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**PROTECTING U.S. BIOMEDICAL RESEARCH:
EFFORTS TO PREVENT
UNDUE FOREIGN INFLUENCE**

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED SEVENTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING PROTECTING U.S. BIOMEDICAL RESEARCH, FOCUSING ON
EFFORTS TO PREVENT UNDUE FOREIGN INFLUENCE

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**PROTECTING U.S. BIOMEDICAL RESEARCH:
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Thursday, April 22, 2021

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:01 a.m., in room 430, Dirksen Senate Office Building, Hon. Patty Murray, Chair of the Committee, presiding.

Present: Senators Murray [presiding], Casey, Hassan, Hickenlooper, Rosen, Burr, Cassidy, Braun, Marshall, Romney, and Moran.

OPENING STATEMENT OF SENATOR MURRAY

The CHAIR. Good morning. The Senate Health, Education, Labor, and Pensions Committee will please come to order. Today we are holding a hearing on protecting U.S. biomedical research. Ranking Member Burr and I will each have an opening statement and I will introduce today's witnesses. After the witnesses give their testimony, Senators will each have five minutes for a round of questions.

Before we begin, I again want to walk through our COVID-19 safety protocols in place. We will follow the advice of the Attending Physician and the Sergeant-at-Arms in conducting this hearing. We are very grateful to our Clerks and everyone who has worked so hard to get this set up and help everyone stay safe and healthy. Committee Members are seated at least six feet apart and some Senators are participating by video conference. And while we are unable to have the hearing fully open to the public or media for in-person attendance, live video is available on our Committee website at help.senate.gov.

If you need accommodations, including closed captioning, you can reach out to the Committee or the Office of Congressional Accessibility Services. Our Nation has a long history of leadership when it comes to biomedical research, and I am proud to say that Washington State has contributed to several important chapters in that history, with groundbreaking discoveries related to bone marrow transplants, cell therapies, and precision medicine to help determine the best treatment for each patient. And with nearly 1800 NIH awards going to 75 biomedical science organizations in my state last year, we remain a leader when it comes to life saving re-

search. Protecting and supporting that research has always been important to families and patients across the country.

But the COVID-19 pandemic has put a spotlight on the value of this work in developing treatments and cures for diseases, the importance of promoting global collaboration and information sharing in the biomedical research community, and the need for transparency and accountability to ensure this work is based on data and science and protected against undue influence of any kind. That means promoting—protecting scientific work from political interference like we saw from the Trump administration, as well as protecting it from undue foreign influence, which can take many forms.

Global collaboration is critical in biomedical research. Talented researchers from around the world have played a key role in some of the major breakthroughs our country has made. In fact, in recent decades, more than a third of the Nobel Prizes in medicine, physics, and chemistry awarded to Americans were awarded to immigrant or foreign-born scientists. Our ability to lead the world in biomedical research is directly tied to our ability to work with the world on biomedical research. But successful collaboration requires trust and trust requires transparency. It is important that researchers with foreign affiliations and potential conflicts of interest, for example, participation in foreign talent programs, or commitments to file patents in or move laboratories to foreign nations, fully disclose those issues when applying for Federal grants.

It is not that researchers can't have other affiliations, but they must be transparent about them, and the overwhelming majority of researchers are. The latest report from the National Institutes of Health on undisclosed conflicts of interest found cause for concern with only 507 grant recipients, compared to over 30,000 total grantees in 2020. But we cannot let the few instances of bad actors undermine the U.S. biomedical research enterprise, including our ability to partner with talented researchers around the globe. We also have to protect confidential information, for example unpublished research or sensitive human genomic data, from being improperly shared.

That means protecting against threats like the cyber-attacks we saw last year when North Korea tried to hack COVID-19 vaccination data, and bad actors who misuse their access to research, including during the peer-review process. The National Institutes of Health has made progress in implementing policies and procedures to raise awareness of, prevent, and address undue foreign influence among the biomedical research community. But as investigations from the Department of Health and Human Services, Office of the Inspector General, the Department's Office of National Security, and the Government Accountability Office made clear, there is more NIH can be doing here. So, I am pleased to have witnesses from each of those offices, as well as the NIH Office of Extramural Research, which investigates grantees who are credibly thought to have undisclosed conflicts of interest.

I look forward to hearing more from each of you today about what steps Congress can take to ensure accountability and transparency in the grant process. Families are counting on us to get this right, not just to make sure their tax dollars are not misspent,

our intellectual property isn't stolen, and National Security isn't undermined, but so potentially lifesaving research on cancer and Alzheimer's and other diseases is not delayed or derailed by undue influence. Congress has a long record of bipartisan support for biomedical research.

I am proud to have fought hard to make necessary investments in this work, and I hope we will be able to work in a similarly bipartisan way on this Committee to take steps to protect those investments. With that, I will recognize Ranking Member Burr for his opening remarks.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Madam Chair, and I don't know about you, but I can't wait until witnesses can—and Members can be back in person. And I might say, given the most recent vaccine data, over the next four weeks, every American that wants to have a vaccine will have had the opportunity to have a vaccine and maybe normalcy will also return to the hearing rooms. Madam Chair, this is a topic that I know well because where I spend the other half of my day in the Senate Intelligence Committee, from where I sit now and how I spend my time, I want to impress upon my colleagues here today, virtually, this threat is real, it is credible, and it is dangerous to our way of life in America. We cannot be complacent.

This hearing is about the efforts of foreign actors to influence biomedical research enterprise. The Government of the people of the Republic of China and the Chinese Communist Party are the most sophisticated perpetrators, but other foreign actors are also engaged in efforts to subvert our biomedical research. Our adversaries are engaging in a systematic effort to infiltrate the academic research community and siphon away the results of United States spending on biomedical research. Last week in the Intelligence Committee's annual world watched threats hearing, the Director of National Intelligence Avril Haines said, China's Government, "is an unparalleled priority," in our intelligence community.

The 2021 annual threat assessment report reads, China will remain the top threat to U.S. technology competitiveness as the Chinese Communist Party targets key technology sectors and research institutions. Our enemies are targeting vulnerabilities in our biomedical research enterprise. Why? Because it is easy. They are not going to take us on in a single straight up fight because they know they will lose. So instead, they exploit the openness of our society and the collaborative culture that the academic research community encourages.

This means that our advancements in biomedical research are at grave risk. It means that billions of taxpayers' dollars that are invested each year toward discoveries are leveraged or outright stolen by our adversaries. And it means that our enemies can capitalize on the billions of dollars that American taxpayers invest every year to beat us to the punch on the next game changing technology to save lives or to cause unimaginable harm. Because they know it is easier to get to home base when you steal your way to third. We are here today to focus specifically on this threat in the context of protecting biomedical research. This year, Congress ap-

propriated \$43 billion to the NIH for biomedical research. And we know that over time, for every one dollar we spend on basic research at NIH, the private sector spends eight dollars. What a tremendous leverage. That is a lot of money in the United States has historically been the undisputed leader in biomedical innovation.

It is easy to see why the government of China is trying to steal our secrets and eliminate our competitive advantage. Global collaboration has been and will always be the key to our success in maintaining global leadership and our advancements. As I have said before, all smart people don't exist just here in the United States. Innovation is a global race and competition is good for innovation. So, we must think about how to foster greater innovation at home, mitigate potential risk associated with foreign influence, and maintain America's edge because deception and theft are not a valid competitive tool, and we need to be aware that this is happening more than we would like to admit it.

I made this case for Five Eyes partners, the intelligence alliance comprising Australia, Canada, New Zealand, the United Kingdom, and the United States, to tackle the issue of 5G for our cellular technology. And I think it also makes sense that we discuss our funding and advancements in biomedical research as well. The NIH partners with academic centers all over the country to support foundational research that leads to discoveries that improve, excuse me, the quality of life for Americans. And the research benefits the rest of the world with innovative drugs, devices, and treatments best evidenced by vaccines this year. North Carolina benefits each year from over \$1 billion in NIH funded research.

Along with their accomplishments and discoveries, our research institutions have seen firsthand what our enemies will do to steal our most valuable secrets, valuable secrets and assets in research. There is a concerted effort by individuals from China, backed by their Government, to be educated in America, to work here for 10 years, and then to the full extent possible to bring back to China's Government everything they can learn, store, or steal. The government of China also worked to recruit Chinese expatriate and researchers of other nationalities who may be attracted by the benefits that the Chinese Government is able to offer them. I have cautioned the research institutions in my state to prepare for a reality with different revenue streams and encourage them to rely less on researchers from countries whose governments seek to do us harm.

We must balance the rewards of this research with the risks to our country. HHS and other Federal agencies recognize the urgency of this issue and the threat it poses to our country. The NIH has come a long way from the announcement that Dr. Collins made to this Committee in August 2018, and I am glad that he took the initiative to form a working group to solve NIH's blind spots in the undue influence of foreign actors and adversaries. This is a challenge that will affect all corners of HHS. Our systems that house Medicare data must be secure just as our programs to protect priceless COVID vaccine development data must be fortified. This threat reaches into many facets of our country.

The private sector is also experiencing this threat and our solutions to these issues will require their input, their participation, and more importantly, their partnership. There is no easy path,

but if we concede the innovation race, our global competitiveness and our National Security will be at risk. I want to thank the witnesses that are here with us virtually this morning, for their efforts to inform the Committee, and for your efforts to keep America safe and in the forefront of discovery and innovation. I thank the Chair.

