Although NIH currently uses the Dashboard on a limited basis, it plans to use the Dashboard more widely and to make it more comprehensive. NIH reported that it is also considering whether it is feasible to use the Dashboard to identify evidence of potential breaches in real time.

NIH has taken a range of actions against peer reviewers found to have breached confidentiality

OIG's analysis of NIH-provided data indicates that NIH has taken action against peer reviewers who breached confidentiality. NIH's actions also have extended more broadly than a single reviewer.

- As of November 2019, NIH had flagged 77 peer reviewers across both CSR- and IC-organized study sections as Do Not Use because of a breach of peer review confidentiality.[46] A reviewer who is flagged as Do Not Use may not participate in further study section meetings or review future applications until the flag is removed.

- Between February 2018 and November 2019, NIH terminated the service of 10 peer reviewers who not only had undisclosed foreign affiliations, but had also disclosed confidential information from grant applications. For example, some of these reviewers shared critiques of grant applications with colleagues or shared their NIH account passwords with colleagues.

- Between April 2018 and November 2019, NIH contacted more than 70 institutions with concerns about possible undue foreign influence. For 1 of these 70 institutions, NIH had concerns about possible undue foreign influence specifically among peer reviewers. NIH may communicate with peer reviewers' institutions to discuss concerns or request that institutions—as reviewers' employers— enforce additional consequences. In response to NIH's communications, at least two institutions terminated the employment of faculty members found to have disclosed confidential information from grant applications while serving as peer reviewers. Other institutions responded to NIH's concerns by temporarily prohibiting reviewers who had breached confidentiality from serving as principal investigators on NIH grants for a certain time.

- Between January 2018 and November 2019, OIG received 23 referrals from NIH that alleged that researchers had not complied with the terms and conditions of NIH's grants. According to NIH, a majority of the agency's referrals include individuals who are actively serving as peer reviewers. NIH also reported that two of its referrals involved reviewers who also breached the

confidentiality of peer review. NIH can refer peer reviewers to OIG or other law enforcement when it determines that cases warrant further investigation.

- As of November 2019, NIH had referred one reviewer to the HHS Suspension and Debarment Official for that reviewer to be suspended or debarred across the Federal Government. This referral occurred in October 2019. An individual who is suspended or debarred cannot receive Federal funds, including NIH grants. NIH reported that it plans to refer additional individuals to the Suspension and Debarment Official.

- As of November 2019, NIH dissolved two study sections because of evidence of systemic collusion among the reviewers in the section. At least one instance involved the disclosure of confidential information. NIH dissolved the first study section in 2017 and the second in 2018. All grant applications that the study sections reviewed were reassessed by different reviewers.

Finally, NIH told us that if it observes that multiple confidentiality breaches originate with peer reviewers from the same institution, NIH may consider excluding that institution from future funding opportunities.

NIH actively responds to instances of suspected undue foreign influence in peer review, but is in the early stages of addressing it systemically

Recognizing that undue foreign influence could lead peer reviewers to breach confidentiality, NIH has started to take steps to address it. Undue foreign influence in peer review could involve foreign entities encouraging NIH peer reviewers to disclose confidential information. NIH has learned of instances of undue foreign influence in peer review largely by following up on intelligence from its national security partners or from NIH program staff working directly on the grants. NIH has responded to these incidents on a case-by-case basis. However, NIH's efforts to systemically address concerns of undue foreign influence are more preliminary. NIH's training materials about peer review currently include little information about undue foreign influence, and its planned revisions to these materials include only one reference to this topic.

NIH becomes aware of instances of potential undue foreign influence primarily from its national security partners and NIH staff

One way NIH learns about instances of possible undue foreign influence is through its national security partners. Since 2017, NIH has increasingly worked with the FBI on emerging foreign threats to NIH-funded research. NIH reported that in 2018, the FBI provided it with referrals of researchers— some of whom were also peer reviewers—who had NIH grants and were alleged to have undisclosed foreign affiliations. NIH also works with other law enforcement agencies, such as the HHS Office of National Security, to address potential foreign threats. The Office of National Security

provides guidance to HHS programs on intelligence, information security, and safeguarding classified information.[47]

NIH also learns about instances of possible undue foreign influence through its staff. Specifically, NIH Program Officers, who manage specific NIH grants, may notice affiliations or funding awards listed in a grantee's publication that had not been disclosed to NIH as required by NIH policy.[48] For instance, program staff may notice that a grantee's publication lists undisclosed foreign grants in addition to NIH funding. NIH program staff then report these findings to NIH's OER, which conducts additional research. In these instances, OER staff may confirm through NIH's grant management systems that the grantee did not disclose the foreign affiliation and then determine how to follow up on the issue. Additionally, NIH may receive allegations of possible undue foreign influence from anonymous complaints, grantee institutions, or peer reviewers.

