

NIH Advisory Committee to the Director (ACD)

ACD Working Group for Foreign Influences on Research Integrity

December 2018 Report

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Advisory Committee to the Director Working Group Report

Introduction

Over the decades, the American scientific landscape has benefitted greatly from the important contributions of foreign nationals. For example, since 2000, 39% of U.S. Nobel prizes in Physics, Chemistry, and Medicine have been awarded to foreign-born scientists¹. On a broader scale, American institutions and universities are shaped by foreign trainees, investigators, and employees, and U.S. scientists routinely collaborate productively with investigators in foreign countries. These interactions are critical to scientific advances and are vital to maintain. In a 2017 analysis published in *Nature*², the authors posit that countries could reap the most benefit from their scientific investment by funding the best science, regardless of where it takes place, and by ensuring that their domestically-based scientists are linked with these projects.

Unfortunately, some foreign governments have initiated systematic programs to unduly influence and capitalize on U.S.-conducted research, including that funded by NIH. As members of these programs, small numbers of scientists have committed serious violations of NIH's policies and systems by not disclosing foreign support (i.e., grants), laboratories, or funded faculty positions in other countries. When disclosed to both the home research institutions or organizations and to NIH, these forms of support may be determined to be fully appropriate.

Violations to the peer review process have also occurred in relation to undue foreign influences. While uncommon, given the central importance of the peer review process in decision making, any deviation from the regulatory framework that undergirds peer review is extremely problematic. These include compromising the confidentiality of peer review by sharing information and/or applications and altering priority scores in an attempt to influence review results based on elements unrelated to scientific merit and the normal and appropriate NIH funding decision process.

These efforts by foreign governments to obtain a competitive advantage in critical areas of research and innovation at the cost of the U.S. research enterprises, the federal government, and the American taxpayer are few, but serious. These behaviors related to these efforts must be addressed in ways that build and continue important and successful relationships with foreign scientists in all countries while simultaneously protecting the Nation's research integrity.

Executive Summary

American institutions and universities are shaped by foreign trainees, investigators, and employees, and U.S. scientists routinely collaborate productively with investigators in foreign countries. These interactions are critical to scientific advances and are vital to maintain. Unfortunately, some foreign governments have initiated systematic programs to unduly influence and capitalize on U.S.-conducted research, including that funded by NIH. As members of these programs, small numbers of foreign

¹ <http://nfap.com/wp-content/uploads/2017/10/Immigrants-and-Nobel-Prizes-1901-to-2017.NFAP-Policy-Brief.October-20171.pdf>

² *Open Countries have Strong Science*, *Nature*, October 4, 2018; <https://www.nature.com/news/open-countries-have-strong-science-1.22754>

scientists have committed serious violations of NIH's policies and systems. Issues identified by NIH include not disclosing foreign financial conflicts; not fully and accurately disclosing other financial support during grant application, award, and implementation processes; and not disclosing conflicts of commitment. In some instances, foreign scientists have failed to disclose other affiliations and positions that often come with resources and equities. Finally, NIH has seen peer review violations that range in severity.

The Advisory Committee to the Director working group for Foreign Influences on Research Integrity was established to develop recommendations to address behaviors related to these efforts in ways that build and continue important and successful relationships with foreign scientists in all countries while simultaneously protecting America's research integrity.

With the importance of upholding relationships with foreign nationals in mind, the ACD working group makes several recommendations to the ACD, under the umbrella of three main themes:

- Communication and Awareness: Opportunities where existing procedures are in place but in need of education, clarification, or increased attentiveness;
- Risk Mitigation: Opportunities for change or enhancement of existing tools that safeguard research integrity; and
- Monitoring, Actions, and Consequences: Opportunities for ongoing monitoring, verification, trust-building, and remediation.

Universities, institutions, and organizations that apply for and receive NIH grant money must work together with NIH to identify and allow for best practices to allow for institutional variation in implementing these recommendations.

I. Working Group Report

A. Background

NIH must maintain the public trust as stewards of taxpayer dollars to support U.S. biomedical research. Foreign influences on research integrity are concerns to Congress, NIH, other federal funding agencies, and the broader biomedical research community.