The CHAIR. Thank you, Ranking Member Burr. I will now introduce today's witnesses. I am pleased to start by welcoming Dr. Michael Lauer. Dr. Lauer is the Deputy Director for Extramural Research in the Office of the Director at the National Institutes of Health and the principal authority and adviser to the Director of NIH on the quality and effectiveness of NIH extramural research programs. Dr. Lauer, welcome. Glad to have you with us today.

Next, I would like to introduce Lisa Aguirre. Ms. Aguirre is the Acting Director of the Office of National Security for the Department of Health and Human Services, where she manages Department wide oversight on issues of National Security, such as cybersecurity, counterintelligence, and safeguarding classified information. Welcome, Mrs. Aguirre. Thank you for joining us today.

Next, I would like to introduce Gary Cantrell. Mr. Cantrell is the Deputy Inspector General for Investigations at the Office of the Inspector General for the Department of Health and Human Services, where he has overseen thousands of civil and criminal actions to protect HHS programs and program recipients from fraud. Mr. Cantrell, welcome to you and thank you for joining us.

Finally, I would like to introduce Candice Wright. She is the Acting Director of Science, Technology, Assessment and Analytics at the U.S. Government Accountability Office and is overseeing GAO's work on federally funded research, intellectual property protection and management, and commercializing innovative technologies, and enhancing U.S. economic competitiveness.

Thank you to all of you for joining us today. We look forward to your testimony, and Ms. Wright—and Dr. Lauer, we will begin with your opening statements. Dr. Lauer.

**STATEMENT OF MICHAEL LAUER, M.D., DEPUTY DIRECTOR
FOR EXTRAMURAL RESEARCH, NATIONAL INSTITUTES OF
HEALTH, BETHESDA, MD**

Dr. LAUER. Thank you. Good morning, Chair Murray, Ranking Member Burr, and distinguished Members of the Committee. 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, NIH sets the global standards, innovation and scientific discovery that aims to advance the health of all Americans while promoting the highest levels of scientific integrity, public accountability, and social responsibility in the conduct of science. We promote open collaboration with scientists and research institutions around the world, which is imperative to solving the most pressing and perplexing health challenges that are facing the American public.

Foreign born scientists contribute to improving health, fostering innovation, and advancing science. Unfortunately, a few governments have initiated systematic programs to exploit the collaborative nature of biomedical research and unduly influence U.S. sup-

ported 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 has taken and continues to take a proactive approach to identifying, resolving, and preventing three areas of concern. First is the failure by some researchers at NIH funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments and businesses.

Second is diversion of proprietary information, including grant applications or produced by NIH-supported biomedical research to other entities, including other countries. And third, failure by some peer reviewers to keep information grant applications confidential, including in some instances disclosure to foreign entities or other attempts to influence funding decisions. NIH identifies and monitors emerging threats internally and through partnerships with intelligence and law enforcement colleagues across the Government.

When specific concerns are identified, we work with leadership within awarding institutions to 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, including but not limited to terminations, suspensions, and relinquishment of NIH funds. In addition, we are working closely with other Federal agencies through the Office of Science and Technology Policy, that is OSTP, to coordinate Federal outreach efforts and standardize relevant policies and procedures of research funding agencies.

I am privileged to serve as a co-chair of the OSTP subcommittee on Research Security, and I am pleased that we—I am pleased to report that we issued government-wide best practices for research institutions in January of this year. 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 morale of honest and dedicated foreign researchers, particularly in the context of the pandemic that has exacerbated acts of discrimination and harassment against Asian Americans. 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. 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 bridges 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 answering your questions.

[The prepared statement of Dr. Lauer follows:]

PREPARED STATEMENT OF MICHAEL LAUER

Good morning Chair Murray, Ranking Member Burr, and distinguished Members of the Committee. 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 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

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

(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 as 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 website).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

² <https://www.research.psu.edu/international-affiliations>.

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 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 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.

The CHAIR. Thank you very much.
We will turn to Ms. Aguirre.

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

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=X0yuzUUC9yY>.

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>.

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

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

STATEMENT OF LISA AGUIRRE, ACTING DIRECTOR, OFFICE OF NATIONAL SECURITY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Ms. AGUIRRE. Good morning, Chair Murray, and Ranking Member Burr, and distinguished Members of the Committee. It is an honor to appear before you today to discuss the Office of National Security, ONS' mission. ONS is the Department of Health and Human Services, HHS, point of contact for the intelligence community and is responsible for coordination with the IC for intelligence support to HHS senior policymakers and consumers of intelligence across the Department.

Additionally, ONS is responsible for safeguarding classified National Security information across the Department and for the appropriate sharing of intelligence, homeland security, and law enforcement information externally and internally within HHS, among the operating and staff divisions. ONS is headed by the Director who reports directly to the HHS Deputy Secretary. The Director also serves as a National Security adviser to the Secretary, and in this role, as the HHS Secretary's Senior Intelligence Official on National Security, intelligence, and counterintelligence issues. The Director also serves as the Department's Federal Senior Intelligence Coordinator, or FSIC.

ONS' vision is for HHS personnel to successfully accomplish missions worldwide in a security informed manner and with the actionable intelligence needed at the right time for operational and policy decisions. ONS' responsibilities include integrating intelligence and security information into HHS policy and operational decisions, assessing, anticipating, and warning of potential security threats to the Department and our National Security, and providing policy guidance on and managing the Office of the Secretary's implementation of the Department's security, intelligence, and counterintelligence programs. ONS' programs include National Security Clearance Adjudication, Classified National Security Information Management, Secure Compartmented Information Facilities Management, Communications Security, Safeguarding and Sharing of Classified Information, Cyber Threat Intelligence and Counterintelligence.

ONS' counterintelligence mission is to conduct activities to identify, detect, deter, neutralize, mitigate, and protect Department personnel, information technology systems, and critical assets from insider threats, foreign intelligence entities, and foreign influence. While not pervasive, some foreign government actors target top scientific and technical expertise sectors in the United States in an effort to enhance their competitive advantage in the fields of research, and medical, technical innovations. These foreign actors seek to exploit Government, private sector, and academic development efforts in order to advance their own national interests while providing sponsorship to a variety of nontraditional activities to steal and co-opt U.S. research, specifically targeting biotechnology companies and university research centers.

Nontraditional collectors can include foreign researchers who have been recruited by foreign talent recruitment programs, cyber hackers and foreign students who have been co-opted or coerced into spying for foreign governments and their intelligence services.

There is substantial reporting suggesting nontraditional collector activity against U.S. equities in an effort to—I am sorry, there is substantial reporting suggesting that nontraditional collector activity against U.S. equities in an effort to misappropriate sensitive U.S. research and development data and information. In an effort to mitigate risk to HHS equities, ONS conducts all source intelligence analysis on foreign nationals attempting to obtain positions within HHS and affiliates with HHS equities.

ONS conducts vetting, and research related to grants, funding overlaps, scholarships, foreign travel, foreign associations, foreign recruitment activities, and foreign patents. ONS works jointly with HHS Operating and Staff Divisions, and interagency partners to assist in determining risk evaluations and research engagements. ONS' nontraditional collection research is provided to HHS Office of Inspector General and the FBI as counterintelligence referrals. Also, ONS has been working within the Department on a counterintelligence education and awareness program titled, Safeguarding Science. We have also begun work on a program planned for extramural education and awareness training with the National Counterintelligence Task Force, a multiagency task force led by the FBI. This training will likely be targeted toward NIH extramural staff and academic institutions applying for NIH grants.

While an ONS staff member, on detail to ONS from the FBI, has also been involved in extramural outreach over the last year. We are excited about the development of a comprehensive plan for extramural research. Additionally, ONS has a foreign visitor vetting program, and we conduct vetting of foreign national visitors for 10 operating divisions and 14 staff divisions. ONS also has a counterintelligence review program where we review material transfer agreements, supply chain risk management from a counterintelligence angle, CI review of FDA emergency use authorizations, CFIUS cases which are Committee on Foreign Investment in the US, as the Department lead. We work closely in several ways with the NIH as we do with other operating divisions.

We receive, for example, information from the NIH Deputy Director for Extramural Research, Dr. Lauer. ONS reviews correspondence received related to foreign nationals who are active participants in or seeking to engage in research and grant activities involving HHS equities. In an effort to identify and deter potential foreign influence on research integrity, ONS conducts all source research on foreign nationals that pose a potential counterintelligence and, or national—and, or nontraditional collection concerns to HHS equities. Since July 2020, ONS has received 78 emails from Dr. Lauer, and from these there were nine findings.

We did intelligence products based on these, passed them back to Dr. Lauer, passed them on to counterintelligence and insider threat staff, and when appropriate, referred them to the OIG. In closing, ONS has worked significantly over the last few years to further enhance our counterintelligence programs in coordination with HHS operating and staff divisions. And we are dedicated to protecting Department personnel, information technology systems, and critical assets. Thank you very much and I will be happy to answer any questions.

