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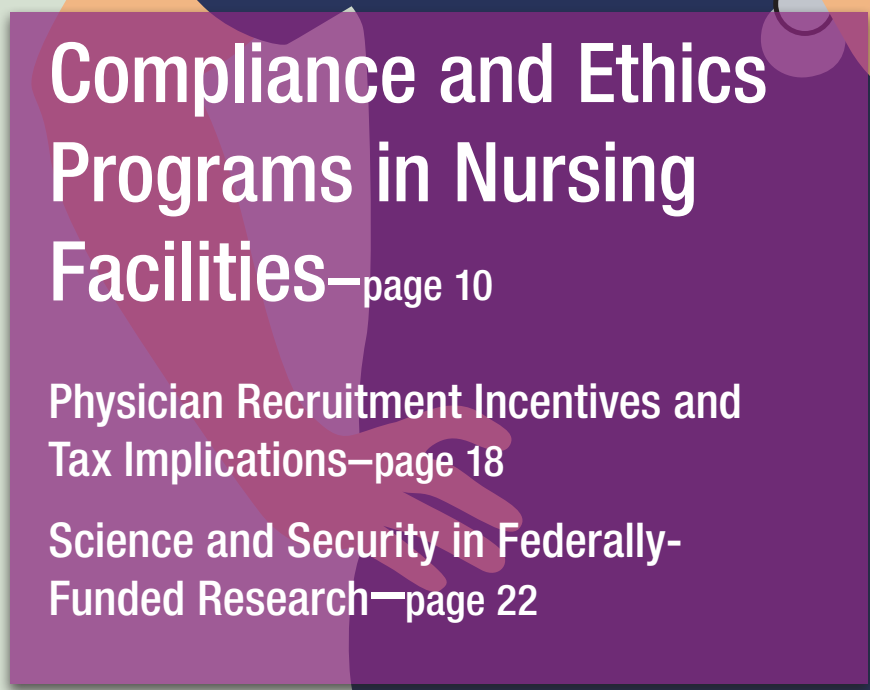
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# Science and Security in Federally-Funded Research

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In 2018, thousands of U.S. institutions received a letter from the National Institutes of Health (NIH) warning of inappropriate “foreign influence” in federally-funded research. NIH Director Dr. Francis S. Collins announced that the letters were a response to “systematic programs to influence NIH researchers” that had been undertaken by foreign entities, leading to “unacceptable breaches of trust.” Since then, the NIH has sent targeted inquiry letters asking institutions to investigate nearly 200 individual scientists and has referred at least 25 cases for further action by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) and the Department of Justice (DOJ).

The NIH inquiry letters are part of a broader governmental effort to address concerns that U.S. technology, basic and applied research, and intellectual property and capital held by U.S. universities and academic medical centers are exposed to efforts of appropriation undertaken by foreign governments, primarily the People’s Republic of China (PRC). Other federal research funders, including the National Science Foundation (NSF) and the Departments of Defense and Energy, are undertaking similar activities. DOJ has started bringing civil claims and criminal prosecutions of university researchers for allegedly failing to disclose completely or making false statements regarding their activities with PRC-based academic institutions.

On December 19, 2019, DOJ announced a False Claims Act (FCA) settlement with an NIH grantee, the Van Andel Research Institute, following allegations that two investigators had participated in China’s “Thousand Talents” program, a PRC government-backed effort to expand scientific knowledge in China, and received research funding without properly disclosing these affiliations and support to the NIH. As part of the settlement, Van Andel paid \$5.5 million.<sup>1</sup> The case is highly unusual—both because the FCA has been used rarely to address violations of NIH’s grant reporting requirements, and because DOJ expressly criticized Van Andel for failing to investigate the researchers’ activities adequately and mischaracterizing NIH grant requirements. In the government’s view, this episode is part of a broader effort by China to use “non-traditional collectors” to obtain scientific data and intellectual capital to promote China’s economic and national interests, at the expense of the United States.<sup>2</sup>

Government concerns about theft or intentional disclosure of U.S.-funded research and intellectual capital have focused, in large part, on U.S. researchers who have failed to disclose activities and affiliations with individuals, universities, or other entities in the PRC. Universities, academic medical centers, and their advocates are navigating a new landscape, in which some say that institutions are too lax in overseeing faculty activities,

while others charge xenophobia and discrimination in the face of government prosecutors and policymakers who may be bowing to political pressure.