NIH is aware that some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers and take advantage of the long tradition of trust, fairness, and excellence of NIH-supported activities. Some foreign nations have created state-sponsored programs to recruit and sponsor skilled scientists, and a number of the violations NIH and recipient organizations have uncovered were made by members of such programs. Talent recruitment plans, such as China's Thousand Talents Program, have been recently highlighted in the media^{3,4,5}. The Thousand Talents Program is reported to consist of some 56,000 recruits, including at least 6,000 top-tier recruits, across many scientific disciplines and at highly prestigious institutions, and its self-stated mission is "...to gather

³ *China hides identities of top scientific recruits amidst growing US scrutiny*, Nature, October 24, 2018
<https://www.nature.com/articles/d41586-018-07167-6>

⁴ *Visa Restrictions for Chinese Students Alarm Academia*; New York Times

⁵ *Can the US stop the scientific brain drain to China?*; Boston Globe

the global wisdom and create the China great exploit⁶.” One key qualification of its members is access to intellectual property (IP). These kinds of Information collection efforts are not unique to China, and NIH is not the only funding agency affected.

On August 21, 2018, the NIH Director, Dr. Francis Collins, initiated broad communications with the biomedical community and NIH stakeholders. His letters to over 10,000 organizations that are recipients of or applicants for NIH grant awards⁷ highlighted NIH’s concerns (Appendix item 2). Problematic examples include:

- Identical or highly similar applications submitted for funding to both the NIH and a foreign entity, but without disclosure to NIH,
- IP claimed by foreign governments rather than the U.S. government, even though support from U.S. government was clearly used for the discovery, and
- Investigators failing to disclose foreign support to the U.S. institutions that are their employers.

Recipient organizations are key partners in addressing these and related concerns, because as recipients of funding, they have longstanding symbiotic relationships with NIH. As such, the working group to the Advisory Committee of the NIH Director was assembled to work through the issues resulting from undue foreign influences and breaches in peer review.

The working group activities focus specifically on complications of foreign influences as they relate to the extramural NIH community. NIH has begun to examine internal processes related to intramural employees, but these considerations and activities will not be addressed in this report since intramural investigators are government employees and are subject to different requirements due to their federal employment status.

B. NIH Processes and Considerations

i. Extramural funding processes

Accurate reporting of research support and relevant affiliations

NIH Office of Extramural Research (OER) is

... an office within the NIH Office of the Director. OER supports the entire NIH extramural research community by providing policy, guidance, systems and other support to the recipient community, as well as to the 24 NIH Institutes and Centers that award grants. OER serves as a vital interface for the biomedical research community by guiding investigators through the

⁶ <http://www.1000plan.org/en/mission.html>

⁷ Herein referred to as “recipient organizations” – universities, institutions, and other organizations that apply to and/or receive NIH funding

process of attaining grants funding and helping them understand and navigate through federal policies and procedures.⁸

OER communicates disclosure policy and requirements on a webpage that defines other support and explains requirements for reporting (Appendix item 3)⁹.

For all NIH funding, applicants are required to disclose all other funding support and collaborations and have opportunities to do so at multiple steps in the application and funding processes:

- Applicants are asked to check a box on the grant application “Other information” page if they have international collaborators. Any disclosure of foreign support, collaborations, or sharing of resources initiates a clearance process with the State Department that must be completed prior to issuance of awards.
- In new and renewal grant applications, all applicants are asked to complete the Research & Related, Senior/Key Person Profile as part of the Biosketch. Each investigator on the grant must upload a document listing other support and relevant affiliations. This is also an opportunity for each investigator to share this information.
- A subset of applicants who receive an overall impact score of 30 or less are asked via an email auto-generated by eRA Commons to submit additional “Just-in-Time” grant application information. This request provides potential grantees another opportunity to disclose foreign support.
- Investigators who are recipients of NIH funding are required to complete annual NIH progress reports; this is another opportunity to list other relevant or foreign support.