[The prepared statement of Ms. Aguirre follows:]

PREPARED STATEMENT OF LISA AGUIRRE

Good morning Chair Murray, Ranking Member Burr, and distinguished Members of the Committee. It is an honor to appear before you today to discuss the Office of National Security's (ONS) mission. ONS is the Department of Health and Human Services' (HHS) point of contact for the Intelligence Community (IC), and is responsible for coordination with the IC and for intelligence support to HHS senior policymakers and consumers of intelligence across the Department. Additionally, ONS is responsible for safeguarding classified national security information across the Department and for the appropriate sharing of intelligence, homeland security, and law enforcement information externally and, internally within HHS, among the Operating and Staff Divisions. ONS is headed by the Director, who reports directly to the HHS Deputy Secretary. The Director also serves as the National Security Advisor to the Secretary and in this role is the HHS Secretary's Senior Intelligence Official on national security, intelligence, and counterintelligence issues. The Director also serves as the Department's Federal Senior Intelligence Coordinator (FSIC).

ONS' vision is for HHS personnel to successfully accomplish missions worldwide in a security-informed manner and with the actionable intelligence needed, at the right time, for operational and policy decisions. ONS' responsibilities include: Integrating intelligence and security information into HHS policy and operational decisions; assessing, anticipating, and warning of potential security threats to the Department and our national security; and, providing policy guidance on and managing the Office of the Secretary's implementation of the Department's security, intelligence, and counterintelligence programs. ONS' programs include national security adjudication, classified national security information management, secure compartmented information facilities management, communications security, safeguarding and sharing of classified information, cyber threat intelligence, and counterintelligence.

ONS' counterintelligence mission is to conduct activities to identify, detect, deter, neutralize, mitigate and protect Department personnel, information technology systems, and critical assets from insider threats, foreign intelligence entities, and foreign influence. While not pervasive, some foreign government actors target top scientific and technical expertise sectors in the United States in an effort to enhance their competitive advantage in the fields of research and medical/technical innovations. These foreign actors seek to exploit government, private-sector, and academic development efforts in order to advance their own national interests while providing sponsorship to a variety of non-traditional activities to steal and co-opt U.S. research; specifically, targeting bio-technology companies and university research centers. Non-traditional collectors can include foreign researchers who have been recruited by foreign talent recruitment programs, cyber hackers, and foreign students who have been co-opted or coerced into spying for foreign governments and their intelligence services. There is substantial reporting suggesting non-traditional collector activity against U.S. equities in an effort to misappropriate sensitive U.S. research and development data and information.

In an effort to mitigate risks to HHS equities, ONS conducts all-source intelligence analysis on foreign nationals attempting to obtain positions within HHS and affiliates with HHS equities. ONS conducts vetting and research related to grants, funding overlap, scholarships, foreign travel, foreign associations, foreign recruitment activities, and foreign patents. HHS ONS works jointly with HHS Operating and Staff Divisions, and interagency partners, to assist in determining risk evaluations in research engagements. ONS non-traditional collection research is provided to HHS Office of Inspector General and the Federal Bureau of Investigation (FBI) as counterintelligence referrals.

Also, ONS has been working within the Department on a counterintelligence education and awareness program, titled: Safeguarding Science. ONS has begun work on a program plan for extramural education and awareness training with the National Counterintelligence Task Force, a multi-agency task force led by the FBI. This training will likely be targeted toward National Institutes of Health (NIH) extramural staff (employees, contractors, fellows, and trainees/volunteers) and academic institutions applying for NIH grants (faculty, staff, post-doctoral associates, graduate research assistants, trainees/volunteers). While an ONS staff member, on detail to ONS from the FBI, has been involved in extramural outreach over the last year, we are excited about the development of a comprehensive plan for extramural outreach.

Additionally, ONS has a foreign visitor vetting program. ONS conducts vetting of foreign national visitors for 10 Operating Divisions and 14 Staff Divisions. ONS also conducts vetting for foreign national employees who will be authorized access to gov-

ernment systems and data. In 2020, ONS vetted 13,138 foreign national visitors; 7936 were to NIH. ONS also vetted 2,854 foreign national employees; 1,574 were to be employed in NIH. ONS also has a counterintelligence review program, where we review:

- Material Transfer Agreements (transfers from HHS to foreign governments);
- Supply Chain Risk Management (SCRM) from the counterintelligence angle;
- CI Review of FDA Emergency Use Authorizations; and
- Committee on Foreign Investment in the U.S. (CFIUS) cases, as Department lead.

ONS also has a program that focuses on the non-traditional collection vulnerabilities within HHS.

ONS has worked closely in several ways with NIH, as we do with other Operating Divisions. One example: ONS receives information from the NIH Deputy Director for Extramural Research (Dr. Lauer). ONS reviews correspondence received related to foreign nationals who are active participants in or seeking to engage in research and grant activities involving HHS equities. In an effort to identify and deter potential foreign influence on U.S. research integrity, ONS conducts all-source research on foreign nationals that pose a potential counterintelligence and/or non-traditional collection concern to HHS equities. If ONS identifies a potential concern, our office produces a formal product on our findings and presents the data to the appropriate HHS components. Since July 2020, ONS has received 78 portal emails from the NIH Deputy Director for Extramural Research, and from these there were nine findings. Those nine findings were put into intelligence products and provided to the NIH Deputy Director for Extramural Research counterintelligence and insider threat staff, and when appropriate, referred to OIG.

In closing, ONS has worked significantly over the last few years to further enhance our counterintelligence programs, in coordination with HHS Operating and Staff Divisions, and we are dedicated to protecting Department personnel, information technology systems, and critical assets. I will be happy to answer any questions.

The CHAIR. Thank you.
Mr. Cantrell.

STATEMENT OF GARY L. CANTRELL, DEPUTY INSPECTOR GENERAL FOR INVESTIGATIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. CANTRELL. Good morning, Chair Murray, Ranking Member Burr, and distinguished Members of the Committee. I am Gary Cantrell, Inspector General for Investigations, HHS, OIG. I appreciate the opportunity to appear before you to discuss how we are working in conjunction with our HHS and law enforcement partners to protect medical research against foreign threats. OIG has identified the threat of foreign government action aimed at unduly influencing and capitalizing on taxpayer funded medical research as a top management challenge for HHS. And we also suggest doing more to address this vulnerability in OIG's top 25 recommendations.

OIG takes a multi-pronged approach to foreign influence related oversight and enforcement activities. We work collaboratively to minimize vulnerabilities and mitigate grant fraud through audits, evaluations, and proactive training. And we investigate allegations of criminal misconduct to make referrals for criminal, civil, or administrative action as appropriate. First, I will discuss our investigative and enforcement efforts. Foreign theft of taxpayer funded

medical research is a high profile, complex issue as the cases under our purview all involve aspects of traditional grant fraud, a subject which OIG has extensive experience investigating.

OIG receives allegations of grant fraud or uncovers potential fraud in a variety of ways, including our OIG hotline, referrals from HHS, law enforcement partners, and whistleblower disclosures. Upon receiving an allegation pertaining to grant fraud, OIG evaluates the allegation and determines whether we will open an investigation, refer the matter to another agency of jurisdiction, or send it back to the originating operating division for administrative review and potential action. When OIG identifies a potential violation of civil or criminal law, we present the facts to DOJ for prosecutorial consideration. As part of the foreign influence investigative process, OIG coordinates with NIH, the HHS Office of National Security, the FBI, and U.S. attorneys' offices to ensure coordinated, efficient, and investigative resolutions.

My testimony highlights two such investigations, one leading to a criminal plea by a researcher who admitted he lied on applications in order to use approximately \$4.1 million in NIH grants to enhance China's expertise in the areas of rheumatology and immunology. Another resulting in a civil settlement with a research institution to resolve allegations that violated the False Claims Act by submitting grant applications and progress reports to NIH which failed to disclose that two of the institution's researchers were funded by Chinese Government grants.

OIG also works with stakeholders to increase their ability to detect and prevent fraud. In proactive training, OIG increases HHS employee, contractor, and grantee awareness of how to identify and report allegations pertaining to grant fraud, including foreign threats. For instance, OIG has provided numerous grant fraud training sessions at the NIH regional seminars and town hall meetings. We have also partnered with several academic institutions to present best practices for preventing, detecting, and reporting research fraud to their research integrity, excuse me, compliance officers. OIG also conducts important oversight of NIH funded research through audits and evaluations. Our work is informed by concerns raised by Congress, NIH, and other Federal law enforcement agencies.

In addition to their existing resources for NIH oversight, Fiscal Year 2019, OIG began receiving transferred funding of \$5 million each year for oversight of grant programs and operations at NIH. Since this time, OIG has completed nine reviews focused on protecting the integrity of NIH funded research, with 12 additional related reviews planned or underway. This includes but is not limited to assessments of NIH's vetting and oversight of its peer reviewers, and NIH's oversight of financial conflicts of interest and other support.

In conclusion, OIG is committed to working collaboratively to address foreign threats to taxpayer funded medical research, and we will diligently continue both our preventive efforts to minimize risk and vulnerabilities in HHS programs, and to conduct enforcement actions whenever necessary. Thank you for your ongoing leadership in this area and for affording me the opportunity to discuss this important topic with you today.

[The prepared statement of Mr. Cantrell follows:]

PREPARED STATEMENT OF GARY L. CANTRELL

Good morning, Chair Murray, Ranking Member Burr, and distinguished Members of the Committee. I am Gary Cantrell, Deputy Inspector General for Investigations with the Department of Health and Human Services (HHS) Office of Inspector General (OIG). I appreciate the opportunity to appear before you to discuss how HHS-OIG is diligently working, in conjunction with our HHS and law enforcement partners, to protect taxpayer-funded medical research.

