



# **NIH Inquiries into Foreign Affiliations, Research Support, and Award Components**

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# Agenda

- **Background**
- **Applicable Requirements**
- **Handling NIH Inquiries**

# Background

- In the past year, the National Institutes of Health (“**NIH**”) has partnered with the Federal Bureau of Investigation (“**FBI**”) to investigate possible foreign interference with the integrity of federally-funded biomedical research.
  - NIH Director’s Advisory Committee has reviewed the situation and made recommendations to NIH.
    - Committee’s report includes actionable suggestions for institutions.
  - NIH has sent letters to specific institutional grant recipients inquiring into possible failures to disclose investigators’ foreign affiliations, foreign research support, and foreign components.
    - All NIH inquiries to date have, to our knowledge, **focused on support from Chinese governmental, academic, and foundation entities**, and have not yet expanded to possible failures to disclose funding originating from other foreign countries.

# NIH “Dear Colleagues” Letter – August 20, 2018



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

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;

Concurrent with these efforts, we are using this opportunity to reach out to you for your help. We recently reminded the community<sup>1</sup> 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,<sup>2</sup> 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](mailto:grantsinfo@od.nih.gov).

Sincerely yours,

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

# Advisory Committee Report on Foreign Influences on Research Integrity – December 13, 2018

## Foreign Influences on Research Integrity

117th Meeting of the Advisory Committee to the Director

*December 13, 2018*



Lawrence A. Tabak, DDS, PhD  
Principal Deputy Director, NIH

M. Roy Wilson, MD, MS  
President, Wayne State University

### Working Group Charge

- Identify approaches for NIH and applicant/grantee organizations to partner to ensure that research support, affiliations, and financial interests are accurately reported
- Propose 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 to protect the integrity of the peer review process
- Address the issue in ways that
  - Reflect tradition of partnership between NIH and grantee institutions
  - Emphasize the value of foreign nationals in the American scientific enterprise



# Advisory Committee Report on Foreign Influences on Research Integrity – December 13, 2018

- Advisory Committee Report specifically identifies **China's Talents Program**, for which there have been tens of thousands of recruits, many of whom also receive U.S. federal funding.
- Also notes that, while the current focus of concern is on China, the issue is **not unique to China**.

## Talents Recruitment



Tens of thousands of recruits<sup>1</sup>, including at least 6,000 top-tier recruits<sup>2</sup>

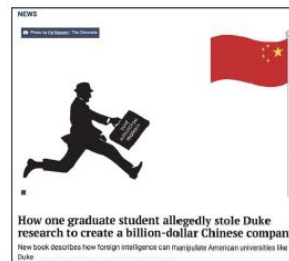
Key qualification:  
Access to intellectual property

Most recruits receive federal funding (NIH and other agencies)

1. 1000 Talents website: <http://www.1000plan.org/en/history.html>
2. China's Plan to Recruit Talented Researchers, Nature, 2018: <https://www.nature.com/articles/d41598-018-00538-g>

7

## The Talents Program



### Education or espionage? A Chinese student takes his homework home to China

Ruopeng Liu believes his work at a Duke lab was simply "fundamental research" that he brought back to China. His former professor thinks otherwise.

By CYNTHIA McFADDIN, ALLEN NAGS and Courtney MOSE / JUL 24, 2018 / 7:49 AM EDT

<https://www.duke.edu/news/2018/07/24/how-one-graduate-student-allegedly-stole-duke-research-to-create-a-billion-dollar-chinese-company>

8

## NIH considers restrictions to counter foreign influence in research

*An agency working group advises stronger security measures stigmatizing foreign researchers in the United States.*

Sara Reardon

Classified information provided to the agency by the FBI about such breaches “forced all of us who wanted not to believe this to have to take it seriously”, says Collins.

He adds that the NIH is currently investigating more than ten institutions that have failed to comply with disclosure rules. Collins hopes that the working group’s recommendations will help to prevent mistakes, although he acknowledges that the proposed measures won’t deter a determined government or criminal from stealing intellectual property.