The regulation 42 CFR Part 50 Subpart F¹⁰ applies to each recipient organization (domestic, foreign, public, private, but not Federal) and serves to ensure that investigators’ conflicting financial interests do not bias NIH funding of grants, cooperative agreements, and contracts. It does not apply to Phase I SBIR/STTR applicants/recipients. Financial Conflicts of Interest (FCOIs) occur when the recipient organization determines that an investigator’s significant financial interest is related to his/her NIH-funded research and could directly and significantly affect the design, conduct, or reporting of the research. FCOIs are not prohibited, but the regulation ensures that they are identified and managed through investigator disclosure, institutional review and management, and reporting to NIH.

Recipient organizations are required to develop a policy, make it publicly available on a website, and enforce the policy¹¹. They must review investigator disclosures, manage those that are determined to be FCOIs, and report to the NIH. If FCOIs are identified for any senior/key personnel in the grant application

⁸ <https://grants.nih.gov/aboutoer/intro2oer.htm>

⁹ <https://grants.nih.gov/grants/forms/othersupport.htm>

¹⁰ <https://grants.nih.gov/grants/policy/coi/index.htm>

¹¹ <https://grants.nih.gov/grants/funding/welcomewagon.htm>

or in any report submitted to NIH, prior to the expenditure of funds, the recipient organization must make publicly available the following information:

- Investigator's name, title, and role with respect to the research project;
- Name of the entity in which the Significant Financial Interest is held;
- Nature of the Significant Financial Interest; and
- Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Investigators are defined in the regulation as the Principal Investigator, Project Director, and any other person, regardless of position, responsible for the designing, conducting, and reporting NIH-funded research. The definition also includes the investigator's spouse and dependent children. Per the regulation, investigators must comply with institutional policy, and disclose to their recipient organization significant financial interests, including:

- Publicly traded entities (remuneration and equity interest exceeding \$5,000 in aggregate)
- Non-publicly traded entities (remuneration exceeding \$5,000 in aggregate and any equity interest)
- Intellectual property rights and interests exceeding \$5,000 upon receipt of income
- Reimbursed or sponsored travel related to Institutional responsibilities

At the recipient organization level, the institutional signing official signs applications as a certification and assurance that the grant application package is accurate. This institutional certification is also ensuring that there is a policy in place at the organization to manage financial conflicts.

NIH is required to provide technical assistance and oversight through engagement with the recipient organization (e.g., information about disclosures, questions about FCOI management, questions about policy). To help ensure compliance, NIH reviews institution policies, reviews FCOI reports, follows up on media reports and complaints, and works with institutions to address non-compliance.

To communicate to stakeholders regarding the FCOI requirements, NIH released a guide notice on March 20, 2018 (Appendix Item 4)¹². It reminded the NIH community that the financial conflict of interest regulation is to "promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research is free from bias resulting from Investigator financial conflicts of interest." It emphasized that while U.S. entities are exempt from the disclosure requirement as any financial conflict is handled at the institution level, all applicants and awardees are required to disclose in NIH grant applications any foreign financial relationships with foreign government or institution of higher education.

¹² <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html>

As part of ongoing outreach and mitigation efforts, NIH works with the specific recipient organization when staff uncover issues of non-disclosure. In past examples, the issue is communicated to the institution, and in severe cases where the employee has also not disclosed foreign support to the recipient organization, he/she has been fired.

ii. Peer Review

Peer review is a cornerstone of NIH activities and fundamental to scientific enterprises and advances. NIH receives about 81,000 applications a year. Approximately 78% of these applications are reviewed by Center for Scientific Review (CSR), and the rest are screened through reviews coordinated by the Institutes and Centers. CSR oversees over 200 study sections, 18,500 reviewers, and 1,600 annual review meetings, and employs nearly 250 scientific review officers. All reviewers are invited to serve at the discretion of the NIH. Service on peer review is viewed as an honor; it is not an entitlement.

