NIH Foreign Interference: General Principles, Case Studies, Publicly Available Information on Specific Cases, and Oversight Reports.

From the NIH Office of Extramural Research (OER)

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For detailed information see https://grants.nih.gov/policy/foreign-interference.htm.

General Principles

- American research is built on the bedrock principles of scientific excellence, unassailable integrity, and fair competition.
- The United States' innovation leadership is made possible because the overwhelming majority
 of researchers, whether U.S. or foreign-born, are honest contributors to the advancement of
 knowledge that benefits us all.
- The principles that have driven the U.S. Government and its global research partners for decades are openness, transparency, and reciprocal collaboration; these are essential for advancing the frontiers of knowledge.
- The U.S. Government must also ensure that taxpayer-funded research is conducted based on these principles to the benefit of the American people.
- Over the past few years, NIH and other government agencies have been made aware of subversive efforts by foreign entities to target U.S. scientists – primarily but not exclusively of Chinese ethnicity – to intentionally violate the terms and conditions of grant awards for personal gain.
- These activities are the antithesis of collaboration.
- In August 2018, the NIH Director communicated his concerns about threats to the integrity of
 U.S. biomedical research in a <u>statement</u>, in <u>congressional testimony</u>, and in a letter to NIH
 grantee and applicant communities.
- The primary areas of concern are:
 - Failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments, during the grant application process, which threatens to distort funding decisions;
 - Diversion of intellectual property and pre-publication information in grant applications or produced by NIH-supported biomedical research to other entities, including other countries; and
 - 3) Sharing of confidential information by peer reviewers with others, including in some instances with foreign entities, or otherwise attempting to influence funding decisions.
 - 4) Repeated dishonesty when answering questions posed by the NIH and by institutional officials about outside activities and financial interests.
- NIH identifies these potential violations through:
 - 1) Notification by the FBI;
 - 2) Notification by an NIH-funded institution or an anonymous tip;
 - 3) Identification by NIH program staff during annual review of award progress and publications resulting from the award that specifies funding or affiliations with outside organizations that were not disclosed in grant documents as required.
- When NIH identifies potential threats, we notify our grantee institutions and ask them to
 investigate to ensure they are complying with the terms and conditions of the NIH grant award.
 The grantee institutions work with NIH, and potentially other government agencies such as the
 FBI and the HHS Office of the Inspector General, to remediate confirmed violations.
- NIH has been communicating extensively about these threats through public statements, Congressional hearings, education with NIH grantee institutions, and collaboration and coordination with federal agencies and scientific professional societies.
- We are pleased that these efforts have increased awareness of NIH awardee institutions, many
 of which have proactively initiated reviews to ensure compliance with NIH terms and conditions
 of awards.

Case Studies

See https://grants.nih.gov/policy/foreign-interference/about-foreign-interference for descriptions of scenarios. See https://grants.nih.gov/policy/foreign-interference/handling-allegations for a detailed description of how we handle allegations. For general information, see also https://grants.nih.gov/policy/foreign-interference.htm.

The scenarios below are based on over 150 real cases. Given the repetitive patterns we have seen, the scenarios below cannot be linked to any one individual.

Case 1: Duplicative Funding

- An NIH-funded scientist is employed by both
 - o an American medical school on a 12-month schedule, and
 - o a foreign university on a 6-month contract.
- The American medical school is unaware of the 6-month foreign contract.
- The foreign university contract includes >\$500,000 per year of funding support, along with provision of laboratory space, equipment, and trained staff. There is a personal signing bonus of \$150,000, a salary of >\$100,000 per year, a housing allowing of \$75,000, and covered travel.
- The scientist has told the American medical school that he is giving a few lectures at the foreign university, but nothing more. On his internal disclosure documents, he checks "No" when asked about outside research activities and outside employment.
- The scientist has a fully functioning lab in the foreign university.
- After receiving support for a project proposal on an NIH grant award, the scientist arranges for the same proposal to be translated into a foreign language and submitted to a foreign government funding agency through his foreign university employer.
- The foreign funding agency issues the award to the scientist through the foreign university.
- Six months later the scientist is asked on a standard NIH progress report, "Has there been any change in other research support for your individual research endeavors?" He answers, "No, NOTHING TO REPORT" a false statement.
- He translates the NIH progress report into a foreign language and submits it to the foreign funding agency as evidence of progress in his foreign university laboratory.
- When the American medical school learned of these previously undisclosed activities, it
 - o took an employment action, and
 - o refunded the NIH >\$1 million for duplicative funding.