# NIH Response to Judiciary Committee Chairman Charles Grassley – December 21, 2018

- Letter includes responses to various questions from the Judiciary Committee Chairman, including:

*What enforcement mechanisms are available to NIH to protect NIH-funded intellectual property and punish foreign agents for violating NIH policies and rules? Does NIH require additional authorities to effectively punish and deter wrongdoers? If so, what are they?*

. . . Depending on the severity and duration of the noncompliance, NIH may decide to take one or more actions, which are also described in the NIH GPS, Section 8.5, Specific Award Conditions and Remedies for Noncompliance, including **imposing specific award conditions, disallowing costs, withholding future awards for the project or program, suspending the award activities, making a referral for suspension or debarment, terminating the award, or revoking or taking title to the inventions** made with the Federal support and pursuing patent protection or licensing the invention itself. . .



# The New York Times – January 6, 2019

## *U.S. Officials Warn Health Researchers: China May Be Trying to Steal Your Data*



In other cases, scientists who received grants from the N.I.H. had shadow laboratories in China, which also received funds from the Chinese government. The foreign funding and affiliations were, in some cases, unknown to the National Institutes of Health and even to the American universities where the scientists worked.

The National Institutes of Health has a budget of \$44 billion, with \$4 out of every \$5 distributed to researchers around the world.  
Pablo Martinez Monsivais/Associated Press

By Robert Pear

# Summary

- NIH's concerns are **broader than disclosure failures**, and include:
  - Operating undisclosed “shadow labs” in foreign countries, creating plausible claim that work generating IP occurred outside the U.S.
  - Theft of biomedical IP from confidential grant applications under review by NIH or from research supported by NIH.
  - Breaking confidentiality of NIH peer review of grant applications to influence NIH award decisions.
- However, **disclosures are the area in which institutions' own obligations under federal funding requirements are most likely to be affected.**

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# PHS Conflict of Interest Regulations

- The Public Health Service (“**PHS**”), of which the NIH is part, has issued conflict of interest regulations requiring investigators engaged in PHS-supported research to disclose to their institutions all significant financial interests as well as reimbursed and sponsored travel:
  - “Each institution shall . . . require that each Investigator who is planning to participate in the PHS-funded research **disclose to the Institution's designated official(s) the Investigator's significant financial interests** (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.” 42 C.F.R. § 50.604(e).
  - “Investigators also must disclose **the occurrence of any reimbursed or sponsored travel** (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), **related to their institutional responsibilities.**” 42 C.F.R. § 50.603.

# PHS Conflict of Interest Regulations

- The PHS regulations exclude from the definition of a significant financial interest certain governmental and academic relationships:
  - “The term *significant financial interest* **does not include** the following types of financial interests . . . income from seminars, lectures, or teaching engagements **sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education**; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.” 42 C.F.R. § 50.603.



# NIH Guide Notice NOT-OD-18-160

- On March 30, 2018, the NIH released guidance clarifying that financial interests with ex-U.S. institutions and governments do not fall within the PHS regulations' disclosure exception:
  - “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).**” Guide Notice NOT-OD-18-160.

# NIH Grants Policy Statement – “Other Support”

- Additional, non-NIH sources of support for an NIH-approved project must be submitted to NIH for review to ensure there is no scientific, budgetary or commitment overlap:
  - **“Information on other active and pending support will be requested** as part of the Just-in-Time procedures. 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 are not included.”
  - **“Other support is requested for all individuals designated in an application** as senior/key personnel—those devoting measurable effort to a project.”

NIH GPS § 2.5.1.

# NIH Grants Policy Statement – Foreign Component

- NIH’s **prior approval must be obtained to add a “foreign component”** to a project supported by an NIH grant. See NIH GPS § 8.1.2.10.
  - NIH defines a foreign component as:

“The performance of **any significant scientific element or segment of a project outside of the United States**, either by the recipient or by a researcher employed by a foreign organization, **whether or not grant funds are expended.**”

*(continued, next slide)*

# NIH Grants Policy Statement – Foreign Component

*(continued)*

- **“Activities that would meet [NIH’s definition of a foreign component]** include, but are not limited to:
  - (1) the involvement of human subjects or animals,
  - (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or
  - (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.