When a violation of peer review is reported, CSR works with the Office of Extramural Research (OER) to follow up on allegations. Some cases are referred to the NIH Office of Management Assessment (OMA), which is independent of CSR and OER, to further investigate and issue reports with findings. To date, reactive actions against peer review violations have included removing the violator from serving on a peer review committee, notifying the recipient organization (which may lead to personnel actions, depending on the policies of the employee's home recipient organization), disbanding/reconstituting review committees, and deferring and withdrawing applications of concern. In sufficiently egregious cases, NIH has

- canceled the results of a review meeting and convened an entirely new panel to review a slate of applications, and
- pursued government-wide suspension and debarment through the Health and Human Services [Office of the Inspector General](#), and criminal violations through referral to other federal agencies.

To proactively mitigate violations of peer review, CSR has conducted web-based orientations, in which integrity is discussed in depth, for incoming chairs. CSR and OER are initiating new training on review integrity for scientific review officers, study section chairs, and reviewers. They are also enhancing security measures for their information technology systems.

C. Recipient Organizations Processes and Considerations

The working group discussed the processes that the members' recipient organizations use to enact the NIH requirements for tracking FCOI. Each working group member indicated that his or her recipient organization has a centralized FCOI reporting processes. Recipient organization employees are required to disclose financial support, and the recipient organization is responsible for determining if the outside funding is in conflict with the NIH-funded research. Staff review FCOI reports, and if conflicts are reported or issues are raised by investigators, the FCOI is investigated and managed. The current systems, at least those that the group is aware of, rely on the honesty and integrity of investigators to be forthcoming in their disclosures.

The group raised the possibility that disclosure processes can be subject to unintentional inaccuracies. Memory plays a role in people's actions, and investigators may simply forget that certain information needs to be disclosed. They also may not personally define funding from foreign governments as a financial conflict, and therefore not disclose it to their home recipient organization as part of the FCOI process, or in the grant application as required by NIH (Appendix item 4).

Recipient organizations often have scientific misconduct or other similar policies to deal with fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. While withholding information about augmented support for certain projects, or access to additional resources such as a fully staffed laboratory at another institution or university, may be considered research misconduct at some recipient organizations, these policies vary greatly across recipient institutions. In the vast majority of places, research misconduct policies do not specifically address violations of peer review, conflicts of interest, or conflicts of commitment.

For example, Massachusetts Institute of Technology is committed to responsible and ethical conduct in the classroom, workplace and laboratory. This commitment is reflected in a series of robust policies¹³ that establish the expectations for the ethical behavior of its faculty, staff and students. These policies allow the Institute to take appropriate action against an individual who has failed to act in a responsible and ethical manner.

Designing, and then implementing, effective policies is challenging. Requirements and flexibilities vary from recipient organization to recipient organization, sometimes based on whether a recipient organization is funded privately or receives state funding. One requirement for designing a policy that is actionable and effective is that lawyers are involved in reviewing all sections of the policy as they are published for implementation.

Recommendations

NIH and recipient organizations should act on recommendations with care and consideration of the important relationships and collaborations with foreign scientists and organizations. Community engagement is critical to avoid disengaging foreign nationals, and NIH and recipient organizations should work together and with AAU, APLU, ACGE, AAMC, ACE and other prominent educational organizations on outreach regarding these matters.

The recommendations are options and opportunities that the working group members identified but realize that the extent to which they can be implemented (should they be accepted by the ACD and Dr. Collins) will vary across recipient organizations. Recipient organizations and NIH should work together to identify best practices to allow for variation in how these issues are addressed comprehensively and successfully, for example, through workshops around the country to share information.

With the importance of upholding relationships with foreign nationals in mind, the ACD working group makes several recommendations to the ACD, under the umbrella of three main themes:

¹³<http://conduct.mit.edu/>

- Communication and Awareness: Opportunities where existing procedures are in place but in need of education, clarification, or increased attentiveness
- Risk Mitigation: Opportunities for change or enhancement of existing tools that safeguard research integrity
- Monitoring, Actions, and Consequences: Opportunities for ongoing monitoring, verification, trust-building, and remediation

The working group includes a set of recommendations for NIH (or for NIH to lead), and a set of recommendations for recipient organizations to pursue.

