

Monitoring Researchers' Foreign Affiliations: Staying Ahead of the Curve

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In the past couple of years, research funding agencies, enforcement agencies, and the media have increased their focus on the impact of undue foreign influence on federally funded research in the United States. In the last couple of years, the Department of Justice has reported several enforcement actions leading to arrests, convictions, and settlements with researchers who fail to disclose their foreign ties to the U.S. government in connection with federally received research grant money. Media stories regarding the firing and criminal investigations of researchers at reputable institutions like Harvard University and Emory University have been prolific.

In August 2018, the Director of the National Institutes of Health (NIH), Francis Collins, sent a letter to over 10,000 institutions warning them of foreign threats to U.S. biomedical research, including theft and diversion of intellectual property, unethical sharing of confidential information outside of the peer review process, and a failure to disclose foreign ties and support received by researchers.¹ In October 2019, the NIH reported that it had investigated at least 180 scientists at more than 65 institutions for violating policies requiring the reporting of foreign affiliations.² NIH identified more than 100 instances of foreign influence on extramural research, including a failure to report information about funding sources and conflicts of interests and violating the confidentiality of peer review.³ Out of those investigations, NIH referred 21 cases to the HHS Office of Inspector General (OIG) for debarment to prevent scientists from receiving federal grant money.⁴

In the months following the NIH's announcement regarding these investigations, news stories have consistently featured stories regarding arrests, criminal actions, and terminations of renowned scientists at reputable institutions. Several of these news stories focus on researchers' involvement with China's Thousand Talents Plan, a program created by the

central government of China to recruit top scientists to work at Chinese universities. The program has come under governmental scrutiny for rewarding individuals for stealing proprietary information. A number of recent news stories have highlighted researchers' failure to disclose their participation in China's Thousand Talents Plan and other foreign talents programs.

In January 2020, Dr. Charles Lieber, the Chair of the Department of Chemistry and Chemical Biology at Harvard University, was arrested and charged with one count of making a materially false, fictitious, and fraudulent statement for lying about his involvement in China's Thousand Talents Plan and role as a "Strategic Scientist" at Wuhan University of Technology (WUT) in China.⁵ Dr. Lieber received more than \$15 million in grant funding from the NIH and Department of Defense as the Principal Investigator of the Lieber Research Group at Harvard University.⁶ In connection with a three-year Thousand Talent contract, WUT paid Lieber \$50,000 U.S. dollars per month, as well as approximately \$158,000 in living expenses and awards totaling more than \$1.5 million to establish a research lab at WUT.⁷

In December 2019, six Florida researchers at the Moffitt Cancer Center were forced to resign after failing to disclose their ties to the Chinese Thousand Talents Program.⁸ The researchers included the center's chief executive and the head of its research center.⁹ In May 2019, Emory University dismissed two researchers receiving NIH funds that had failed to disclose funds they had received from Chinese sources.¹⁰ Emory University's investigation was prompted by the letter that NIH circulated to academic research institutions.

The government recently upped the ante in terms of consequences for research institutions with undisclosed financial ties. In December 2019, an independent research institute in Grand Rapids entered into a \$5.5 million settlement to resolve allegations that it violated the False

Claims Act for failing to disclose research grants from the Chinese government.¹¹ Van Andel Research Institute (VARI) is alleged to have received research funding for two of its researchers from Chinese sources, including China's Thousand Talents Program, while it was applying for NIH funds on their behalf.¹²

The government further alleged that VARI had policies and procedures in place to address conflicts of interest and had received specific information about its researchers' Chinese affiliations and support from the Chinese Thousand Talents Program.¹³ The government, however, claimed that VARI did not take adequate additional steps to investigate its researchers' foreign funding sources.¹⁴ VARI allegedly informed the NIH that it was not required to disclose information about one of its researcher's foreign grants because "there was no undisclosed overlap of any budgetary resources, commitment, or scientific endeavor" between the Chinese grants and the NIH grants.¹⁵ The government noted that NIH requires disclosure of all financial resources available in support of an individual's research activities.¹⁶

To date, only one government agency, namely the Department of Energy (DOE), has expressly prohibited recipients of its federal grants from participating in a talent program.¹⁷ Specifically, the DOE prohibited its employees, contractors, and grantees from participating in a foreign talent recruitment program, specifically with China, Russia, Iran, and/or North Korea.

As noted above, while the NIH has not prohibited participation in a foreign talent program, it requires disclosure of participation under such a program as part of the "other support" resources related to a research grant, as discussed further below.

NIH AWARD OBLIGATIONS

Researchers and research institutions receiving federal grant money from the NIH have a number of requirements they are obligated to comply with.

Managing Financial Conflicts of Interest

To receive federal funding from the NIH, researchers and institutions receiving Public Health Service grants or cooperative agreements must comply with the requirements of the Code of Federal Regulations (CFR), Title 42, Part 50, Subpart F—Promoting Objectivity in Research. Also known as the financial conflict of interest (FCOI) regulation, the FCOI regulation promotes “objectivity in research” by ensuring that the funding of its grants “will be free from bias resulting from Investigator financial conflicts of interest.”¹⁸

The regulations require researchers to disclose any significant conflict of interest related to an NIH-funded research project and could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.¹⁹ A “significant financial interest” includes any of the following interests of the investigator (and those of the investigator’s spouse and dependent children) that appear to be reasonably related to the investigator’s institutional responsibilities, including:

- remuneration where the value received from a publicly-traded or non-publicly traded entity exceeds \$5,000 over the course of 12 months; or
- income related to intellectual property rights and interests (*e.g.*, patents, copyrights).²⁰