Examples of other grant-related activities that may be significant are:

- **Collaborations with investigators at a foreign site anticipated to result in coauthorship;**
- Use of facilities or instrumentation at a foreign site; or
- Receipt of financial support or resources from a foreign entity.

[However,] foreign travel for consultation is not considered a foreign component.” NIH GPS § 1.2.

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# NIH Inquiries

- NIH has identified potential deficiencies in institutions' reporting of investigators' interests to NIH by **reviewing investigators' publications in which there are disclosed both (1) NIH support and (2) foreign support, affiliations, or components**, such as:
  - Investigators' dual appointments with foreign universities or institutes.
  - Foreign grant support.
  - Foreign components of supported projects (such as many foreign co-authors listed on publications of research supported by NIH).
- NIH has written letters to institutions, describing the potential reporting failures.

# NIH Inquiries

- These letters request that the recipient institutions:
  - **Review the potential issues** flagged by NIH to determine whether investigators disclosed the relationships to the institution.
  - **Respond with a description of any identified non-compliance and corrective actions taken.**
- Institutions receiving such NIH letters must engage in substantial fact-finding investigations in order to respond to NIH's inquiry.

# Institutional Investigations

- Institutions may find that:
  - Investigators **did not understand the need to disclose to the institution:**
    - Foreign sources of support for research that did not have direct scientific overlap with their U.S.-based research.
    - Foreign institutions' sponsorship of the investigators' travel expenses or per diem expenses when visiting the foreign institutions.
    - Collaboration with foreign investigators on an NIH-grant funded research project resulting in the co-authorship (as this is considered a "foreign component").

# Institutional Investigations

(cont.)

- Investigators maintained concurrent laboratories abroad and in the U.S.
- Staff from a foreign laboratory, paid by the foreign institution, work as unpaid volunteers in the U.S. laboratory.
- Investigators hold an academic appointment in a foreign country.
- Investigators have not understood legal restrictions on export controls.

# Institutional Investigations

(cont.)

- Investigators have **“over-disclosed” support of NIH and foreign institutions in publications**, resulting in “false positives” identified by NIH.
  - This may be an effort to comply with many publications’ broad standards for disclosure of financial interests.
  - For example, investigators may disclose all sources of support to their laboratory, even though it was not direct support for the project that led to the publication.



# What May be on the Horizon?

- NIH may:
  - Initiate **additional inquiries**, working in conjunction with the FBI.
    - When an institution has multiple apparent violations and is not receptive to NIH's concerns, it **may face an institution-wide assessment by NIH.**
  - Expand its **disclosure requirements**, including to cover instances in which investigators have no financial remuneration from a foreign source, but have a foreign collaboration that overlaps with the scope of the NIH award.
  - Define material non-disclosures as **research misconduct.**

See NIH Advisory Committee, Foreign Influences on Research Integrity (Dec. 13, 2018).

# What May be on the Horizon?

- NIH encourages institutions to:
  - Notify NIH of newly discovered information affecting an award.
  - Schedule a briefing to cover current areas of concern with the local FBI office.

# What May be on the Horizon?

- The NIH Advisory Committee notes that institutions can:
  - Conduct an **education campaign** to raise awareness of disclosure requirements and topics of scientific interest to untoward actors.
  - Develop processes for **securely hosting foreign visitors** to laboratories while avoiding unwanted information gathering.
  - Provide scientists with **“pre-travel” briefings**.
  - Review robustness of **scientific data breach prevention and identification processes**.
  - **Revise scientific misconduct and other policies** to expressly address these new challenges.
  - Develop misconduct **review processes appropriate to foreign influence** issues.
  - Implement **vetting of potential employees** for potential conflicts of interest and commitment prior to hire.
  - Implement **systematic audits** to ensure accurate reporting of conflicts of interest and commitment.

See NIH Advisory Committee, Foreign Influences on Research Integrity (Dec. 13, 2018).

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**THANK YOU**