Senator Charles Grassley, Chairman of the Senate Finance Committee, is among congressional leaders focused on risks arising from PRC affiliations. In addition to holding hearings and sending oversight letters to NIH, NSF, and the Department of Defense, he asked the Government Accountability Office to report on federal agency financial conflict of interest policies last June. His expressed motivation: “whether the U.S. public is realizing the full benefit of taxpayer-funded research given the implications of foreign-researcher engagement in federally-funded research.”<sup>3</sup> Senator Grassley wrote: “These issues are simply too important to take a relaxed approach . . .”<sup>4</sup> In November 2019, the Senate Homeland Security and Governmental Affairs Committee, Permanent Subcommittee on Investigations, amplified this perspective in a comprehensive report emphasizing the need for agencies like NIH to do more to protect taxpayer-funded research. Concurrently with releasing the report, the Committee convened a hearing, *Securing the U.S. Research Enterprise from China’s Talent Recruitment Plans*, in which witnesses from NIH, NSF, the Federal Bureau of Investigation, and the Department of State concurred in the threat assessment and the need to undertake more actions to protect U.S. interests.<sup>5</sup>

## Current Requirements for Research Reporting

NIH has deployed three main requirements as tools in connection with “foreign influence” in research, all of which are aimed to ensure adequate disclosure and vetting of foreign ties. The first two require applicants and awardees to report investigators’ financial conflicts of interest and other support for research, and the third requires pre-approval if substantial parts of a specific research award are to occur outside of the United States, called “foreign components.” Below is a brief summary of these standards.

*Financial Conflict of Interest (FCOI)*: Investigators engaged in U.S. Public Health Service (PHS)-supported research must disclose to their institutions all “significant financial interests” (SFI), as well as reimbursed and sponsored travel. Institutions applying for PHS research funding then review these interests to determine if they represent a FCOI, meaning an SFI that “could directly and significantly affect the design, conduct, or reporting of PHS-funded research.”<sup>6</sup> The regulations define an SFI in one of several ways, depending upon the source of an interest. If an interest is from a publicly-traded entity, an SFI will exist if an individual (including spouse and dependent children) receives aggregate remuneration, such as salary, consulting fees, honoraria, or equity interest(s), exceeding

\$5,000 in a preceding 12-month time period. For non-publicly-traded entities, an SFI arises if an investigator (including spouse and dependent children) receives aggregate remuneration that exceeds \$5,000, or holds equity interest of any amount. An SFI may also arise for any intellectual property rights upon receipt of royalties.

The FCOI regulation excludes salary, remuneration, and royalties received from an investigator's current employer and some other sources. These exceptions include income related to teaching; lectures or seminars from institutions of higher education as defined in 20 U.S.C. § 1001(a); academic medical centers, teaching hospitals, or research institutes affiliated with such institutions; and federal, state, or local government agencies. In 2018, as its concern about foreign influence began to grow, the NIH issued guidance clarifying that "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 sub-recipient 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)."<sup>7</sup>

In addition to SFI reporting, investigators must report sponsored or reimbursed travel "related to institutional responsibilities," such as their scientific research and teaching activities.<sup>8</sup> Here too, an exception applies if the travel is paid by a domestic institution of higher education as defined in 20 U.S.C. § 1001(a) or academic medical centers or research organizations affiliated with those institutions. The exception does not apply, however, to travel paid by a non-U.S. institution.

*Other Support:* NIH is committed to assure that other research commitments or interests an investigator possesses do not conflict, as a scientific, budgetary, or commitment matter, with the funding NIH provides. Consequently, investigators must disclose "other support" that they receive or anticipate receiving, e.g., from grants sought but not yet funded. "Other support" is defined as "all resources made available to researcher or senior key personnel 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. Other support does not include training awards, prizes, gifts or start-up support from the US based institution." Included also "are resource 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.)."<sup>9</sup>

*Foreign Component:* Before an NIH-funded project can involve a "foreign component," NIH review is required. NIH defines a foreign component as "[t]he 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."<sup>10</sup> NIH does not define the meaning of the term "significant." But NIH provides examples of foreign compo-

nents from which meaning may be inferred. For example, a foreign component includes (1) "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"; and (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."<sup>11</sup> NIH excludes from the definition "foreign travel for consultation."<sup>12</sup> Additionally, NIH states that conduct that "may be significant" and qualify as a foreign component includes (1) "collaborations with investigators at a foreign site anticipated to result in co-authorship," (2) "use of facilities or instrumentation at a foreign site," and (3) "receipt of financial support or resources from a foreign entity." These examples are long-standing and unchanged since the focus on foreign influence began two years ago.