OIG is responsible for overseeing HHS's \$2.2 trillion in expenditures made in fiscal year 2020, and our work spans the over 100 programs at HHS. We combat fraud, waste, and abuse in those programs; promote their efficiency, economy, and effectiveness; and protect the beneficiaries they serve. To accomplish this, OIG employs tools such as data analysis, audits, evaluations, and investigations. We are a multidisciplinary organization comprised of investigators, auditors, evaluators, analysts, clinicians, and attorneys. We depend on our strong public and private partnerships to ensure coordinated enforcement success.

The Office of Investigations is the law enforcement component of OIG that investigates fraud and abuse against HHS programs. Our special agents have full law enforcement authority and effect a broad range of actions, including the execution of search warrants and arrests. We use traditional as well as state-of-the art investigative techniques and innovative data analysis to fulfill our mission.

Introduction

Today, I will cover how OIG enhances the Federal Government's ability to detect, deter, and take enforcement action to ensure the integrity of taxpayer-funded medical research against foreign threats.

To date, the National Institutes of Health (NIH) has referred to OIG for investigation numerous allegations of noncompliance with its terms and conditions for receiving a medical research grant. The allegations primarily deal with the failure of grantee principal investigators to disclose foreign government affiliations. Because most of these referrals are still active, to avoid compromising ongoing investigations, I cannot provide much further specific details at this time. However, I can cover how we generally handle grant fraud allegations related to taxpayer-funded medical research.

Although foreign theft of taxpayer-funded medical research is a high-profile complex issue, the cases under our purview all involve aspects of grant fraud—something which OIG has extensive experience investigating. HHS is the largest grant-making organization and second-largest contracting agency in the Federal Government. It is also the second-largest payer under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. Given this nexus, OIG has made oversight and enforcement of grant fraud and related grant program integrity a priority.

Proactive Grant Fraud Education, With Enforcement When Needed

We take a two-pronged approach to preventing and acting against grant fraud. First, OIG works collaboratively to educate key stakeholders—including HHS operating divisions and grant recipient organizations—on ways to detect and prevent grant fraud through proactive training. Second, we take action, when needed, against grant fraud by investigating allegations of criminal misconduct and making appropriate referrals for criminal, civil, or administrative action.

OIG receives allegations of grant fraud or uncovers potential fraud in a variety of ways, including OIG hotline complaints, referrals from HHS operating divisions and law enforcement partners, whistleblower disclosures, and proactive data analysis. Our hotline's mobile compatible web form is specifically designed to easily collect grant and contract fraud complaints from the public and/or HHS employees, and we also have an Operating Division portal that is only available to our HHS operating division partners so they can quickly refer grant and contract related matters to OIG for immediate review.

Upon receiving an allegation pertaining to grant fraud involving NIH or other HHS operating division, OIG evaluates the allegation and determines whether we will open an investigation; refer the matter to another agency with appropriate authorities; or, when appropriate, refer the matter back to the HHS operating division involved for administrative review and potential action.

When evaluating referrals involving allegations of foreign threats to taxpayer-funded medical research, OIG is sensitive to the fact that academic and professional reputations could easily be damaged by erroneous allegations. All complaints are treated with confidentiality and discretion, and we only proceed with investigations when sufficient factual information supports such investigative activity. When OIG identifies a potential violation of civil or criminal law during an investigation, OIG presents the facts to the Department of Justice for prosecutorial consideration.

To protect the integrity of medical research, OIG coordinates with the HHS Office of National Security (ONS). In some instances, OIG works on matters with the Federal Bureau of Investigation's (FBI's) Joint Terrorism Task Forces and National Cyber Investigative Joint Task Force, the Department of Homeland Security, and components at FBI Headquarters and local field offices. When appropriate, we work together with NIH and ONS to develop follow-up approaches and mitigation strategies for such cases.

To illustrate the types of grant fraud investigations OIG conducts, I will offer summaries of two recent research integrity investigations.

A professor of internal medicine and researcher who led a team conducting autoimmune research at The Ohio State University and Pennsylvania State University, pled guilty in late 2020 to making false statements to Federal authorities as part of an immunology research grant fraud scheme. As part of his plea, the professor/researcher admitted he lied on applications in order to use approximately \$4.1 million in NIH grants to develop China's expertise in the areas of rheumatology and immunology. According to his plea, he submitted materially false and misleading statements on NIH grant applications, seeking to hide his participation in a Chinese Talent Plan and his affiliation and collaboration with a Chinese university controlled by the Chinese government. He is now awaiting sentencing.

In late 2019 Van Andel Research Institute (VARI) agreed to pay \$5.5 million to resolve allegations that it violated the False Claims Act by submitting Federal grant applications and progress reports to NIH in which VARI failed to disclose Chinese government grants that funded two VARI researchers. The settlement further resolves allegations that in a Dec. 21, 2018, letter, VARI made certain factual representations to NIH with deliberate ignorance or reckless disregard for the truth regarding the Chinese grants. The Government specifically alleged that between January 2012 and December 2018, one of the researchers received grants and research support from a variety of Chinese sources, including the People's Republic of China's Thousand Talents Program.

As mentioned earlier, OIG's approach to addressing grant fraud includes working collaboratively with stakeholders to increase their ability to detect and prevent grant fraud through proactive training. OIG works with representatives of the Federal law enforcement community and HHS's Office of Research Integrity (ORI) to promote awareness of research misconduct and improve efforts to protect against such conduct. In addition to joint training efforts, ORI notifies OIG when conduct that might be criminal arises in the course of a research misconduct investigation. OIG's work is independent of ORI's, and ORI must refer all credible allegations of criminal conduct they uncover to OIG. In short, OIG's enhanced collaboration with ORI adds a layer of scrutiny to ensure that both ORI and OIG can take appropriate actions to protect U.S. biomedical research investments.

OIG increases HHS employee, contractor, and grantee awareness of how to identify and report allegations pertaining to grant fraud as well as foreign threats to taxpayer-funded medical research through training and presentations. For instance, OIG has provided numerous grant fraud training sessions at NIH Regional Seminars and NIH SBIR and STTR Town Hall meetings.

To educate grant recipient organizations, OIG has partnered with several academic entities to address best practices to ensure Research Integrity Officers and Compliance Officers are informed on the roles, responsibilities, and authorities of OIG. We tailor our efforts for each grant recipient organization to address what best practices are most helpful to serve its unique needs.

Risk Mitigation Through Minimizing Vulnerabilities

OIG conducts oversight of NIH through audits and evaluations, some of which relate to protecting the integrity of NIH-funded research. Our work is informed by concerns raised by Congress, NIH, and other Federal law enforcement agencies about foreign threats to the integrity of U.S. medical research and intellectual prop-

erty. OIG has identified the threat of foreign government action aimed at unduly influencing and capitalizing on medical research programs funded and overseen by the Department as part of the 2020 Top Management Challenges Facing HHS. Furthermore, one of OIG's Top 25 Recommendations to HHS is that NIH should build on its efforts to identify and mitigate potential foreign threats to research integrity.

In fiscal year 2019, OIG began receiving transferred funding of \$5 million for oversight of grant programs and operations of NIH, including NIH efforts to ensure the integrity of its grant application evaluation and selection processes. This funding has been provided in addition to existing resources for NIH oversight, and has continued through fiscal year 2021.¹ As an associated requirement attached to this funding each year, OIG must submit an NIH oversight plan to the Committee on Appropriations of the House of Representatives and the Senate. OIG recently submitted to Congress its fiscal year 2021–2022 NIH Oversight Plan. The fiscal year 2021–2022 plan was developed, as required, in consultation with the Committees on Appropriations in the House of Representatives and the Senate and focuses on four key areas:

- **Cybersecurity protections.** OIG plans to conduct audits related to cybersecurity controls built into NIH's enterprise network and IT contracts.
- **Compliance with requirements for grants, contracts, and other transactions.** Our oversight activities will help ensure NIH-funded research institutions comply with Federal requirements and NIH policies that establish controls for NIH grants, contracts, and other transactions.
- **Integrity and management of grant application and selection processes.** OIG's planned oversight activities will examine NIH's efforts to ensure the integrity and the effective management of its grant application and selection processes.
- **Intellectual property and research integrity.** OIG's oversight will examine NIH's efforts and grantee institutions' implementations of internal controls and effective oversight practices in response to threats, including foreign threats, to intellectual property and research integrity.

Since the beginning of fiscal year 2019, utilizing both this supplemental funding as well as our permanent funding streams, OIG has completed nine related reviews focused on NIH. In addition, OIG has eight related ongoing reviews that have started since the beginning of fiscal year 2020. This work includes, but is not limited to:

- *Assessments of NIH's vetting and oversight of its peer reviewers.* OIG assessed NIH's vetting and oversight of the 27,000 peer reviewers who review grant applications for NIH each year. Peer reviewers have access to confidential information in grant applications. NIH has raised concerns about some peer reviewers inappropriately disclosing confidential information, including to foreign entities.

We found that NIH focuses its vetting of peer reviewer nominees on scientific skills and preventing undue influence generally, but it has not focused its vetting specifically on undue foreign influence. We recommended that NIH: (1) update its guidance on vetting peer reviewer nominees to identify potential foreign threats to research integrity, in consultation with national security experts as needed, and (2) work with HHS Office of National Security to develop a risk-based approach for identifying nominees who warrant additional vetting. NIH agreed with both recommendations.