Case 2: Undisclosed Financial Conflict of Interest

- An NIH-funded scientist is employed by an American medical school on a 12-month schedule.
- He owns majority equity interest in a foreign company valued at \$20 million. The company is receiving patents and selling products derived from his American NIH-funded research.
- The American medical school is unaware of the scientist's equity interest in the foreign company.
- On annual internal disclosure form, he checks "No" when asked about significant financial interests a false statement.
- On NIH grants, his institution declares that there are no financial conflicts of interest to disclose or manage.
- When the American medical school learned of these previously undisclosed financial interests, it took an employment action.

Case 3: Dishonesty After-the-Fact

- An NIH-funded scientist is employed by
 - An American medical school on a 12-month schedule
 - o A foreign university on a full-time "Talents" contract
- The American medical school had a long-standing rule that any outside employment or outside research support must be pre-approved by a high-level institutional official.
- The Talents award contract include \$1,000,000 start-up funds followed by \$250,000 of research
 funds per year, along with laboratory space, equipment, and trained staff. There is a personal
 signing bonus of \$150,000, a salary of >\$100,000 per year, a housing allowing of \$75,000, and
 covered travel.
- The Talents award contract requires the scientist to apply for additional funds from a foreign science funding agency through his foreign employer. The scientist successfully applies for several grants, stating that he will commit 9 calendar months per year to work on those foreign grants. He is already committed for 6 months on NIH grants.
- The scientist acknowledges support from the foreign grants on his publications, in which he identifies the foreign university as his primary affiliation.
- The American medical school is unaware of the full-time foreign Talents contract and the foreign grants.
- NIH learns of the Talents awards and asks the American medical school for information to assess possible scientific, budgetary, commitment overlap, and/or financial conflict of interest.
- The American medical school asks the scientist about these activities, and he categorically denies any foreign employment or grant support. He says that the Talents award is "just an honor, nothing more." He says that any foreign grants were written by others without his permission.
- The American medical school discovers
 - Signed Talents application
 - Talents shortlisting notification
 - Signed Talents contract which includes financial support for research
 - Signed foreign university contract
 - Funded foreign grants, along with correspondence indicating that the scientist played an active role in writing the proposals
- When confronted, the scientist continued to deny any foreign activities other than the "honor."
- The American medical school took an employment action.

Case 4: Overcommitment and Dishonesty After-the-Fact

- NIH-funded scientist is employed by both
 - An American medical school on a 12-month schedule, and
 - A foreign university on a full-time contract
- His American medical school is unaware of the full-time foreign contract.
- Through his foreign affiliation, the scientist has been supported on 5 foreign grants over the past 7 years; at least 2 foreign grant awards are active. None of the foreign grants have been mentioned in any NIH grant document.
- The scientist cites the foreign grants as sources of support in multiple publications.
- NIH contacts the American medical school, asking about the undisclosed foreign grants.
- The American Medical School states that the scientist denies receiving any foreign funds.
- When the NIH pushes back, the American Medical School locates several foreign grant applications which clearly identify the scientist as the PI. Furthermore, foreign web sites, along with publications, identify the foreign grants as linked to the PI.
- The scientist now claims that the apparent link between him and the foreign grants is because he allowed his name to be used as PI in order to help a former student now based in the foreign country. The scientist claims he never even read the grant (the grant in which he is designated as PI).
- Upon further investigation, the American Medical School determines that the PI in fact played a
 major role in writing the grant and in overseeing the work supported by the grant at the foreign
 university. The American Medical School found that he spent an inordinate amount of time
 away from campus, far more than allowed under outside activity rules.
- The American medical school
 - Took employment actions
 - Refunded the NIH for time spent charging for salary when the scientist was based at his foreign employer

Publicly available detailed information on specific cases:

