

Foreign Influence Lessons From Research Org FCA Deal

By John Richter, Mark Polston, Beverly Lorell, Edmund Power, Sumon Dantiki and Zachary Harmon

(March 3, 2020, 4:36 PM EST) -- The U.S. Department of Justice recently announced that it reached a \$5.5 million settlement with the Van Andel Research Institute, a biomedical research institute that received National Institutes of Health grant funding, to resolve allegations that it violated the False Claims Act by failing to disclose Chinese government grants that funded two research scientists.

In a press release[1] the U.S. attorney for the Western District of Michigan stated:

It's unfair to other grant applicants and to the NIH for any institution to withhold requested information about whether the research that an institution wants the NIH to support may be getting funding from outside sources, specifically including foreign governments.

Beginning in 2018, the NIH has warned thousands of grantee institutions and initiated investigations into at least 180 individual scientists as well as dozens of institutions regarding potential failure to disclose outside funding, including funding from foreign entities. This settlement signals an escalation of the use of federal enforcement tools — in particular the federal FCA — to pursue issues of undue foreign influence in a research institution's oversight of NIH-funded grants and the scientists conducting the research.

The FCA empowers the federal government to pursue treble damages against parties that submit false claims to the government or make false statements that lead to the submission of false claims.[2] The federal government has now signaled its intention to pursue this FCA remedy to recover grant funding and a multiplier of damages for failure to disclose foreign research funding during the NIH grant or renewal process.

The government's announcement also highlights the need for increased proactive vigilance by grantee institutions in ensuring timely and truthful required disclosures to NIH as well as readiness for responses to federal inquiries and enforcement actions.



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Background

This DOJ action occurred in the broader context of increased concern by federal security authorities about undue foreign influence in federally regulated research, including state-sponsored theft of research data and technology as well as hidden financing and inducements to key personnel involved in the research.

A coordinated federal effort has been led by the Federal Bureau of Investigation and the National Security Division of the DOJ in coordination with the NIH and U.S. Department of Health and Human Services, the Office of the Director of National Intelligence, the U.S. Department of Education, the U.S. Department of Energy, and other federal departments and agencies.

Since 2018, in collaboration with other federal authorities, the NIH has progressively escalated its actions to identify and mitigate foreign influence in NIH-funded extramural research.

August 2018

NIH Director Francis S. Collins issued a statement[3] and letter[4] to over 10,000 grantee institutions that identified the threat of active systematic programs mounted by foreign entities to influence NIH research including: (1) diversion of intellectual property in grant applications or produced by NIH-supported research; (2) disclosure of confidential information by NIH peer reviewers to foreign entities during the grant application peer review process; and (3) failure by researchers at NIH-funded U.S. institutions to disclose substantial financial resources from foreign governments.

The NIH advised that institutions may be contacted by the NIH Office of Extramural Research regarding questions or requests related to these issues and encouraged institutions to “reach out to an FBI field office to schedule a briefing” on the matter. The director also established an NIH Advisory Committee to the Director regarding foreign influences on research integrity.

July 2019

The NIH released a formal notice[5] that underscored that the NIH Grants Policy Statement[6] requires applicants and awardees to disclose all financial conflicts of interest pursuant to Title 42 of Code of Federal Regulations Part 50, Subpart F and other support available to the researcher, including foreign support and affiliations even in the absence of monetary value; in addition, foreign components disclosures must be submitted and approved by the NIH.

Concurrently, Michael S. Lauer, the NIH Deputy Director for Extramural Research, issued a statement[7] which emphasized that depending on the severity and duration of noncompliance, it has the authority to disallow award costs, withhold future awards, suspend the award activities, terminate the award or make a referral for investigator suspension or debarment.



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The NIH disclosed[8] that it has investigated at least 180 scientists at more than 65 institutions for violating policies requiring grantees to report their foreign ties, and that it referred 21 cases to the HHS Office of the Inspector General for debarment and referred additional cases for potential prosecution. The disclosure emphasized that the NIH is working closely with the FBI and DOJ, as well as the U.S. Department of Homeland Security, to conduct investigations into foreign influence on extramural research.