Recommendations for NIH

Communication and Awareness

- NIH, in collaboration with other federal agencies and the national security community, should implement a broad education campaign to raise awareness about the need to disclose other support, international affiliations, international collaborations, and foreign financial interests
 - Help universities develop best practices for how to handle these challenges
- To avoid developing different guidance from different agencies, NIH should develop communications materials, additional training guidelines, policy updates, and changes to reporting requirements in collaboration with other U.S. government agencies, especially key funding agencies, to streamline and unify requests and requirements
- NIH should evaluate existing policies and forms and make explicit what must be reported as other support
 - Ensure that instructions are communicated to recipient organization support staff and investigators by adding specific instructions
 - For example, explicitly state in application instructions that applicants should specify foreign support, conflicts of commitment, and gifts
- If NIH and federal agencies, including OSSI and other security agencies, become aware of new threats or information, they should contact and work with recipient organizations to address concerns
- As a bridge to share information, NIH should foster trusted relationships with universities and organizations in foreign countries

Risk Mitigation

- NIH should update policy to require disclosure of foreign collaborations and affiliations. In particular, NIH should consider expanding its current regulatory approach concerning conflicts of interest to expressly account for interest in which no financial remuneration is indicated but which still clearly overlaps with the scope of the NIH award (e.g., conflicts of commitment)
- NIH should expand the scope of their conflict of interest and disclosure policies for grants to include not just key personnel, but also technical support staff, postdoctoral fellows, and graduate students who are working on the NIH-funded award

- NIH should collaborate with the Office of Research Integrity (ORI) or appropriate oversight authority to determine whether and to what extent material nondisclosures to the NIH regarding funding (and overlap in effort) should be considered as research misconduct under 42 DVF Part 93.100 *et seq.*¹⁴
- NIH should reexamine and perhaps clarify the ownership of NIH grant-funded research data, to make clear that these non-commercialized data, resources, and tools developed under an NIH grant are the property of the recipient organization and are to be shared among the scientific community subject to the oversight of the recipient organization, not the PI¹⁵
 - There are many controls frameworks, such as the controls within the National Institute of Standards and Technology (NIST) Special Publication 800-53 (rev. 4)¹⁶, that can be mapped directly to the research laboratory environment to reduce the risk of data misappropriation. NIH should consider, as a precondition to grant awards, requiring recipient organizations to provide independent certification of full adherence to and compliance with specific control and security frameworks, which would provide a higher degree of protection for the federal investment in research and discovery and would mitigate risks for intellectual property diversion.
- NIH should consider adding to grant terms and conditions a statement addressing nondisclosure of other financial support or affiliations and peer review violations
- To reduce peer review violation, NIH should:
 - Improve system controls at NIH
 - Limit reviewer access, for example, limit ability to download, print, or otherwise share materials to only the applications assigned to them – consider making the Internet Assisted Review (IAR) scoring process a truly closed ecosystem by mandating that all scoring and editing during the peer review process take place exclusively within the IAR, barring written approval from the SRO
 - Add a pop-up message with log-in reminding users that materials are confidential and that log-in can be tracked
 - NIH should notify the designated official at recipient organizations should promptly of any allegation of peer review violation and any resulting findings so that recipient organization can meaningfully assist the NIH with oversight and review of conflicts of interest in the peer review process
 - Make new training on review integrity for Scientific Review Officers, study section chairs, and reviewers available to recipient organizations as soon as possible

Consequences and Actions

- In cases where peer review is violated, NIH should:

¹⁴ *Should Failure to Disclose Significant Financial Conflicts of Interest Be Considered Research Misconduct?* JAMA, October 26, 2018; <https://jamanetwork.com/journals/jama/fullarticle/2712193>

¹⁵ [https://grants.nih.gov/grants/policy/nihgps/HTML5/section 8/8.2.1 rights in data publication and copyright ing .htm?Highlight=data](https://grants.nih.gov/grants/policy/nihgps/HTML5/section%208/8.2.1%20rights%20in%20data%20publication%20and%20copyright%20ing.htm?Highlight=data)