Once NIH learns of instances of possible undue foreign influence, it examines the allegations by further researching possible foreign affiliations. NIH reviews referrals—from the FBI and other sources—of researchers alleged to have undisclosed foreign affiliations. As of November 2019, NIH determined that allegations against 207 researchers were potentially substantiated. Of those 207 researchers, NIH determined that 129 had served as peer reviewers in 2018 and/or 2019. NIH designated 47 of these 129 peer reviewers as Do Not Use. When OIG asked NIH about the remaining 82 peer reviewers—i.e., those who had potentially substantiated allegations but who had *not* been designated as Do Not Use—NIH did not respond.

NIH has confirmed a small number of peer reviewer confidentiality breaches related to foreign influence

Between February 2018 and November 2019, NIH confirmed 10 cases involving peer reviewers who were stealing or disclosing confidential information from grant applications or related materials and who also had undisclosed foreign affiliations.[49] Two of these 10 cases involved peer reviewers who were selected for China's Thousand Talents program. The breaches of confidentiality included disclosing scoring information, sharing study section critiques, and forwarding grant application information to third parties. In some of these instances, reviewers shared confidential information with foreign entities. NIH learned about these breaches from the FBI and from NIH staff, as well as through reports from grantee institutions and peer reviewers.

NIH responded to these breaches of confidentiality by disciplining the involved peer reviewers. NIH terminated the peer review service of the individuals involved in the 10 cases. NIH also contacted the reviewers' institutions to alert them to the allegations and gather further information about the reviewers. NIH referred some cases to the Office of Management Assessment for further investigation. In two cases, NIH dissolved a study

section and assembled a new study section with different reviewers to re-review the affected grant applications.

NIH training materials about the peer review process rarely include information about undue foreign influence

NIH has not systemically incorporated concerns about undue foreign influence into its oversight of peer reviewers. NIH's training materials for peer reviewers and SROs rarely include discussions of undue foreign influence. Currently, training materials specifically for peer reviewers do not cover undue foreign influence at all. Additionally, training materials specifically for SROs—the NIH staff members responsible for managing the peer review process—include only one discussion of foreign affiliation. Those training materials ask SROs to consider whether they should select a researcher who has academic appointments in both the United States and China to serve as a peer reviewer.[50, 51] At the time of our data collection, no training materials for SROs included information about how to recognize signs of undue foreign influence among active peer reviewers. NIH reported that it considers this to be outside the scope of SROs' duties; indeed, the SROs whom we interviewed reported that they would not know how to identify possible undue foreign influence among peer reviewers.

Although peer reviewers and SROs are not responsible for identifying undue foreign influence among reviewers, NIH staff indicated that the agency expects peer reviewers and SROs to be aware of emergent foreign threats to peer review. NIH is trying to address this by updating its training materials for peer reviewers and SROs to raise awareness of potential undue foreign influence. The revised training materials will include at least one example related to undue foreign influence among peer reviewers.

CONCLUSION AND RECOMMENDATIONS

NIH places a high value on peer reviewers evaluating NIH grant applications in a fair, independent, and expert manner that is free of undue influence. Recently, the confidentiality of the peer review process has been compromised, putting the integrity of NIH's review of grant applications at risk. A small number of peer reviewers are known to have violated peer review integrity by disclosing or stealing confidential information from grant applications—in some cases, at the behest of foreign research institutions. This can put U.S. taxpayer-funded intellectual property at risk, undermine confidence in the integrity of peer review, and diminish NIH's reputation. To address some of these risks, NIH has been working with grantee institutions and national security partners—such as the HHS Office of National Security and Federal law enforcement (including the FBI and OIG)—to address concerns about foreign threats to research integrity in other contexts, such as researchers who have active NIH awards and who fail to disclose their foreign financial interests as required. NIH also has worked to better secure the systems that peer reviewers use when they access grant applications.

We found that NIH has taken steps to try to prevent, detect, and respond to breaches of confidential information by peer reviewers; that it has worked with law enforcement and other entities to address instances of suspected undue foreign influence among peer reviewers; and that it is starting to incorporate concerns about undue foreign influence into its general oversight of peer reviewers. However, we concluded that NIH can do more to systemically and directly address concerns about foreign threats to the confidentiality of the peer review process. Previous OIG work that looked at NIH's vetting of peer reviewer nominees found similar results—that NIH's vetting process focuses on preventing undue influence generally, but not specifically on undue *foreign* influence.