- H. Lee Moffitt Cancer Center (Sheng Wei, Howard McLeod, Alan List, Tom Sellers, Dan Sullivan, Perlie K. Epling-Burnette): https://npr-brightspot.s3.amazonaws.com/legacy/sites/wusf/files/202002/MoffittAbstractFinal.pdf
- Harvard University (Charles Lieber): https://www.justice.gov/usao-ma/pr/harvard-university-professor-convicted-making-false-statements-and-tax-offenses
- Ohio State University (Song Guo Zheng): https://www.justice.gov/opa/pr/university-researcher-sentenced-prison-lying-grant-applications-develop-scientific-expertise
- Emory University (XJ Li): https://www.justice.gov/opa/pr/former-emory-university-professor-and-chinese-thousand-talents-participant-convicted-and
- Augusta University (Joe Tsien): https://www.propublica.org/article/a-visionary-without-a-country
- University of California at San Diego (Kang Zhang): https://inewsource.org/2019/07/06/thousand-talents-program-china-fbi-kang-zhang-ucsd/
- Van Andel Research Institute ("Professor 1" and "VARI Professor"):
 - https://www.justice.gov/usaowdmi/pr/2021 0901 Van Andel Research Institute Settlement
 - o https://www.justice.gov/usao-wdmi/pr/2019_1219_VARI

Oversight Reports (pertinent recommendations)

NIH Advisory Committee to the Director:

- Report on Foreign Influences on Research Integrity (December 2018)
 - Recommendation: "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 though communication with the recipient organization and depend on the extent of the violation."

United States Senate

- Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs <u>Bipartisan Report</u> on Threats to the US Research Enterprise: China's Talent Recruitment Plans (November 2019)
 - Main finding: "Based on this investigation, the Subcommittee finds that the federal government has failed to stop China from acquiring knowledge and intellectual property from U.S. taxpayer funded researchers and scientists. Nor do federal agencies have a comprehensive strategy to combat this threat."
 - Recommendation: "U.S. grant-making agencies should implement a compliance and auditing program to ensure grantees accurately report conflicts of interest and conflicts of commitment. Congress should provide adequate resources to support agency compliance programs and inspectors general."
 - Note that in FY2022 and FY2023 Congress appropriated \$2.5 million to the NIH
 Office of Extramural Research (OER) to address foreign interference concerns.

Government Accountability Office (GAO):

- GAO-21-130: Federal Research: Agencies Need to Enhance Policies to Address Foreign Influence (December 2020)
 - Recommendation for NIH: "The Secretary of Health and Human Services should instruct
 the Director of the National Institutes of Health to update the agency's conflict of
 interest policy to include a definition on non-financial conflicts, such as the one
 developed by OSTP, and address these conflicts, both foreign and domestic."
- GAO-21-523T: Federal Research: NIH Should Take Further Action to Address Foreign Influence (April 2021)
 - o Follow-up to GAO-21-130
- GAO-22-105434: Federal Research: Agency Actions Needed to Address Foreign Influence (October 2021)
 - o Follow-up to GAO-21-130

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- GAO-23-106114: China: Efforts Underway to Address Technology Transfer Risk at U.S.
 Universities, but ICE Could Improve Related Data (November 2022)
 - o Finding: "U.S. agencies that fund research increased investigations of researchers for fraud and failures to disclose potential sources of foreign influence, according to agency data. These investigations have resulted in the removal of individuals from research positions because of undisclosed affiliations, such as receiving funding from a PRC-affiliated institution. While agency officials acknowledged concerns related to racial bias in their investigations involving China, they emphasized that no decisions are based on individual characteristics such as nationality or visa status."
 - Recommendations for NIH: None

Office of the Inspector General (OIG):

- OEI-03-20-00210: Opportunities Exist to Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interests and Other Support (June 2022)
 - equirements to train investigators regarding disclosure of significant financial interests; (2) ensure that grantees conduct the required review of investigators' significant financial interests to determine whether conflicts exist; (3) specifically require grantees to provide trainings and to maintain a written policy regarding investigators' disclosure of other support; (4) modify its reporting mechanisms to require grantees to report whether investigators' significant financial interests and other support involve foreign entities; (5) conduct outreach to grantees with R13 conference grants to clarify requirements regarding the disclosure and review of investigators' significant financial interests and other support; (6) clarify whether and how grantees should verify investigators' significant financial interests and other support prior to submitting information to NIH; and (7) establish a method for grantees to share their best practices for identifying and reviewing investigators' foreign significant financial interests and other support."