¹⁶ <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf>

- Determine extent of the compromise
 - For example, whether applications that were affected had pre-patent and pre-licensing-relevant information and whether the material could have been incorporated into unrelated grant or patent applications
- Determine under which circumstances applicants will be notified
- In cases where NIH identifies violations (e.g., not reporting foreign support or affiliations), they will alert the recipient organizations and work with them to rectify issues
 - NIH actions and resulting consequences are determined through communication with the recipient organization and depend on the extent of the violation
- When recipient organizations have multiple violations of peer review or investigators not reporting other support or affiliations, and are not receptive to adjudicating concerns regarding undue foreign influences, NIH should consider an institution-wide assessment of the recipient organization

Recommendations for Recipient Organizations

Communication and Awareness

Recipient organizations should consider acting on the following recommendations to the extent they are able:

- Recipient organizations should implement a broad education campaign to raise awareness about the need to disclose other foreign support and international collaborations as part of disclosure processes for NIH, and international affiliations, international collaborations, and financial interests to home recipient organization
 - Incorporate these messages into regular Responsible Conduct of Research training
 - Increase training and awareness for new faculty who are foreign nationals
 - Ask investigators to document in writing their conversations and decisions about what each student and post-doctoral fellow will take with them when they leave a laboratory
- As part of raising awareness and assessing risks, recipient organizations should consider educating leadership, officials, and investigators regarding the scientific topics that are more prone to interest by untoward actors.
 - Identify all key stakeholders (PDs/Pis, peer reviewers, visiting scientists and scholars, hosting and sponsoring faculty, laboratory administrators, and faculty administrative support) and tailor the communications plans accordingly
- Discuss how to safely host laboratory and VIP medical visits, which can be potential entry points for unwanted information gathering, especially if associated with suspicious activities like adding unrelated additional visitors with little advance
- Consider developing guidelines or considerations for securely hosting visiting scholars or students
 - Recipient organizations should also encourage additional vetting or discussions regarding project ownership and appropriate data exchange

- For all international travel to selected countries, recipient organizations should consider initiating broadly pre-travel ‘safety briefings’ to educate investigators and encourage precautions

Risk Mitigation

- Recipient organizations should consider assessing the physical, technical, and administrative controls frameworks they employ that host foreign scientists for the risk of data misappropriation and exfiltration. This would include:
 - Examine the robustness of internal processes to identify potential breaches
 - Initiate or amplify cybersecurity approaches that may identify possible data breaches or inappropriate use of authorization credentials to access systems, or inappropriate sharing of information
 - Evaluate and implement mechanisms for identifying and verifying financial support, for example, using ORCID number to disambiguate individuals, or asking companies for lists of researchers working in foreign universities with company support
 - Have other support/foreign support and cybersecurity monitoring reported and tracked centrally (e.g., Office of Sponsored Research) using a single, accessible database
- Consider suggesting that faculty or staff traveling to certain regions to use loaner computers and electronic equipment
- Prior to hiring potential foreign employees, recipient organizations should consider vetting through unclassified searches, reviewing any agreements they have with businesses, organizations, and institutions; checking their FCOI and conflicts of commitment
- Consider adding to existing scientific misconduct or other similar policies:
 - That employees must disclose other funding support (i.e., financial conflicts)
 - That employees must disclose positions and affiliations at other universities or institutions (i.e., conflicts of commitment)
 - Language explicitly addressing the need to uphold peer review integrity and consequences of violations of NIH peer review
- Ensure that newly amended policies are actionable and commit to enforcing them
 - Develop review and adjudication processes that are appropriate for examining potential misconduct related to foreign influences
 - Include conflicts of commitment in FCOI policy and processes
 - Implement systematic audits to ensure FCOIs and conflicting commitments are accurately reported
 - The reporting system through which recipient organizations implement these audits may vary (for example, may be conflict of interest annual reporting system for all employees, or FCOI system put in place for NIH grantee reporting specifically)
 - May be random checks or initiated by ‘flags’ (see below), or a combination of both approaches
- Always proactively notify NIH about peer review violations and inaccurate or undisclosed foreign support or affiliations with outside organization