NIH has opportunities to strengthen its oversight of peer reviewers to further protect the confidential information in grant applications in two important ways: (1) enhancing training for peer reviewers and SROs and (2) developing a risk-based approach to target the agency's oversight of peer reviewers. With a measured, risk-based approach, NIH can focus its oversight efforts on those circumstances or reviewers shown to pose the greatest risk to peer review integrity. Therefore, we recommend that as NIH's approach to oversight of peer reviewers evolves, NIH should:

Conduct targeted, risk-based oversight of peer reviewers using analysis of information about threats to research integrity

NIH should conduct targeted oversight of peer reviewers using risk indicators identified from analysis of research integrity threats and peer

review integrity violations. To identify risk indicators to target its oversight, NIH first should analyze information about research integrity threats identified by law enforcement and national security partners as well as specific violations of peer review integrity—including cases of confidentiality breaches related to possible foreign affiliations—and data from its Forensics Dashboard. For example, if NIH's analysis indicates that grant applications containing particularly sensitive information or having highly lucrative commercial purposes pose greater risks to research integrity, NIH could target its oversight attention on peer reviewers reviewing those applications. As new cases are identified or as threats evolve, NIH should update and refine its risk indicators. Using a risk-based approach to oversight would also address potential concerns about the burden of increasing oversight for the approximately 27,000 peer reviewers.

Update its training materials routinely to include information about breaches of peer reviewer confidentiality and possible undue foreign influence

NIH should routinely update its training materials for peer reviewers and SROs with the most relevant and up-to-date information about confidentiality breaches and undue foreign influence. NIH should include relevant information from newly identified cases and/or the results of its analysis of Forensics Dashboard data. At the time of our data collection, NIH's training materials for peer reviewers included information about maintaining confidentiality but did not include any sample scenarios of undue foreign influence. NIH reported that it is in the process of updating its peer reviewer training materials to include at least one scenario of undue foreign influence. We encourage NIH to follow through on this update, and, to ensure that its trainings are updated regularly, NIH should establish a policy or procedures outlining how often and under what circumstances it will update its training materials.

Require all peer reviewers to attend periodic trainings about peer review integrity

NIH should require all peer reviewers to attend periodic trainings that convey the most relevant and up-to-date information about confidentiality breaches and undue foreign influence. NIH currently requires only new peer reviewers to attend a training, but NIH should instead require *all* reviewers to attend periodic trainings that remind them of their responsibilities to ensure the integrity of the peer review process. NIH should determine how frequently such trainings for all peer reviewers should occur. For example, NIH could require all peer reviewers to attend an annual training that includes the most recent, relevant information.

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 has already collaborated with Federal law enforcement and national security partners to respond to instances of undue foreign influence in peer review. NIH should continue to consult law enforcement or national security partners to bolster its efforts and to support a risk-based approach to oversight in this area. As part of this consultation, NIH should specifically seek advice from law enforcement and national security experts about identifying and mitigating peer review risks. For example, NIH could work with law enforcement and national security experts to identify potential red flags that could indicate undue foreign influence in the peer review process.

AGENCY COMMENTS AND OIG RESPONSE

NIH concurred with all four of our recommendations.

In response to our first recommendation, NIH stated that it is coordinating with Federal partners to explore approaches to conduct targeted, risk-based oversight of peer reviewers using analysis of information about threats to research integrity and peer review. NIH also said that it will provide OIG with an action plan to address this recommendation.

In response to our second recommendation, NIH stated that it has released a series of reports and case studies about maintaining integrity in peer review and provided links to the blog posts in which it did so. NIH added that it will continue to assess its training materials for peer reviewers three times a year. NIH's actions are encouraging, and we recommend that when NIH next assesses its training materials for peer reviewers, it should incorporate the concepts from its blog posts into the training materials to raise awareness—among all peer reviewers—of possible threats to the integrity of peer review.

Regarding our third recommendation, NIH reported that CSR has developed a new online training module about peer review integrity. Additionally, NIH stated that by April 2020, OER will revise instructions for peer reviewers about protecting the security of NIH grant applications. We believe these are positive steps. However, NIH's new online training module does not address undue foreign influence. Therefore, we continue to recommend that NIH require *all* peer reviewers—not only new peer reviewers—to take periodic trainings that provide the most relevant and up-to-date information about confidentiality breaches and undue foreign influence.

In response to our fourth recommendation, NIH stated that it is working with Federal partners to develop a systematic, risk-based, data-driven approach to identifying peer reviewer nominees who warrant additional scrutiny. These actions address concerns about peer reviewer nominees, but they do not address concerns about the oversight of *existing* peer reviewers or about the integrity of the peer review process as a whole. We continue to recommend that NIH consult Federal law enforcement and national security partners to identify and address potential risks to the confidentiality of the peer review process, including possible undue foreign influence.

For the full text of NIH's comments, see the Appendix.

APPENDIX A: Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES   Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

DATE: March 4, 2020

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

FROM: Director, NIH

SUBJECT: NIH Comments on Draft Report, *NIH Has Acted to Protect Confidential
           Information Handled by Peer Reviewers, But Could Do More*
           (OEI-05-19-00240)

Attached are the National Institutes of Health's comments on the draft Office of
Inspector General (OIG) report, *NIH Has Acted to Protect Confidential Information
Handled by Peer Reviewers, But Could Do More* (OEI-05-19-00240).

