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INSIGHT

Foreign Interference in NIH Research: Policy Implications

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Recent congressional hearings and media reports have raised the issue of foreign interference in research funded by the National Institutes of Health (NIH), the primary federal agency for biomedical research and development (R&D). An NIH investigation, conducted in partnership with the Federal Bureau of Investigation (FBI), uncovered numerous potential violations of laws and policies (some confirmed, others subject to ongoing investigation), including

- scientists involved in the NIH peer review process sharing details of research proposals with foreign entities;
- failure of scientists to disclose foreign ties or funding from foreign governments; and
- research fraud, involving scientists signing employment contracts and earning salary from both U.S. and foreign institutions for concurrent positions.

NIH has stated, "The focus of current concern is China—but this issue is not unique to China." NIH highlighted the Thousand Talents recruitment program, which encourages participants to transfer research and other propriety information from the United States to China.

In FY2019, NIH received $39.3 billion in appropriations—making it the largest nondefense research agency and the largest single public funder of biomedical research in the world. Through its extramural research program (about 80% of the budget), NIH supports research conducted by over 300,000 scientists and staff at more than 2,500 institutions (e.g., universities, medical centers) located in all 50 states and around the world.

As a condition of receiving NIH grant funds, scientists and research institutions must comply with NIH grant policies based on relevant laws and regulations. Such policies include those related to financial conflicts of interest (FCOI), research misconduct, and reporting of other research support. NIH grants are awarded to institutions, not to researchers; therefore, institutions are primarily responsible for compliance. NIH recently issued a notice to clarify how such policies apply to research with foreign components (e.g., international collaborations). In addition to grant policies, peer reviewers agree to keep research proposals confidential.

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Biomedical Research: An International Perspective

The U.S. biomedical research enterprise has long involved foreign-born scientists and international collaborations. From 2000 to 2017, 39% of science-related Nobel Prizes won by Americans (33 of 85) were awarded to foreign-born scientists. In 2017, over half of U.S. biomedical science postdoctoral fellows were temporary visa holders. Foreign institutions, including those in China, have been involved in major NIH research initiatives, such as the Human Genome Project. NIH data show 12,067 international research collaborations or direct awards supported by the agency in FY2017.

As China's economy has grown, China has increased its support for medical research. China has plans to become a world leader in science and technology. The FBI has stated,

> While the vast majority of students and researchers from China are in the United States for legitimate academic reasons and contribute to the diversity of backgrounds and ideas important in our society, the Chinese government uses some students ... and professors to operate as non-traditional collectors of intellectual property.

In light of the investigations, some universities are reportedly reassessing international collaborations. At the same time, concerns are emerging about racial profiling of scientists of Chinese descent.

Oversight of NIH Foreign Interference

Agency assessments and independent investigations in both the executive and legislative branches have explored the issue of foreign interference in NIH research and made recommendations for NIH policy changes.

The Department of Health and Human Services (HHS) Office of the Inspector General (OIG) issued four reports in 2019 related to foreign interference at NIH:

- A February 2019 report addressed potential national security risks in permitting foreign scientists access to genomic data. HHS OIG made recommendations to strengthen controls on such data, including controls and policies specifically targeted at foreign scientists.
- A September 2019 report assessed the NIH process for vetting peer reviewers, and recommended that NIH update its guidance to help identify potential foreign threats and also develop a risk-based approach to identify nominees who warrant additional vetting.
- Two other September 2019 reports on FCOIs recommended that NIH (1) ensure that grantee institutions have publicly available FCOI policies; (2) enhance agency monitoring of institutions' FCOI policies; (3) perform periodic quality assurance reviews of FCOIs reported by institutions; and (4) use information already collected to decide to revise the FCOI review process.

NIH concurred with most of the recommendations though not with some related to genomic data sharing. In its response to the February 2019 report NIH asserted "the improbability of weaponizing this information" and stated that "if policies were set up to counter every possible theoretical risk, the entire scientific enterprise would arguably come to a halt under the weight of government red tape."

Recently, an investigation by the Senate Committee on Homeland Security and Governmental Affairs (HSGAC) reviewed policies to address foreign interference across many agencies, including NIH. Its recommendations include that federal agencies

- develop a comprehensive strategy against foreign interference in research;
- harmonize conflict of interest and foreign support disclosure requirements;

- promote best practices for international collaboration; and
- bar awards to participants of foreign talent recruitment programs absent full disclosure of the terms and conditions of such programs.

The White House Office of Science and Technology Policy has sought to coordinate agency efforts on this issue, and has issued a letter to the U.S. research community and a request for information on the American research environment.

Other Policy Considerations

Given the growing foreign interest and investments in science and technology, Congress may consider the following to address the competiveness and security of U.S. biomedical research:

- How can the United States balance the aims of deterring the illicit transfer of research and proprietary information with preserving a welcoming environment for law-abiding foreign national and U.S.-based foreign-born scientists and collaborators?
- Obtaining a U.S. academic biomedical scientist position has become increasingly difficult. A large share of U.S. graduate students and postdoctoral fellows are nonimmigrant visa holders. Should policies be adopted to enable foreign NIH trainees to more easily pursue careers in the United States?
- Would additional vetting and/or visa restrictions for biomedical science trainees from countries with known academic espionage programs deter such programs?
- Emerging biotechnologies may pose new national security risks, such as bioengineering methods that can make bacteria more dangerous. Should policies be aimed at addressing these risks?
- The Bayh-Dole Act of 1980 (P.L. 96-517) allows extramural grantees to patent inventions that result from federally funded research. These patent holders and any assignees may grant exclusive licenses to a party only if they agree that products embodying the subject invention will be "manufactured substantially in the United States." Funding agencies can waive this requirement in certain circumstances. However, the act did not establish oversight responsibilities, and stakeholders have found the provision confusing. Is oversight and/or clarification of the Bayh-Dole requirements needed?

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