Ongoing Monitoring

- Recipient organizations should consider working with their professional organizations (APLU, AAU, etc.) to obtain guidance for developing processes for ongoing monitoring that are consistent with the risks associated with the research on the campus
- Consider developing a list of ‘flags’ that may trigger a recipient organization to conduct an audit, particularly if inconsistent with funding
 - Parameters may include: frequent foreign travel; lab resources inconsistent with funding; unexpected or inappropriate assets; personnel count disproportionate to funding; publishing frequently with collaborators outside the U.S., especially if no other authors are from the home recipient organization
 - If ‘flag’ is raised, consider unclassified searches, including viewing public posts
- Consider initiating post-travel follow-up questionnaires for research-related trips to select countries
 - Track at the department level international travel that triggers questionnaire completion
- Work with OSSI and other security agencies to gather lessons learned and best practices for identifying potential threats. Through this collaboration, recipient organizations may also receive guidance regarding access to unclassified databases used by the FBI and the federal Office of Personnel Management

APPENDIX

Charge to the group

The working group is charged to:

- identify the best approaches for NIH and Universities, Research Institutions, and other Applicant Organizations, to partner to ensure that all sources of research support and all relevant affiliations and financial interests are accurately reported to the NIH
- propose best approaches to facilitate appropriate collaboration with scientists across the globe, while helping to safeguard intellectual property in NIH applications or developed in whole, or in part, with support from the U.S. government
- propose additional steps that NIH might employ to protect the integrity of the peer review process
- carry out these actions in a way that reflects the long tradition of partnership between NIH and grantee institutions, and that emphasizes the compelling value of ongoing honorable participation by foreign nationals in the American scientific enterprise



August 20, 2018

Dear Colleagues:

For many decades, the National Institutes of Health (NIH) and institutions like yours have participated in productive partnerships that greatly advance biomedical science. Scientists at universities and academic medical centers, supported by NIH, have made seminal biomedical discoveries that have led to dramatic improvements in human health. The scientists whose work NIH is proud to help support come from all over this country and the world, bringing rich, diverse perspectives and backgrounds to the biomedical research enterprise.

The NIH-funded biomedical enterprise depends on a competitive system, which, to be successful, must be fair, transparent, and trustworthy.

Unfortunately, threats to the integrity of U.S. biomedical research exist. NIH is aware that some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers and to take advantage of the long tradition of trust, fairness, and excellence of NIH-supported research activities. This kind of inappropriate influence is not limited to biomedical research; it has been a significant issue for defense and energy research for some time. Three areas of concern have emerged:

1. Diversion of intellectual property (IP) in grant applications or produced by NIH-supported biomedical research to other entities, including other countries;
2. Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and
3. Failure by some researchers working at NIH-funded institutions in the U.S. to disclose substantial resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds.

NIH is working with other government agencies and the broader biomedical research community, including NIH-funded institutions and U.S. university professional organizations, to identify steps that can help mitigate these unacceptable breaches of trust and confidentiality that undermine the integrity of U.S. biomedical research.

These efforts will be supported by a working group of the Advisory Committee to the (NIH) Director that will tap experts in academic research and security to develop robust methods to:

1. Improve accurate reporting of all sources of research support, financial interests, and relevant affiliations;

2. Mitigate the risk to IP security while continuing NIH's long tradition of collaborations with foreign scientists and institutions; and
3. Explore additional steps to protect the integrity of peer review.

Concurrent with these efforts, we are using this opportunity to reach out to you for your help. We recently reminded the community¹ that applicants and awardees must disclose all forms of other support and financial interests, including support coming from foreign governments or other foreign entities. We therefore expect you to work with your faculty and with your administrative staff to make sure that, in accordance with the NIH Grants Policy Statement,² all applications and progress reports include all sources of research support, financial interests, and relevant affiliations.

In addition, in the weeks and months ahead you may be hearing from our Office of Extramural Research (OER) regarding grant administration or oversight questions or requests about specific applications, progress reports, policies, or personnel from, or affecting, your institution. We also expect and encourage your institution to notify us immediately upon identifying new information that affects your institution's applications or awards. Lastly, we encourage you to reach out to an FBI field office to schedule a briefing on this matter. We greatly appreciate your willingness to work closely with OER to address these ongoing concerns.