Government concerns about theft or intentional disclosure of U.S.-funded research and intellectual capital have focused, in large part, on U.S. researchers who have failed to disclose activities and affiliations with individuals, universities, or other entities in the PRC.

Collectively, these three requirements can be complex, and the NIH's effort to clarify them over the last two years has raised questions and, in some cases, been followed with retraction or revision of agency guidance.<sup>13</sup> From the government's view, however, these rules have been clear, and investigators or institutions who have failed to meet them, in many cases, have failed to be effective stewards of the federal funding entrusted to them. Among other examples, the NIH has found that investigators and research awardees have failed to disclose: (1) ex-U.S. laboratory and research operations, including equipment and personnel; (2) foreign government grants and other research or personal funding, e.g., housing and honoraria; (3) time commitments to foreign academic institutions inconsistent with time commitments to their U.S. employer and NIH; and (4) requirements for intellectual property or authorship that conflict with international norms or commitments to investigators' U.S. employers. In many cases, NIH has found that these problems have arisen when investigators are affiliated with "Talent" programs sponsored by the PRC.





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### Thousand Talents Program and Similar Programs

In contrast to the hard line voiced by members of the U.S. Congress and taken by law enforcement and the NIH, the PRC “Thousand Talents Program” (also called the “Recruitment Program of Global Experts” and other names) was viewed as recently as January 2018 as a career opportunity. A commentary in the “career center” of *Nature*, a prominent journal read widely by scientists and researchers around the world, stated: “Now in its tenth year, the Thousand Talents Plan is helping China to attract foreign researchers and provides an incentive for Chinese scientists living abroad to return home.”<sup>14</sup> According to the commentary, over 7,000 researchers had enrolled in the program since it began a decade ago, working with universities across China, and receiving through the program financial incentives for their participation.

In addition to the December 2019 FCA settlement described above, in August 2019 a faculty member at a prominent U.S. university was indicted on one count of wire fraud and three counts of program fraud for failing to report an affiliation in PRC while also receiving funding from the U.S. Department of Energy and the NSF. According to the indictment, Associate Professor Feng Tao committed to work as part of a Talent Program-like arrangement (the Changjiang Scholar Distinguished Professor program) for five years, full-time, with Fuzhou University beginning in May 2018, but did not disclose

his agreement to the university as required under its financial conflicts of interest reporting policy, nor did he report it as part of any federal funding applications or reports.

Professor Tao allegedly engaged in “double dipping” by receiving funding from multiple parties (i.e., the Changjiang Scholar program and the U.S. NSF) for overlapping commitments. While the funds at issue were not large—about \$37k—Tao’s failure to disclose his PRC affiliation apparently contributed to the decision to bring criminal charges. Summarizing the government’s perspective, Assistant Attorney General for the National Security Division John Demers indicated: “Any potential conflicts of commitment by a researcher must be disclosed as required by law and university policies. The Department will continue to pursue any unlawful failure to do so.”<sup>15</sup> If convicted, Tao faces up to 20 years in prison and a fine up to \$250,000 on a count of wire fraud, and up to ten years in prison and a fine up to \$250,000 on each program fraud count.

### Stressing University Values

Although NIH and others engaged in supporting scientific discovery have emphasized that the PRC Talent Programs and other foreign influence concerns should not override important university values, stresses are apparent. In announcing the Tao indictment to the university community last August, the university’s chancellor emphasized the importance of international collaboration and maintaining an environment in which scientific exploration may flourish. He expressly recognized that engaging in the increasingly global academic community is a fundamental component of the university’s success:

We . . . reaffirm our commitment to the collaborative environment that serves as a cornerstone in the pursuit of scientific knowledge. As reinforced in a recent op-ed column from the presidents of the Association of American Universities and the Association of Public and Land-grant Universities, international scholars—including those from China—are critical to our success, and they play a vital role in our educational and research enterprises.<sup>16</sup>

The chancellor’s statement addressed simmering concerns from across the academic community that foreign-born scholars and students are being singled out for additional scrutiny by federal law enforcement agencies.<sup>17</sup> Last July, former NIH Director Elias Zerhouni raised concern about “consternation, [a] sense of targeted discrimination, and fear” being felt across the community of American scientists of Chinese ancestry.<sup>18</sup> The President of the Massachusetts Institute of Technology in an open letter to the university community last summer warned about adverse consequences from the expanded oversight and pressure on global collaboration:

Protracted visa delays. Harsh rhetoric against most immigrants and a range of other groups, because of religion, race, ethnicity or national origin. Together, such actions and policies have turned the volume all the way up on the message that the US is closing the door—that we no



longer seek to be a magnet for the world's most driven and creative individuals. I believe this message is not consistent with how America has succeeded. I am certain it is not how the Institute has succeeded. And we should expect it to have serious long-term costs for the nation . . .<sup>19</sup>

In asserting that ethnic bias may undercut important academic values, these academic leaders are among many recognizing that the foreign influence enforcement efforts are materially distinct from other research grant compliance concerns.