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 ACTED TO PROTECT CONFIDENTIAL INFORMATION HANDLED BY PEER REVIEWERS, BUT COULD DO MORE" (OEI-05-19-00240)

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:
Conduct targeted, risk-based oversight of peer reviewers using analysis of information about threats to research integrity.

NIH Response:
NIH concurs with OIG's finding and corresponding recommendation regarding risk-based oversight of peer reviewers using analysis of information about threats to research integrity and to peer review. In close coordination with federal partners (DHHS/ONS, DHHS/OIG, OSTP, NSTC, NSF, DOE, DoD, FBI, NSC, and DNI), NIH is exploring a variety of approaches. NIH will provide the OIG an action plan to address the recommendation in our 180-day management decision letter.

OIG Recommendation 2:
Update its training materials routinely to include information about breaches of peer reviewer confidentiality and possible undue foreign influence.

NIH Response:
NIH considers the recommendation closed.

Since the OIG's audit, the NIH launched a series of reports and case studies to raise awareness, encourage dialogue, and inspire creative problem solving of the challenges in maintaining integrity in peer review (e.g., Favorable Treatment and Undisclosed Conflict of Interest).

NIH has and will continue to assess the training materials for peer reviewers three times a year in March, July, and November. The assessment ensures that the training materials align with changes in the NIH review policy.

OIG Recommendation 3:
Require all peer reviewers to attend periodic trainings about peer review integrity.

NIH Response:
NIH concurs with OIG's finding and corresponding recommendation regarding required, periodic trainings for reviewers on peer review integrity. In 2020, CSR launched a Review Integrity pilot training module. By April 2020, OER will revise its instructions for reviewers entitled, "Protecting the Security of NIH Grant Applications".

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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 ACTED TO PROTECT CONFIDENTIAL INFORMATION HANDLED BY PEER REVIEWERS, BUT COULD DO MORE" (OEI-05-19-00240)

OIG Recommendation 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 confidentiality of the peer review process, including possible undue foreign influence.

NIH Response:
NIH concurs with OIG's finding and corresponding recommendation regarding consulting Federal law enforcement and national security experts to determine possible additional steps to identify and address potential risks to confidentiality of the peer review process. NIH is working with Federal experts (see Recommendation 1) to develop a systematic, risk-based, data-driven approach to identifying peer review nominees who warrant additional scrutiny. NIH will provide the OIG an action plan to address the recommendation in our 180-day management decision letter.

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ACKNOWLEDGMENTS

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

ENDNOTES

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

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[4] OIG, *Vetting Peer Reviewers at NIH's Center for Scientific Review: Strengths and Limitations*, OEI-01-19-00160, September 2019.

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[10] Testimony of Dr. Lawrence A. Tabak, Principal Deputy Director, NIH, before Senate Committee on Finance, June 5, 2019, p. 3. Accessed at https://www.finance.senate.gov/imo/media/doc/05JUN2019TabakSMNT.pdf on June 20, 2019.

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[12] NIH, Letter to grantee institutions, August 20, 2018. (See Endnote 6 for URL information.)

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[14] NIH, *Foreign Influences on Research Integrity: 117th Meeting of the Advisory Committee to the Director*, December 13, 2018, slides 2 and 4. Accessed at https://acd.od.nih.gov/documents/presentations/12132018ForeignInfluences.pdf. Accessed on June 20, 2019.

[15] NIH, *Grants Policy Statement*, October 2018, § 2.4, p. I-67–I-68. Accessed at https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf on July 9, 2019.

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[18] Testimony of Dr. Lawrence A. Tabak, Principal Deputy Director, NIH, before Senate Committee on Finance, June 5, 2019, p. 4-5. (See Endnote 10 for URL information.)

[19] NIH Advisory Committee to the Director, *ACD Working Group for Foreign Influences on Research Integrity: December 2018 Report*. (See Endnote 7 for URL information.)

[20] Testimony of Captain Michael Schmoyer, Assistant Deputy Secretary for National Security, Director, Office of National Security, before Senate Committee on Finance, June 5, 2019, p. 6-7. Accessed at https://www.finance.senate.gov/imo/media/doc/05JUN2019SchmoyerSMNT.pdf on August 13, 2019.

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[25] NIH, *CSR Advisory Council Update*, September 2018, slide 11. Accessed at https://public.csr.nih.gov/AboutCSR/Organization/CSRAdvisoryCouncil/Presentations on January 2, 2020.

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[38] OIG, *As Funding for BPA Research Increased, NIEHS Followed Its Peer Review Process While Also Exercising Its Discretion*, OEI-01-15-00150, August 2017.

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