

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Testimony before the Senate Health, Education, Labor and Pensions Committee

Hearing on

Protecting U.S. Biomedical Research: Efforts to Prevent Undue Foreign Influence

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Good morning Chair Murray, Ranking Member Burr, and distinguished members of the Subcommittee. It is an honor to appear before you today to discuss how NIH works to protect the integrity of the U.S. biomedical enterprise and neutralize foreign threats to the integrity of taxpayer-funded research.

The United States is the world leader in biomedical research. As the largest public funder of that research, NIH sets the standard for innovation and scientific discovery that aims to advance the health of all Americans. We exemplify and promote the highest levels of scientific integrity, public accountability, and social responsibility in the conduct of science. We promote open collaboration by leveraging formal and informal collaborations with scientists at research institutions around the world, which is imperative to solving the most pressing and perplexing health challenges that are facing the American public. This exchange of knowledge is an essential part of innovation, and it is critical to our global competitiveness. Foreign-born scientists contribute to improving health, fostering innovation, and advancing science.

Many recent scientific advances, such as sequencing the human genome, or the development of the gene-editing tool kit known as CRISPR-Cas were predicated upon international collaborations. Since 2000, 38 percent of U.S. Nobel prizes in physics, chemistry, and medicine have been awarded to foreign-born scientists.¹ Foreign-born scientists, trainees, and employees at American universities are hard at work assisting in the advancement of knowledge. U.S. scientists routinely collaborate productively with investigators in foreign countries, resulting in many scientific successes.

Global health and research partnerships have proven their worth in every phase of the current pandemic. When faced with the universal threat of the SARS-CoV-2 virus, scientists across the globe

¹ <https://nfap.com/wp-content/uploads/2019/10/Immigrants-and-Nobel-Prizes.NFAP-Policy-Brief.October-2019.pdf>

were asking the same questions at the same time – what is the virus, how does it spread, who is vulnerable, what are the symptoms, how do we prevent and treat it? Global partnerships made it possible for scientists and physicians to learn from one another, to take more full advantage of the research capacity by coordinating research so that more theories and therapies were studied. For example, NIH’s National Institute of Allergy and Infectious Diseases (NIAID) utilized its existing domestic and international clinical trials infrastructure, originally established to conduct research on HIV and influenza, and worked with partners in the public and private sectors to establish the COVID-19 Prevention Network (CoVPN). The CoVPN has supported multiple COVID-19 vaccine candidates to progress in record time from concept to authorization for emergency use by the U.S. Food and Drug Administration (FDA).

Unfortunately, a few foreign governments have initiated systematic programs to exploit the collaborative nature of biomedical research and unduly influence U.S.-supported researchers. It is essential for us to continue our vigilance and take additional actions to protect the integrity of the U.S. biomedical research enterprise, while also protecting important relationships with foreign scientists worldwide.

NIH’s three areas of concern are:

- 1) failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments and businesses, which threatens to distort decisions about the appropriate use of NIH funds and accurate evaluation of commitment of effort to US-supported research;
- 2) diversion of proprietary information included in grant applications or produced by NIH- supported biomedical research to other entities, including other countries; and
- 3) failure by some peer reviewers to keep information in grant applications confidential; including, in some instances, disclosure to foreign entities or other attempts to influence funding decisions.

NIH has taken, and continues to take, a proactive approach to identifying, resolving, and preventing these issues of concern.

NIH identifies and monitors concerns through several channels. We regularly partner with colleagues at the Department of Health and Human Services (HHS), and other federal agencies, such the Federal Bureau of Investigation (FBI), to exchange information on emerging threats. In addition, NIH maintains an open channel of communication with our funded research institutions and their investigators, several of which have proactively contacted us with concerns.

NIH partners with the HHS Office of Inspector General (OIG) in two ways: we refer cases of concern to the OIG for investigation and possible debarment, and we participate in audits of our own grant systems and internal controls by the OIG and the GAO to improve our approach. In the past 4 years, we have implemented dozens of recommendations and continue to work through recommendations as they are issued. We have also actively taken steps to increase awareness about peer review integrity with our employees who lead scientific programs and review meetings. For example, NIH staff were specifically trained to identify and report suspicious activity on the part of key scientists designated in grant applications and peer reviewers to the Research Integrity Officer in their NIH Institute or Center, or directly to our central research integrity official within the Office of the Director.

When concerns are identified, we work with leadership within the awardee institution to quickly address the issue as appropriate. As of April 2021, we have contacted more than 90 awardee institutions regarding concerns involving over 200 scientists. This process is ongoing. While in some instances our outreach reveals simple misunderstandings, these efforts have uncovered inappropriate behaviors leading to actions by awardee institutions (who have the authority to take certain actions as employers).

Such actions include:

- Terminations or suspensions of scientists who have engaged in egregious violations of NIH grant terms and conditions and institutional policies.
- Interventions to address previously un-reported affiliations with foreign institutions.
- Relinquishment or refund of NIH funds.