December 2019

The NIH presented an update[9] on foreign influence in research integrity that, while acknowledging the important role of international collaboration in biomedical research, highlighted the findings of the Senate investigation[10] regarding the Chinese government's Thousand Talent Plan to obtain confidential research information, set up shadow labs in China and use legally binding contracts between U.S. researchers and Chinese institutions to incentivize the transfer of U.S. intellectual capital.

The NIH continues to issue written inquiry letters to NIH grantee institutions that require accurate responses to specific questions regarding potential foreign influence. In some cases, based on referrals from the HHS OIG, FBI agents are contacting the institution's NIH grant officials and researchers to request interviews as well as conducting formal investigations.

These actions have had significant consequences and led to multiple researchers resigning or being terminated by their institutions due to allegations of accepting funding from the Chinese government in violation of NIH policy.[11]

Insights From the DOJ FCA Settlement

According to the DOJ press release, VARI was the grantee institution for two researcher scientists that received NIH grant awards. In the grant submissions and during the period of the grant award, the institution allegedly failed to disclose foreign research funding of the researchers, including failure to disclose foreign components as mandated by NIH requirements.

The DOJ alleged that both researchers received research funding from Chinese sources during the period between 2012 and 2018, including support from the Chinese government's Thousand Talents Program. The government claimed that the institution received specific information about the researchers' Chinese affiliations and support.

For example, VARI was alleged to have received a letter from a Chinese institution indicating that one of the researchers received support from the Thousand Talents Program and held a directorship at a Chinese research institution. Further, VARI was alleged to have continued to fail to disclose the Chinese support despite receiving the NIH's August 2018 letter reminding grantee institutions to disclose support "coming from foreign governments or other foreign entities," as well as a direct communication from NIH citing specific concerns about potential nondisclosures. The case was settled without admission of liability by VARI.

The DOJ's press release outlined its concerns in this area:

- Responsibility of the grantee institution — The DOJ underscored that the grantee institution is obliged to ensure that required NIH disclosures for researchers, including foreign components disclosures, are submitted to the NIH.

- Failure to investigate and report to NIH after becoming aware of potential illegal foreign support of the researchers — Upon learning of potential Chinese grant support, the grantee institution not only failed to confirm and report to the NIH but also proactively removed public references to the foreign support.
- Continued failure to investigate and report even after receiving a direct inquiry from the NIH — The grantee institution continued to fail to investigate and make disclosures even after receiving a direct inquiry from the NIH citing specific concerns about potential nondisclosures.

In the press release, the U.S. attorney emphasized that grantee institutions, which are concerned about a prior statement on a grant application, should be aware that entities that make “proactive, timely, and voluntary self-disclosures” receive credit during the resolution of a False Claims Act case.

Recent Criminal Charges

Grantee institutions should also be aware that the DOJ has also increasingly used criminal charges in cases involving alleged undue foreign influence in research institutions.

For instance, in January, the DOJ issued a press release^[12] announcing that it had criminally charged professor Charles Lieber, chair of Harvard University’s chemistry and chemical biology department, for making materially false statements. Specifically, the DOJ alleged that Lieber, who had received over \$15 million in NIH and U.S. Department of Defense grants, had failed to disclose and lied about his contractual involvement in China’s Thousand Talents Plan, causing Harvard to make false statements to the NIH.

Key Takeaways

This recent DOJ FCA settlement highlights the ongoing cooperation among the HHS OIG, the FBI and the DOJ in investigating potential undue foreign influence in NIH-funded research. It also emphasizes the importance of grantee institutions ensuring full awareness of and compliance with the NIH requirements for truthful and accurate submissions of financial conflicts of interest, other support and foreign components disclosures in grant submissions and during the award period.