We thank you in advance for working with us on this serious matter. Should you have questions, please send them to grantsinfo@od.nih.gov.

Sincerely yours,



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

¹ NOT-OD-18-160, Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html>)

² <https://grants.nih.gov/policy/nihgps/index.htm>

OER Other Support Page

Resource: NIH Office of Extramural Research website

Title: About Grants, Other Support

URL: <https://grants.nih.gov/grants/forms/othersupport.htm>

Other Support

Note: the terms “current and pending support,” “other support,” and “active and pending support” are used interchangeably.

Information on Other Support is required for all applications that are to receive grant awards, except Program Directors, training faculty and other individuals involved in the oversight of training grants.

Information on Other Support is also required in the progress report for all senior/key personnel, excluding consultants, when there has been a change in active other support. Other Support is not required in progress reports for Program Directors, training faculty, and other individuals involved in the oversight of training grants.

Other 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/or institutional awards. Training awards, prizes, or gifts do not need to be included. Find instructions, blank format pages, and sample Other Support documents below.

There is no "form page" for reporting Other Support. Information on Other Support should be provided in the format indicated in the Other Support format page listed in the table below. Information collected includes: Project number, Contact Principal Investigator, source of support, title of project/subproject, dates of approved/proposed project and person months.

Form Name	Form Number	Description	How to Access	Instructions	Additional Information	Updated Date
Other Support Format Page (New and Renewal)		Information on Other Support is used for grant awards and	Other Support format page	NIH Grants Policy Statement, Section 2.5.1: Just-	Sample Other Support - competing	July 2018

Form Name	Form Number	Description	How to Access	Instructions	Additional Information	Updated Date
Applications)		progress reports.		in-Time Procedures		
Other Support Format Page – (Progress Reports)		Information on Other Support is used for grant awards and progress reports.	Other Support format page	NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures	Sample Other Support – non-competing	July 2018

Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests

Resource: NIH Office of Extramural Research, Grants Guide

URL: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html>

Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests

Notice Number: NOT-OD-18-160

Key Dates

Release Date: March 30, 2018

Related Announcements

None

Issued by

National Institutes of Health ([NIH](#))

Purpose

The purpose of this Guide Notice is to remind the NIH extramural research community that the requirements of 42 CFR Part 50, Subpart F, Objectivity of Research, apply to each institution, domestic and foreign, that applies for or receives NIH research funding in the form of grants or cooperative agreements. The regulation, also known as the Financial Conflict of Interest (FCOI) regulation, applies to both prime and subrecipient institutions, domestic or foreign, and through implementation, to each Investigator who is planning to participate in, or is participating in, such research. These regulations do not, however, apply to Phase I Small Business Innovative Research and Small Business Technology Transfer applications or awards.

The purpose of the regulation is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research is free from bias resulting from Investigator financial conflicts of interest. Therefore, it is critical that there is a clear understanding of the applicability of these regulatory requirements. Equally important is that the regulation is a term and condition of all NIH grant and cooperative agreement awards, which means that compliance with the requirements is a condition of funding.

One such area of the FCOI regulation requiring clarity is Investigator disclosures with respect to foreign financial interests. The regulation refers to exclusions of Institutions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency when disclosing financial interests. However, these references refer to a U.S. Institution of higher education or a federal, state, or local government agency within the U.S. Therefore, Investigators, including subrecipient Investigators, must disclose all financial interests received from a foreign Institution of higher education or the

government of another country (which includes local, provincial, or equivalent governments of another country).

For further information about the Financial Conflict of Interest regulations, please see NIH's [Financial Conflict of Interest](#) website, which includes links to the full regulation and extensive FAQs as well as other resources.

Inquiries

Please direct all inquiries to:

Division of Grants Compliance and Oversight
Office of Policy for Extramural Research Administration, OER
Telephone: 301-435-0938
Email: FCOICompliance@mail.nih.gov