With respect to NIH oversight of peer reviewers, we found that NIH enforces policies and procedures that protect confidential information in grant applications handled by peer reviewers, but it could do more to address the risk that undue foreign influence poses to maintaining confidentiality. We recommended that NIH: (1) conduct targeted, risk-based oversight of peer reviewers using analysis of information about threats to research integrity; (2) update its training materials routinely to include information about breaches of peer reviewer confidentiality and possible undue foreign influence; (3) require all peer reviewers to attend periodic trainings about peer review integrity; and (4) consult with Federal law enforcement and national security experts to determine what additional steps it might take to identify and address potential risks to the confidentiality of the peer review process,

¹ The Consolidated Appropriations Act, 2021 (Public Law No. 116–260).

including possible undue foreign influence. NIH agreed with all of these recommendations and has implemented the fourth one.

- *NIH oversight of financial conflicts of interest and other support.* OIG has also examined how NIH ensures that grantee institutions report all sources of research support, financial interests, and affiliations, as well as how NIH reviews financial conflicts of interests that are reported to them. With respect to required reporting, we found NIH has limited policies, procedures, and controls in place for helping to ensure that institutions report all sources of research support, financial interests, and affiliations. Of the 1,875 institutions that received NIH funding in fiscal year 2018 and were required to have financial conflict of interest (FCOI) policies, 1,013 did not have FCOI policies posted on their websites. We recommended that NIH: (1) ensure that the 1,013 institutions we identified as not having FCOI policies on their website post those policies as required, (2) enhance its FCOI monitoring program to ensure that institutions resolve identified deficiencies and to review all grantee websites to ensure that FCOI policies are publicly accessible, and (3) implement procedures to ensure that all institutions required to have FCOI policies actually have FCOI policies. NIH concurred with all of our recommendations. Although NIH has made progress with implementing these recommendations, they all remain unimplemented.

In addition, we found that NIH has improved its tracking and review of investigators' financial conflicts of interest (FCOIs) over the last decade. However, it could improve the consistency and quality assurance over these reviews. Further, NIH has no mechanism to identify FCOIs that involve foreign entities and is not planning to expand its FCOI reporting requirements to include such a designation. We recommended that NIH: (1) perform periodic quality assurance reviews of information to ensure the adequacy of oversight of reported FCOIs; and (2) use information regarding foreign affiliations and support collected during the pre-award process to decide whether to revise its FCOI review process to address concerns regarding foreign influence. NIH agreed with both recommendations and has implemented the first one.

In the second half of fiscal year 2021, OIG plans to begin another four reviews, and our work plan will be updated as individual report designs are finalized. We would be more than happy to brief the Members of this Committee and staff on this work on an ongoing basis.

Conclusion

OIG is committed to working collaboratively to address foreign threats to taxpayer-funded medical research through preventive efforts to mitigate risk and minimize vulnerabilities in HHS programs and conducting enforcement actions whenever necessary. In cooperation with our HHS and law enforcement partners, OIG will continue to leverage our grant fraud investigative work and capabilities to maximize our efforts in this area as authorities, resources, and funding allow.

Thank you for your ongoing leadership in this area and for affording me the opportunity to discuss this important topic with you.

[SUMMARY STATEMENT OF GARY L. CANTRELL]

OIG is responsible for overseeing HHS's \$2.2 trillion in expenditures made in fiscal year 2020, and our work spans the over 100 programs at HHS. We combat fraud, waste, and abuse in those programs; promote their efficiency, economy, and effectiveness; and protect the beneficiaries they serve. To accomplish this, OIG employs tools such as data analysis, audits, evaluations, and investigations.

OIG has identified the threat of foreign government action aimed at unduly influencing and capitalizing on medical research programs funded and overseen by the Department as part of the 2020 Top Management Challenges Facing HHS. Furthermore, one of OIG's Top 25 Recommendations to HHS is that NIH should build on its efforts to identify and mitigate potential foreign threats to research integrity.

Proactive Grant Fraud Education, With Enforcement When Needed: The Office of Investigations is the law enforcement component of OIG that investigates fraud and abuse against HHS programs. Although foreign theft of taxpayer-funded medical research is a high-profile complex issue, the cases under our purview all

involve aspects of grant fraud—something which OIG has extensive experience investigating.

We take a two-pronged approach to preventing and acting against grant fraud. First, OIG works collaboratively to educate key stakeholders—including HHS operating divisions and grant recipient organizations—on ways to detect and prevent grant fraud through proactive training. Second, we take action, when needed, against grant fraud by investigating allegations of criminal misconduct and making appropriate referrals for criminal, civil, or administrative action.

OIG also works collaboratively with stakeholders to increase their ability to detect and prevent grant fraud through proactive training. To educate grant recipient organizations, OIG has partnered with several academic entities.

Risk Mitigation Through Minimizing Vulnerabilities: OIG conducts oversight of NIH through audits and evaluations, some of which relate to protecting the integrity of NIH-funded research. Our work is informed by concerns raised by Congress, NIH, and other Federal law enforcement agencies about foreign threats to the integrity of U.S. medical research and intellectual property. In addition to existing resources for NIH oversight, in fiscal year 2019, OIG began receiving transferred funding of \$5 million for oversight of grant programs and operations of NIH, including NIH efforts to ensure the integrity of its grant application evaluation and selection processes. Since this time, OIG has completed nine related reviews focused on NIH. In addition, OIG has eight related ongoing reviews and we plan to begin another four related reviews this fiscal year. Our work includes but is not limited to assessments of NIH's vetting and oversight of its peer reviewers and NIH's oversight of financial conflicts of interest and other support.

OIG is committed to working collaboratively to address foreign threats to taxpayer-funded medical research through preventive efforts to mitigate risk and minimize vulnerabilities in HHS programs and conducting enforcement actions whenever necessary.

The CHAIR. Thank you.
We will turn to Ms. Wright.

**STATEMENT OF CANDICE N. WRIGHT, ACTING DIRECTOR,
SCIENCE, TECHNOLOGY ASSESSMENT, AND ANALYTICS, U.S.
GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC**

Ms. WRIGHT. Thank you, Chair Murray, Ranking Member Burr, and Members of the Committee. Thank you for the opportunity to discuss undue foreign influence in research funded by U.S. taxpayers. With research expenditures in recent years amounting to over \$40 billion annually, safeguarding the U.S. research enterprise is critically important and to ensure that Federal research is free from undue foreign influence.

This issue is not new and in fact GAO's work in this area dates back to 1992. What is different today is greater international collaboration and the concerted efforts to access sensitive U.S. research and intellectual property, such as through foreign government talent recruitment programs. Some countries can create conflicts of interest for researchers by obligating them to divert intellectual property and U.S. funded research in exchange for salaries and other incentives.

Agencies and university grantees face the difficult task of preventing or at least limiting the extent of foreign influence in federally funded research. Having insight into what activities constitutes a conflict of interest is key. Federal grant making agencies such as NIH can address this by implementing policies and requiring the disclosure of information that may indicate potential conflicts.

Last year, GAO issued a report that examined conflict of interest policies and disclosure requirements. We looked at the Departments of Defense and Energy, as well as NASA and NIH, which collectively account for 90 percent of funding for Federal research, mostly through grants. Today, I will share insights on agency policies and disclosure requirements, monitoring and enforcement efforts, and the research community's views on responding to foreign influence. With regard to the first area, we found that NIH has an agency wide conflict of interest policy. The policy emphasizes which financial interest researchers should disclose to the university receiving the grant.

However, NIH's policy does not address or define non-financial conflicts, sometimes referred to as conflicts of commitment. Such conflicts may include foreign academic appointment and access to laboratory space or biological materials provided by foreign entities. In light of this, we recommended that NIH define and address non-financial conflicts of interest in its policy, as this is a key step to identifying and mitigating undue foreign influence. NIH concurred with our recommendation, and since our December 2020 report, NIH has updated its grant application and forms to require that applicants more fully disclose non-financial interests, including foreign activities and resources.

It will be equally important for NIH to reflect such changes, along with defining non-financial conflicts in its policy. Regarding the second area on monitoring and enforcement, we found that NIH and the other agencies we reviewed rely on universities to monitor and mitigate financial conflicts of interest. They also collect information such as foreign collaborations that could be used to identify non-financial conflicts. In our report, we noted that NIH had identified over 400 researchers of concern dating back to 2018 and referred such cases for investigation.

For the third area, the research community shared perspectives on improving the response to foreign influence. Principal investigators who lead research universities emphasized the need for clear communications about the specific threats and risks involving foreign influence. In fact, a number of the principal investigators we spoke with said that they were not aware of foreign talent recruitment programs.

University administrators called for more information sharing to enhance researchers' awareness of the threats and risks, especially those working on high target research involving artificial intelligence and quantum computing. For its part, NIH has conducted training and issued notices and reminders to researchers on the risks. In closing, international collaborations have helped to fuel many scientific advances, including global mapping of infectious disease. Maintaining an open research environment that promotes collaboration and transparency should not be done without the consideration of threats of foreign influence from countries seeking to undermine U.S. investments and leadership and R&D.

Protecting U.S. biomedical research must begin with having a common language about the threats and risks. An important first step is to start with fully and clearly defining and communicating the types of conflicts that may pose a risk.