Remuneration includes equity interests such as stock, stock options, or other ownership interests. For publicly traded entities, remuneration includes salary and payment for services not identified as salary, including consulting fees, honoraria, and paid authorships.²¹

The regulations also require institutions to:

- Inform their investigators of their conflict of interest policy;
- Train investigators on their conflict of interest policy at least every four years; and
- Post their conflict of interest policy on a publicly accessible Web site.²²

Beyond Financial Conflicts

In addition to FCOI reporting requirements, the NIH requires funding recipients to submit information regarding “other support” received by researchers as part of its Just-in-Time procedures for grant applications and in progress reports.²³ “Other support” is defined as including “all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant.”²⁴ Such resources must be reported by senior/key personnel involved in research, meaning “those devoting measurable effort to a project.”²⁵

Other support is further defined as “resources and/or financial support from all foreign and domestic entities, including but not limited to financial support for laboratory personnel, and provision of high-value materials that are not freely available (*e.g.*, biologics, chemical, model systems, technology, etc.).”²⁶ Training awards, prizes, or gifts are not included in the definition of other support.²⁷

FOCUS ON FOREIGN AFFILIATIONS AND FURTHER CLARIFICATION OF OTHER SUPPORT

In 2018, the NIH director published a “Statement on Protecting the Integrity of U.S. Biomedical Research,” noting, among other concerns, the “failure by some researchers at institutions funded by the NIH to disclose substantial contributions of resources from other organizations, including foreign governments.”²⁸ The statement also declares NIH’s intent to work with NIH-funded academic institutions to improve the accuracy of reporting of all sources of research support, financial interests, and affiliations.²⁹

In July 2019, the NIH issued guidance to “remind the extramural community

about the need to report foreign activities through documentation of other support, foreign components, and financial conflict of interest to prevent scientific, budgetary, or commitment overlap.”³⁰ As emphasized by Michael Lauer, NIH’s Deputy Director for Extramural Research, disclosure of such a report is “critical for prudent fiscal management, accountability, and stewardship of U.S. taxpayer funds.”³¹

Although the guidance indicates that reporting of “other support” has been a longstanding requirement, it also lists specific obligations that must be reported by senior/key personnel, as follows:

1. All domestic and foreign positions and scientific appointments relevant to the application, noting specifically academic, professional, or institutional appointments, as well as affiliations with foreign entities or governments, regardless of whether compensation is received;
2. Information on all resources and other support, regardless of whether compensation is received; the guidance specifies that support includes:
 - foreign financial support, selection to a foreign “talents” or similar-type program, or other foreign or domestic support, and
 - in-kind support such as research or laboratory personnel, lab or office space, scientific materials, equipment, supplies, and employees.³²

The guidance further reminds recipients of their obligation to report foreign components related to NIH-funded research where:

1. A portion of the project will be conducted outside of the United States, and
2. The activities represent a significant scientific element.³³

A series of frequently asked questions (FAQs) related to the guidance lists examples of foreign components that would be considered a significant element of the project as including:

- collaborations with investigators expected to result in co-authorship at a foreign site;
- the use of instrumentation or facilities at a foreign site; and/or
- financial support or resources from a foreign entity.³⁴

The FAQs also clarify that even where a researcher spends time outside of an appointment period conducting research under a foreign award, the work under the foreign award must be reported.³⁵

The guidance clarifies that even if all research is conducted within the United States, if there is a non-U.S. resource that supports the research, the researcher must report the resource as other support.³⁶

INTERNAL PROCESSES FOR MANAGING FOREIGN AFFILIATIONS

While an institution has an obligation to ensure that its researchers are reporting other support and foreign components as tied to its funding process, an increasing number of institutions are also taking measures to identify and manage foreign affiliations by tying the process to their own internal conflicts of interest processes and the implementation of other controls. The Association of American Universities and Council on Governmental Relations have both published guidance with suggested practices for institutions to proactively monitor and manage their researchers' foreign affiliations.³⁷

Both organizations recommend that research institutions implement certain steps to be able to identify, track, and manage their researchers' foreign affiliations and relationships. Some recommended processes include:

- *Conflict of Commitment Policy* - A conflict of commitment policy is designed to complement existing conflict of interest policies. The purpose of such a policy is to identify foreign affiliations and relationships and related financial interests that may present a conflict in regard to a

researcher's responsibilities to the institute or otherwise raise concerns.

- *COI Foreign Affiliations Questions* - Institutions may also wish to incorporate questions into their existing conflicts of interest processes, focused on disclosures related to financial affiliations, interests, and/or participation in a foreign talent program.
- *Agreement Protocols and Templates* - Institutions may consider developing building "caution points," including prompts for certain provisions within agreements that relate to grant terms and conditions, to ensure that contract negotiators and authors are aware of certain red flags related to foreign affiliations and financial interests.
- *Denied Party Screening* - Institutions may consider employing denied party screening techniques and tools for screening foreign sponsors and collaborators, including visitors, visiting scholars, and employees on non-immigrant visas, to identify any restricted or denied parties.
- *Mandatory Review* - Institutions may consider implementing a mandatory process for the disclosure, review, and prior approval of any pending academic appointments that their researchers have at other institutions.

CONCLUSION

As more and more news stories appear related to the investigations, arrests, and terminations of researchers with undisclosed financial ties, now more than ever it is important for organizations to have processes in place to screen their researchers' outside activities and affiliations. Undisclosed foreign ties can lead to loss of federal funding, reputational damage, and even False Claims Act violations. Institutions should take proactive steps to ensure that their researchers are informed about their reporting responsibilities and disclosure obligations and that they have appropriate processes to ensure that those

disclosures are being identified and managed internally.

Endnotes

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