## NIH's Enforcement Initiative and Institutional Legal Defenses

Against the backdrop of heightened congressional interest and a strong law enforcement focus, NIH has been among the federal agencies leading investigations into researchers at U.S. universities and academic medical centers that have undisclosed talent program and other foreign affiliations contrary to their duties as recipients of federal research funding.<sup>20</sup> In 2019, NIH Director Dr. Collins stated that the NIH has identified “utterly unacceptable” and “egregious instances where [NIH] funding of grants in this country is being taken advantage of by individuals who are not following the appropriate rules.”<sup>21</sup> Reflecting on the incidence of problems identified, the NIH's Deputy Director of Extramural Research and lead for investigating these matters, Dr. Michael Lauer, explained in a December 2019 public meeting that NIH has found substantial and serious problems with “about 75%” of the investigators about whom the agency has sent inquiry letters and undertaken intensive scrutiny.<sup>22</sup>

As of November 2019, NIH had sent more than 70 letters involving hundreds of scientists and referred more than 24 cases to the OIG.<sup>23</sup> Among other results, multiple departures and terminations from U.S. institutions, including Emory University, the M.D. Anderson Cancer Center, and the University of Florida, followed.<sup>24</sup> Furthermore many organizations initiated their own self-examination and self-reporting efforts, which have resulted in identification of undisclosed foreign affiliations and some high-profile resignations. The known actions are not limited to Chinese and Chinese-American scientists but involve scientists of an array of backgrounds.


When NIH sends an inquiry letter about possible failure to disclose financial conflicts of interest, other support, or foreign components in connection with the Talents Program or other foreign affiliations, it asks the recipient institution to undertake a thorough internal review and to report back to the agency with specific fact-finding and corrective actions, if any. The agency will review the report and may refer cases to the OIG for possible debarment or other enforcement action. In contrast to a scientific misconduct inquiry, for which specific procedures and protections are set forth at 42 C.F.R Part 93, there is little formal process that surrounds these NIH inquiry letters. Institutions and their counsel have discretion in how they respond.

Some basic steps to consider include freezing investigators' emails and other records for targeted review, examining the investigators' research portfolio and publication history

for possible foreign affiliations, undertaking media and other public record searches, reviewing grant filings and FCOI disclosures, and interviews. These reviews can be costly and resource intensive, and they can present significant challenges to institutions with strong traditions of faculty independence. Failure to undertake a thorough review also presents risks, however, as the NIH letter is notice of the government's concern about a possible compliance violation. Inadequate investigations may lead to more severe penalties, such as NIH's referring an individual or institution for exclusion from receiving federal funds, and risks that may arise under the FCA. Other actions the NIH may take when it identifies noncompliance with the FCOI, other support, and foreign component terms and conditions of NIH awards include disallowing costs, suspending or terminating awards, withholding future awards, and imposing special terms and conditions, such as extra auditing or performance reviews to ensure compliance on future awards.

## Conclusion

With a fiscal year 2020 budget of \$42 billion, the vast majority of which goes to academic medical centers, universities, and others engaged in extramural research, NIH funding often represents a significant percentage of an awardee institution's operating budget. Lawyers counseling these entities need to understand the national landscape described in this article, as well as the NIH's perspective on the legal requirements at issue, its responsibility as a funder, and the broad range of its funding discretion.

In some ways, enforcement and litigation in this area are not new—double dipping, failure to disclose financial conflicts of interest, and hidden conflicts of commitment or other support are not novel issues. However now, tools such as enforcement through the FCA are being deployed; institutions are facing unusual challenges to their research and academic missions; and an academy that has long valued foreign collaboration and respected the value of foreign talent is facing risks that Chinese and Chinese American scientists may feel or be targeted. Successful and efficient proactive protection and reactive defense of these institutions depends upon understanding both the underlying law and the broader government efforts in this arena. 

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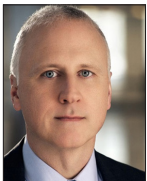
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