Leaving universities to guess what financial or non-financial conflicts should be reported is akin to asking them to take a, you will know it when you see it approach, and that is not prudent, especially given the National Security and economic implications.

Chair Murray, Ranking Member Burr, and Members of the Committee, this concludes my prepared statement. I would be pleased to respond to any questions you may have.

[The prepared statement of Ms. Wright follows:]

GAO@100 Highlights

Highlights of GAO-21-523T, a testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate

Why GAO Did This Study

The federal government reported expending about \$44.5 billion on university science and engineering research in fiscal year 2019. The Department of Health and Human Services funds over half of all such federal expenditures, and NIH accounts for almost all of this funding. Safeguarding the U.S. research enterprise from threats of foreign influence is of critical importance. Recent reports by GAO and others have noted challenges faced by the research community to combat undue foreign influence, while maintaining an open research environment.

This testimony discusses (1) NIH's conflict of interest policy and disclosure requirements that address potential foreign influence, (2) NIH's mechanisms to monitor and enforce its policy and requirements, and (3) the steps NIH has taken to address concerns about foreign influence in federally funded research identified by stakeholders. It is based on a report that GAO issued in December 2020 (GAO-21-130).

What GAO Recommends

In its December 2020 report, GAO recommended that NIH define and address non-financial conflicts of interest in its policy. NIH concurred with our recommendation and has recently updated its grant application forms and instructions to require that applicants more fully disclose non-financial interests, including foreign activities and resources. However, NIH has not yet updated its conflict of interest policy.

View GAO-21-523T. For more information, contact Candice N. Wright at (202) 512-6888 or wrightc@gao.gov.

April 22, 2021

FEDERAL RESEARCH

NIH Should Take Further Action to Address Foreign Influence

What GAO Found

U.S. research may be subject to undue foreign influence in cases where a researcher has a foreign conflict of interest. Federal grant-making agencies, such as the National Institutes of Health (NIH), can address this threat by implementing conflict of interest policies and requiring the disclosure of information that may indicate potential conflicts. GAO found that NIH's policy focuses on financial conflicts of interest but does not specifically address or define non-financial interests, which may include multiple professional appointments. In the absence of agency-wide policies and definitions on non-financial interests, universities that receive federal grant funding may lack sufficient guidance to identify and manage conflicts appropriately, potentially increasing the risk of undue foreign influence. In its report, GAO noted that NIH also requires researchers to disclose information—such as foreign support for their research—as part of grant proposals, and that such information could be used to determine if certain conflicts exist.

National Institutes of Health Disclosure Requirements for Grantees as of December 2020

Researcher biographies	Current and pending support	Foreign components of research
<ul style="list-style-type: none"> Baccalaureate or other initial professional education, such as nursing. Postdoctoral, residency, and clinical fellowship training, as applicable. Relevant publications and positions held, concluding with the present position. 	<ul style="list-style-type: none"> Other support to include all financial resources, whether federal, non-federal, commercial or institutional, available in direct support of an individual's research endeavors. This includes, but is not limited to research grants, cooperative agreements, contracts, and/or institutional awards. 	<ul style="list-style-type: none"> Activities outside the United States or partnership with international collaborators. Provide a justification if the applicant organization is a foreign institution, or if the project includes a foreign component.

Source: GAO presentation of information in agency documents. | GAO-21-523T

NIH relies on universities to monitor financial conflicts of interest, and the agency collects information, such as foreign collaborations, that could be used to identify non-financial conflicts. NIH has taken action in cases where it identified researchers who failed to disclose financial or non-financial information. Such actions included referring cases to the Department of Justice for criminal investigation. Additionally, NIH has written procedures for addressing allegations of failures to disclose required information.

In interviews, stakeholders identified opportunities to improve agency responses to prevent undue foreign influence in federally funded research. For example, agencies could harmonize grant application requirements and better communicate identified risks. NIH has taken steps to address the issue of foreign influence in the areas stakeholders identified.

Chair Murray, Ranking Member Burr, and Members of the Committee:

Thank you for the opportunity to discuss our December 2020 report on foreign influence in federally funded research, as it relates to the actions taken by the National Institutes of Health (NIH).¹ The federal government reportedly expended about \$44.5 billion on university science and engineering research in fiscal year 2019.² The Department of Health and Human Services (HHS) funds over a half of all such federal expenditures, and NIH accounts for almost all of this funding.³

Safeguarding U.S. taxpayers' investment in federally funded research from undue foreign influence is of critical importance. Recent reports by GAO and others have noted challenges faced by the research community to combat undue foreign influence, while maintaining an open research environment that fosters collaboration, transparency, and the free exchange of ideas.⁴ For example, we recently reported on the risk foreign students working at U.S. research universities may pose by "exporting" sensitive knowledge they gain to their home countries.

In August 2018, the Director of NIH sent a letter to over 10,000 universities highlighting concerns over foreign government talent recruitment programs, noting that these programs can influence researchers receiving federal funding to divert intellectual property and

¹GAO, *Federal Research: Agencies Need to Enhance Policies to Address Foreign Influence*, GAO-21-130 (Washington, D.C.: Dec. 17, 2020).

²See National Science Foundation's "Higher Education Research and Development" survey on research and development expenditures provided to higher education institutions in the United States and outlying areas. These were the most recent data available at the time of our testimony. Funding data for fiscal year 2020 have not been released.

³Our review focuses on HHS's sub-agency—NIH—because it expends almost all of the federal research funding on behalf of the agency. For cohesion, we refer to NIH as an agency in this testimony.

⁴GAO, *Export Controls: State and Commerce Should Improve Guidance and Outreach to Address University-Specific Compliance Issues*, GAO-20-394 (Washington, D.C.: May 12, 2020), United States Senate, Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, *Threats to the U.S. Research Enterprise: China's Talent Recruitment Plans*, (Washington, D.C.: November 2019).

federally funded research to other countries.⁵ The letter also highlighted concerns that some researchers with federally funded grants did not disclose financial and other resources provided by foreign governments. For example, in May 2020, a former researcher at one U.S. university pleaded guilty for not reporting hundreds of thousands of dollars in foreign income on his federal tax returns, in relation to his involvement in the Thousand Talents Program, a Chinese-government talent recruitment program.⁶ This case came to light after NIH reviewed the researcher's grant proposals and became concerned that he had failed to disclose, among other things, foreign research activity.⁷

My testimony today summarizes the findings in our December 2020 report on foreign influence in federally funded research, as they relate to the NIH. Accordingly, this testimony discusses (1) conflict of interest policies and disclosure requirements at NIH that address potential foreign influence, (2) mechanisms to monitor and enforce policies and requirements, and (3) the views of selected stakeholders on how to better address foreign threats to federally funded research. For the report, we reviewed relevant laws, regulations, federal guidance, conflict of interest policies and requirements and interviewed agency officials, university

⁵Department of Health and Human Services, National Institutes of Health, "Dear Colleague" letter to university and academic medical school officials (Bethesda, Md.: Aug. 20, 2018). According to the Office of Science and Technology Policy (OSTP), a government sponsored talent recruitment program is an effort directly or indirectly organized, managed, or funded by a foreign government to recruit science and technology professionals in targeted fields. OSTP further noted that some countries sponsor such programs for legitimate purposes, but programs sponsored by other countries include language that creates conflicts of interest for researchers, such as by transferring U.S. funded work to another country. The White House Office of Science and Technology Policy, *Enhancing the Security and Integrity of America's Research Enterprise*, (Washington, D.C.: June 2020).

⁶Department of Justice press release, *Former Emory University Professor and Chinese "Thousand Talents" Participant Convicted and Sentenced for Filing a False Tax Return*, (Washington, D.C.: May 11, 2020) available at <https://www.justice.gov/opa/pr/former-emory-university-professor-and-chinese-thousand-talents-participant-convicted-and>. According to a Senate subcommittee report, the Thousand Talents Plan, launched in 2008, incentivizes individuals engaged in research and development in the United States to transmit the knowledge and research gained to China in exchange for salaries, research funding, lab space, and other incentives. United States Senate, Permanent Subcommittee on Investigations, *Threats to the U.S. Research Enterprise*.

⁷This researcher worked simultaneously at Emory University performing federally funded biomedical research, and at two Chinese universities performing similar research. The agency's review prompted the university, and later federal law enforcement, to investigate the matter, which revealed the filing of false tax returns.

officials, and researchers about agency and university conflict of interest policies and disclosure requirements.

While this testimony focuses on the actions taken by NIH on this topic, our report reviewed the top five agencies which together accounted for almost 90 percent of all federal research and development expenditures at universities in fiscal year 2018—the Department of Defense, the Department of Energy, the National Aeronautics and Space Administration, NIH, and the National Science Foundation. We also selected 11 universities which received over \$500 million in combined research grant funding in fiscal years 2018 and 2019 from two or more of the five selected agencies. Additional information on our scope and methodology is available in our December 2020 report. Our work was performed in accordance with generally accepted government auditing standards.

Background

Federal agencies that fund research have a strong interest in ensuring that the underlying research is scientifically rigorous and free of bias such as foreign influence. Two tools that agencies may use to address foreign influence are conflict of interest policies and disclosure requirements, such as foreign affiliations and current and pending research support. Among other things, conflict of interest policies help to guard against the researcher's financial interests or conflicts in the design, conduct, and reporting of federally funded research. Agencies may also require researchers to disclose information about their affiliations, associations, and activities which may indicate potential non-financial conflicts, such as conducting the same research for both the U.S. federal government and a foreign government.