- Prohibition of certain individuals from serving as investigators on NIH grants.
- Outreach to FBI for assistance.
- Discovery (through acquisition of certain foreign grants and contracts) of overlapping or duplicative work, or conflicts in stating committed effort to research projects. This discovery has led to NIH suspensions of active grants as appropriate.
- Efforts to raise awareness among institutional faculty about government and institutional policies dealing with foreign affiliations and relationships (see, for example, the Penn State web site).²

There have also been situations in which honest mistakes were made by research investigators who were unaware of the requirement to disclose other funding sources (both domestic and international) or affiliations with foreign entities. In these cases, we worked with the institutions, which took steps to help their employees understand disclosure policies; both why they are important, and how to comply with relevant rules.

We will continue to address issues of concern. To mitigate security breaches, we have improved the electronic systems that are used by researchers to submit applications to NIH, and that are also used by peer reviewers to access applications for evaluations. Our security updates include: two-factor authentication for electronic research system logins; using an all-electronic conflict-of-interest certification; and, development of a dashboard.

A major focus of our preventive efforts is proactive communication to engage the research community as partners. On August 23, 2018, the NIH Director issued a statement on protecting the integrity of U.S. Biomedical Research,³ and sent a letter to officials at approximately 10,000 organizations applying for NIH funding. The letter reinforced that NIH and the U.S. biomedical research community at large have a vested interest in mitigating these unacceptable breaches of trust and confidentiality that undermine the integrity of U.S. biomedical research. NIH has also undertaken a

² https://www.research.psu.edu/international_affiliations

³ <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research>

substantial outreach and training effort. In 2019, NIH launched its series “Taking Action – Case Studies in Peer Review Integrity,” which has drawn attention to review integrity issues as well as the responsibilities of institutional officials in the scientific community.⁴ In 2020, NIH 1) issued internal policy for NIH extramural staff on protecting the confidentiality of NIH peer review information and provided stewardship training for extramural staff; 2) the NIH Center for Scientific Review (CSR) launched the CSR Reviewer Integrity Training module and is requiring all reviewers to complete the training;⁵ 3) the NIH Office of Extramural Research produced the Master Class in Review Integrity as part of the NIH Virtual Seminar;⁶ and 4) NIH strengthened its reviewer conflict of interest policy.⁷

We are working closely with the Office of Science and Technology Policy (OSTP) and other federal agencies to develop coordinated resources to help awardee institutions understand our expectations regarding research investigators who - in addition to NIH funding - receive additional research funding from domestic or foreign sources. The OSTP convened a Subcommittee on Research Security under the National Science and Technology Council to coordinate Federal efforts to effectively communicate and provide outreach to research institutions, develop guidance and best practices for research institutions, and standardize conflict of interest and disclosure policies and procedures of research funding agencies across the federal government. I am privileged to serve as a co-chair of the Subcommittee and I am pleased to report that we issued government-wide best practices for research institutions in January of this year.⁸

While we have taken bold and concrete steps to bolster research integrity and neutralize foreign threats against U.S. biomedical research, we remain conscious of how these actions could affect the

⁴ https://grants.nih.gov/policy/research_integrity/confidentiality_peer_review/case-studies.htm

⁵ <https://www.csr.nih.gov/RevTrainingPubRevNoSurvey/Home>

⁶ <https://www.youtube.com/watch?v=X0yvzUUc9yY>

⁷ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-019.html>

⁸ <https://trumpwhitehouse.archives.gov/wp-content/uploads/2021/01/NSTC-Research-Security-Best-Practices-Jan2021.pdf>

morale of honest and dedicated foreign researchers, particularly in the context of a pandemic that exacerbated acts of discrimination and harassment against Asian Americans. In March 2019, we responded to a joint letter⁹ from three Chinese American biomedical professional societies, in which they expressed concerns that policies designed to protect biomedical proprietary information may be singling out Chinese students and scholars working in the United States. Our response, published in the journal *Science*,¹⁰ acknowledged these concerns, and emphasized that the vast majority of Chinese scientists working in America are committed to the cause of expanding knowledge for the betterment of humankind, and to do so in a fair and honest way. We must say this at every opportunity, and our actions must reflect that understanding. Importantly, NIH reviews have also identified concerns involving individuals who are not foreign born and individuals not of Chinese ethnicity.

The individuals violating laws and policies represent a small proportion of scientists working in and with U.S. institutions. We must ensure that our responses to this issue do not create a hostile environment for colleagues who are deeply dedicated to advancing human health through scientific inquiry. We cannot afford to reject brilliant minds working honestly and collaboratively to provide hope and healing to millions around the world.

In closing, I can assure the Committee that the senior leadership at NIH will continue to diligently protect the integrity of U.S.-taxpayer funded research. Thank you for the opportunity to testify. I look forward to addressing any questions.

⁹ <https://science.sciencemag.org/content/363/6433/1290>

¹⁰ <https://science.sciencemag.org/content/363/6433/1292.full>