Enforcement based on an FCA investigation, accompanied by a settlement with a substantial financial penalty (a multiplier of the government’s damages, which may be the entire amount of grant funding), is a signal that federal authorities are now willing to aggressively use an additional tool in the government’s enforcement toolbox beyond more customary responses for noncompliance with NIH requirements, such as suspension or termination of an NIH grant.

This settlement illustrates that NIH grantee institutions have been put on notice of their compliance obligations with respect to foreign influence disclosure obligations. Institutions face heightened risk for referrals to HHS OIG, the FBI or other entities for the initiation of investigations and potential prosecution if the institution becomes aware of a potential failure to make a required disclosure to the NIH and fails to act.

Notably, the DOJ alleges that VARI made factual representations to the NIH “with deliberate ignorance or reckless disregard for the truth regarding the Chinese grants.” HHS OIG, which initially investigated these allegations, emphasized that it “will continue to investigate allegations of failures to properly report information to ensure the integrity of Departmental programs.”

In response to the escalating attention and enforcement activity related to potential undue foreign influence in NIH-funded research, institutions should implement proactive policies and programs to

ensure that required disclosures are made in NIH grant submissions and during the grant award period.

Such proactive policies and compliance programs will need to be updated on a regular basis and accompanied by training of key personnel and procedures to document relevant efforts. In addition, institutions — and their researchers and employees — should ensure that they are prepared to respond appropriately to informal outreach by the FBI or DOJ as well as formal investigations.

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[1] Press release. Department of Justice, U.S. Attorney’s Office, Western District of Michigan. “Department of Justice Reaches \$5.5 Million Settlement With Van Andel Research Institute To Resolve Allegations Of Undisclosed Chinese Grants To Two Researchers.” December 19, 2019. https://www.justice.gov/usao-wdmi/pr/2019_1219_VARI.

[2] 31 U.S.C. §§ 3729et seq.

[3] “Statement on Protecting the Integrity of U.S. Biomedical Research.” August 23, 2018. Accessed at <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research>.

[4] “Dear Colleagues Letter” from Francis S. Collins. August 20, 2018. Accessed at https://www.insidehighered.com/sites/default/server_files/media/NIH%20Foreign%20Influence%20Letter%20to%20Grantees%2008-20-18.pdf.

[5] NIH Notice Number: NOT-OD-19-114. “Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components.” July 10, 2019. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html>.

[6] “NIH Grants Policy Statement. US Department of Health and Human Services. National Institutes of Health.” Version December 2019. Accessed at <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

[7] NIH Office of Extramural Research. “Clarifying Long-Standing NIH Policies on Disclosing Other Support.” July 11, 2019. Accessed at <https://nexus.od.nih.gov/all/2019/07/11/clarifying-long-standing-nih-policies-on-disclosing-other-support/>.

[8] NIH Record. “NIH Investigates Foreign Influence at U.S. Grantee Institutions.” October 4, 2019. Accessed at <https://nihrecord.nih.gov/2019/10/04/nih-investigates-foreign-influence-us-grantee-institutions>.

[9] “ACD Working Group on Foreign Influences on Research Integrity Updates.” December 13, 2019. Accessed at <https://www.acd.od.nih.gov/documents/presentations/12132019ForeignInfluences.pdf>.

[10] United States Senate. Permanent Subcommittee on Investigations. Committee on Homeland Security and Government Affairs. “Threats to the U.S. Research Enterprise: China’s Talent Recruitment

Plans. Staff Report.” Accessed at <https://www.hsgac.senate.gov/subcommittees/investigations/hearings/securing-the-us-research-enterprise-from-chinas-talent-recruitment-plans>.

[11] The New York Times. “Vast Dragnet Targets Theft of Biomedical Secrets for China.” November 4, 2019; Accessed at <https://www.nytimes.com/2019/11/04/health/china-nih-scientists.html>.

[12] Press release. Department of Justice, Office of Public Affairs. “Harvard University Professor and Two Chinese Nationals Charged in Three Separate China Related Cases. January 28, 2020. Accessed at <https://www.justice.gov/opa/pr/harvard-university-professor-and-two-chinese-nationals-charged-three-separate-china-related>.