In May 2019, the White House Office of Science and Technology Policy's (OSTP), National Science and Technology Council, established the Joint Committee on the Research Environment (JCORE) to address issues related to the safety, integrity, and productivity of the research environment, including balancing an open research environment with national security concerns.⁸ The JCORE Subcommittee on Research Security focuses on developing (1) appropriate and effective risk management for federal agencies and research institutions; (2) consistent, coordinated, and effective outreach to and engagement with academic and research institutions; (3) coordinated guidance for federal

⁸Specifically, OSTP documents noted that JCORE will examine administrative burdens in federally funded research; integrity in research; safe, inclusive, and equitable research settings; and open research environments balanced with security.

agencies; and (4) recommendations for best practices for academic and research institutions. This committee has worked closely with federal grant-making agencies, security agencies, and the research community to develop guidance on addressing foreign threats.

In January 2021, as part of the initiative, the JCORE Subcommittee on Research Security released guidance for research organizations on protecting America's research enterprise. This document serves as a complementary document to the National Security Presidential Memorandum 33 (NSPM-33), which was issued on January 14, 2021 directing actions to strengthen protections of U.S. government supported research and development against foreign government interference and exploitation. Both the guidance document and the memo included substantially similar definitions related to conflicts of interest.⁹

Conflict of interest (financial conflict of interest): A situation in which an individual, or the individual's spouse or dependent children, has a financial interest or financial relationship that could directly and significantly affect the design, conduct, reporting, or funding of research.¹⁰

Conflict of commitment (non-financial conflict of interest): A situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities. Many institutional policies define conflicts of commitment as conflicting commitments of time and effort, including obligations to dedicate time in excess of institutional or funding agency policies and commitments. Other types of conflicting obligations, including obligations to improperly share information with, or withhold information from, an employer or funding agency, can also

⁹These definitions are similar to those previously shared by the JCORE Subcommittee on Research Security in June 2020. The White House Office of Science and Technology Policy, *Enhancing the Security and Integrity of America's Research Enterprise*, (Washington, D.C.: June 23, 2020).

¹⁰*Presidential Memorandum on United States Government Supported Research and Development National Security Policy*, National Security Presidential Memorandum 33, (Jan. 14, 2021). Unless otherwise noted, when discussing conflicts of interest in this report, we are referring to both financial conflicts of interest and non-financial conflicts of interest (also referred to as conflicts of commitment). The memorandum's definition does not include the term "financial conflict of interest."

threaten research security and integrity, and are an element of a broader concept of conflicts of commitment.¹¹

NIH's Policy and Disclosure Requirements Address Financial Conflicts of Interest but Do Not Address Non-Financial Conflicts

In our December 2020 report, we found that NIH has an agency-wide conflict of interest policy that requires researchers to provide certain information to the university as part of the grant proposal process. NIH's policy focuses on financial conflicts of interest, specifies which financial interests should be reported to the university, and requires universities to mitigate any conflicts.¹² In addition, the policy requires universities to develop their own conflict of interest policies, notes specific requirements for identifying conflicts of interest, and includes guidance for universities on mitigating such conflicts, among other things.

NIH's conflict of interest policy does not specifically mention foreign financial interests—including whether such interests should be reported. NIH established its policies in the mid-1990s, when the threat of foreign influence in research was not an issue. NIH officials explained that they require researchers to disclose all financial interests, which, in their view, refers to both domestic and foreign interests.

Furthermore, NIH requires researchers applying for grants to disclose information as part of the grant proposal process. Such disclosures could be used to determine if certain conflicts exist. Specifically, NIH requires grant applicants to provide biographical details for key personnel conducting the research (such as education and professional appointments), information on other research support (such as outside funding or material support), and information on foreign components of the research, such as foreign partnerships or activities outside the United States (see table 1 for disclosure requirements used by NIH for grantees). NIH officials noted that they primarily use disclosures to determine the capacity of the researcher to perform the proposed research, identify

¹¹Presidential Memorandum on United States Government Supported Research and Development National Security Policy, National Security Presidential Memorandum 33. The memorandum's definition does not include the term "non-financial conflict of interest."

¹²While this testimony and associated report focus on the conflicts of interest associated with grantees, GAO has previously reported on NIH's internal scientific integrity policy which describes the importance of avoiding conflicts of interest and cites federal regulations and additional agency guidance on ethical conduct for NIH employees. GAO, *Scientific Integrity Policies: Additional Actions Could Strengthen Integrity of Federal Research*, GAO-19-265. (Washington, D.C.: April 4, 2019).

redundant funding of the same research, and assess the risk of foreign influence.

Table 1: National Institutes of Health Disclosure Requirements for Grantees, as of December 2020

Category	Required information
Researcher biographies	<ul style="list-style-type: none"> Baccalaureate or other initial professional education, such as nursing. Postdoctoral, residency, and clinical fellowship training, as applicable. Relevant publications and positions held, concluding with the present position.
Current and pending support	<ul style="list-style-type: none"> Other support to include all financial resources, whether federal, non-federal, commercial, or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.
Foreign components of research	<ul style="list-style-type: none"> Activities outside the United States or partnership with international collaborators. Provide a justification if the applicant organization is a foreign institution, or if the project includes a foreign component.

Source: GAO presentation of information in agency documents. | GAO-21-523T

Our December 2020 report also found that NIH's agency-wide policy focuses on financial conflicts of interest, but it does not define non-financial conflicts. Such conflicts may include foreign academic appointments and in-kind support—for example, in the form of laboratory space or materials—which can be provided by foreign entities.¹³ Government-wide guidance governing the grants process does not

¹³NIH's Grants Policy Statement indicates that before an award is made, NIH staff will review disclosures of current and pending support, which the agency terms as "other support," to determine whether there is "scientific, budgetary or commitment overlap." Commitment overlap is an example of non-financial interest, although it is not defined as such in NIH policy.

specifically mention or define non-financial conflicts, nor does it mention disclosing foreign affiliations, associations or activities.¹⁴

According to OSTP officials, it is important for agencies to define non-financial conflicts and address the issue in their policies in order to identify and mitigate undue foreign influence. Our December 2020 report recommended that NIH should update its conflict of interest policy to include a definition on non-financial conflicts, such as the one developed by OSTP, and address these conflicts, both foreign and domestic. NIH concurred with our recommendation and has recently updated its grant application forms and instructions to require that applicants more fully disclose non-financial interests, including foreign activities and resources. However, NIH has not yet updated its conflict of interest policy. Taking this action will help ensure uniformity across its policy and guidance documents and better position NIH to receive complete and accurate reporting on potential non-financial conflicts.

NIH Relies on Universities to Monitor Conflicts and Has Written Procedures for Enforcing Requirements

In our December 2020 report, NIH officials stated that they rely on universities to identify and monitor financial conflicts of interest. Specifically, NIH requires universities to have a conflict of interest policy, determine whether a financial interest constitutes a conflict, and develop mitigation plans if the university determines that a conflict exists. If a conflict exists, NIH regulations also require universities to provide financial conflict-of-interest reports to the agency that include specified information about university mitigation plans to address such conflicts.¹⁵ According to NIH officials, the agency reviews the financial conflict-of-interest reports to ensure completeness and to determine whether the mitigation plan sufficiently alleviates the conflict.

In addition, NIH collects information on non-financial interests that could be used to determine potential conflicts, such as foreign collaboration. The foreign collaboration can be with researchers or outside organizations involved in the project or those that provide new sources of

¹⁴While 2 C.F.R. part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, does not include these requirements, NSPM-33, issued on January 14, 2021, among other things, requires the heads of research funding agencies to, within twelve months of the date of issuance and consistent with applicable law, establish policies requiring the disclosure of specific information related to potential conflicts of interest and non-financial conflicts of interest (which it refers to as conflicts of commitment) from participants in the federally funded research and development enterprise.

¹⁵42 C.F.R. § 50.605(b)(1)-(3).

support. NIH collects this information through its annual Research Performance Progress Reports. Through our review of agency documents and interviews with agency officials, we found that NIH also periodically collects information on the progress of funded projects through these progress reports. NIH officials told us that they use this information to detect potential foreign influence by identifying discrepancies between progress reports and other sources, such as publications.

In our December 2020 report, we also found NIH has written procedures detailing how it manages allegations of failure to disclose required information, such as foreign affiliations. In interviews, NIH officials told us that there have been instances where researchers have failed to disclose financial or non-financial information, as required. Specifically, as of September 2020, NIH had identified 455 researchers of possible concern and worked with the Department of Justice to initiate investigations of six criminal complaints. NIH has also referred 32 cases to the Office of the Inspector General (OIG) within the Department of Health and Human Services (HHS). NIH officials explained that they can learn about allegations of failure to disclose required information through universities, tip lines, other agencies (including the Federal Bureau of Investigation), or internal program offices.

In our review of NIH's written procedures, we found that they outline the investigative process, establish roles and responsibilities, and provides flexibility for each case. For example, NIH's written procedures provide details on the routing of allegations to different groups within the agency, provide options for administrative actions, and note that each allegation should be evaluated individually and that NIH actions should be commensurate with degree of noncompliance.

According to officials and agency documents, NIH can take a range of administrative or enforcement actions when an allegation of failure to disclose required information has been substantiated. These actions include asking the researcher's university to open an investigation, suspending the grant, or referring the case for prosecution.

NIH Has Taken Steps to Address Foreign Influence in Federally Funded Research Identified by Stakeholders

As we reported in December 2020, agency officials, university association representatives, university administrators, and principal investigators noted several opportunities to improve agency responses to foreign influence in federally funded research.¹⁶ NIH has taken steps to address foreign influence in the areas stakeholders identified, as detailed below.

Harmonize grant proposal requirements. All stakeholders noted the benefit and importance of harmonizing grant requirements to ensure clear understanding across all parties involved in addressing the risks of foreign influence.

NIH has taken steps to harmonize some aspects of the grant proposal process, according to officials. For example, NIH and NSF collaborated with the Federal Demonstration Partnership in 2019 to develop SciENcv (Science Experts Network Curriculum Vitae), a tool that lets researchers prepare biographical information for grant proposals to either agency. Representatives from university organizations and university administrators noted they support the idea of uniformity and the shared standard format, so all users are using the same form to disclose outside support and other affiliations.

Reduce burden on universities. Agency officials, university association representatives, and university administrators also noted that harmonizing and standardizing agency requirements for disclosing financial and non-financial interests could help reduce the burden on universities associated with ensuring researchers meet requirements for grants from multiple agencies.

NIH participates in interagency efforts with JCORE to develop guidance on reducing burdens on applicants and universities by streamlining the application processes for grantees.

Better communicate identified risks. In interviews, university associations, university administrators, and principal investigators said agencies should better communicate the specific risks of foreign influence they have identified to universities. University administrators told us they would like more guidance on steps agencies recommend to identify, analyze, and mitigate threats of foreign influence.

¹⁶According to NIH, a principal investigator is the researcher on a grant identified as having the appropriate level of authority and responsibility to direct the project or program supported by the grant.

NIH has taken some steps to communicate identified risk of foreign influence. For example, in 2018, it issued a report focused on complications of foreign influence in the extramural research community. The report highlighted specific concerns of foreign government programs that recruit scientists to capitalize on U.S.-funded research. In addition, the report also included recommendations to NIH and universities on raising awareness of foreign influence and safeguarding research integrity, among other things.¹⁷

Disclose participation in foreign talent recruitment programs. Agency officials, university associations, university administrators, and principal investigators, expressed a wide range of views on whether researchers should be allowed to participate in foreign talent recruitment programs. In addition, principal investigators in six out of eight universities we interviewed did not know what these talent recruitment programs were or how to identify them.

In interviews, NIH officials told us they have observed a systematic failure to disclose by participants in certain foreign talent recruitment programs. Further, these officials noted they have observed that some researchers readily disclose funding from some foreign sources, such as the Wellcome Trust, which is located in the United Kingdom, while at the same time not disclosing funding from Chinese sources.¹⁸ NIH officials also stated that, based on their review of contracts with some foreign funding sources, such as talent recruitment programs, these contracts expressly prohibit the researcher from disclosing the funding or their participation in the program to NIH or any other U.S. grant-making agency.

Provide training on foreign risks. Representatives of university associations suggested that agencies provide training to principal investigators on foreign influence in federally funded research. They said such training could improve universities' ability to identify and mitigate potential risks associated with their researchers.

¹⁷National Institutes of Health Advisory Committee to the Director, *ACD Working Group for Foreign Influences on Research Integrity*, (December 2018).

¹⁸The Wellcome Trust is a politically and financially independent foundation in the United Kingdom supporting health and science researchers. As previously noted, The Thousand Talents Plan, launched in 2008, incentivizes individuals engaged in research and development in the United States to transmit the knowledge and research gained to China in exchange for salaries, research funding, lab space, and other incentives.

NIH issued a notice in March 2018 to the extramural research community entitled Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests, to help clarify which foreign financial sources should be reported. In the memo, NIH reminded researchers to report financial support received from a foreign government or foreign institution of higher education.

In conclusion, at a time when there is growing concern about threats of foreign influence, taking the next step to fully implement our recommendation to define and address non-financial conflicts of interest in its policy documents could better enable NIH to receive complete and accurate reporting from universities. This in turn, can strengthen the agency's efforts towards addressing non-financial conflicts, including those involving foreign influence.

Chair Murray, Ranking Member Burr, and Members of the Committee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this testimony, please contact Candice N. Wright, Acting Director, Science, Technology Assessment, and Analytics. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement.

In addition to the contact named above, Farahnaaz Khakoo-Mausel (Assistant Director), Caitlin Dardenne (Analyst-in-Charge), and Ben Shouse made key contributions to this testimony. Other staff who made contributions to the report are identified in the source product.

The CHAIR. Thank you very much to all of our witnesses. We are now going to begin a round of five-minute questions of our witnesses. I ask my colleagues to please keep track of your clocks. Stay within those five minutes. I will remind all of us we have a series of votes beginning at 11:30 a.m. We want to make sure we can be as timely as possible. So, for any Senators who want to participate today, make sure you are available when your time slot is ready for you.

With that, I will start with Dr. Lauer. We know scientific discovery is enhanced when scientists from a variety of backgrounds, including from foreign nations, work together to solve complex biomedical research challenges. This diverse workforce has never been more important as the world combats the COVID-19 pandemic.

However, the failure of a small number of researchers to properly disclose relevant financial and non-financial affiliations can jeopardize NIH's ability to make informed funding decisions. Talk to us about why failing to disclose participation in a foreign talent program rather than participation itself threatens the integrity of our Nation's biomedical research enterprise.

Dr. LAUER. Thank you, Senator. I can give you a few examples that I think illustrate what we are seeing. One is scientists who, unbeknownst to the NIH and to his own institution, had a laboratory in China and was basically being funded by the Chinese Government to do the exact same work that we were funding. Had we known that the same work was being funded, this fund to support the scientists to do this particular research, we never would have funded this grant and some other grant from another scientist would have been funded. So, one problem is that we are making incorrect funding decisions and deserving, honest scientists who should be funded are not being funded.

A second example is, we have seen several cases now of this, quite a few actually, where a scientist has a business, let's say in China, and that business is basically leveraging work that has been paid for by NIH funded research. That is a clear-cut conflict of interest. And had we known about that, we might have decided not to fund the grant because that kind of a conflict would be unmanageable. At the very least, something would have had to happen. So that is a second problem. And then the third is exactly, as you say, Senator, is a problem of trust.

We have seen scientists who have told their American institutions and the NIH that they are spending 100 percent of their time here in the US, when in fact they are spending 50 to 60 percent of their time in China. So, they are lying about how they are spending their time. And that kind of blatant lie affects the credibility and the integrity of the entire enterprise.

The CHAIR. Thank you very much for that. We appreciate it and take that into consideration. Thank you. You know, in recent years, the Government Accountability Office has worked really hard to provide recommendations to help agencies, including NIH, identify, prevent, and reduce undue foreign influence in federally funded activities. With respect to NIH, the GAO concluded the greatest need is addressing non-financial conflicts of interest. Ms. Wright, explain to us why it is important to address non-financial conflicts of inter-

est or conflicts of commitment to prevent and reduce instances of undue foreign influence in biomedical research.

Ms. WRIGHT. Certainly. And these types of nonfinancial conflicts can take shape in many ways in terms of appointments that scientists may have, or it might provide them an opportunity to get access to critical U.S. research that can then be diverted.

It may also take shape in the form of being able to get access to biological materials or other sensitive information, but that, in doing so, can compromise the integrity of U.S. research. Making sure, that U.S. biomedical research is protected and is not being exposed to foreign involvement. There is really an important message there in terms of not just identifying the financial conflicts, but also the non-financial, because those are also great risks, and we just don't see a lot of attention being paid to the non-financial conflicts at this point. And I would say that is something that we found not just with NIH, but certainly the other agencies that we included in our review.

The CHAIR. Thank you. And I will reserve the balance of my time in order to get to as many Senators as possible.

Senator Burr.

Senator BURR. Thank you, Madam Chair. Dr. Lauer, NIH has taken a number of steps to address foreign actors, and much of that was highlighted by Ms. Wright's testimony. What are the biggest gaps today in NIH's capabilities to address these threats?

Dr. LAUER. I think one big problem, Senator, is that the threat is significant, exactly as you say. We have identified over 500 scientists of concern. So far we have reached out to institutions and, over 200. Each of these require a tremendous amount of work to figure out what exactly has been happening and to work carefully with the institution to figure out what has been going on. In addition, we work very closely with our partners, including ONS, OIG, the Department of Justice. I think one of the biggest challenges that we have is simply the challenge of the workload of dealing with a very large number of cases.

Senator BURR. Dr. Lauer, do you have any idea how many employees at NIH have security clearance?

Dr. LAUER. I don't know the exact number, but it is very few.

Senator BURR. Yet to understand fully the threat, you can't fully understand that without either full security clearance or some type of limited security clearance, which we did with academic institution, Senator Warner and I, on this issue and other issues and what we found was startling. And I think it gets to the heart of this next question, Ms. Aguirre. Whose responsibility is it to ID the researchers who have falsified their foreign connections in their grant applications? Is it ONS? Is it the institution? Is it the FBI? Is it at NIH, or is it the IG? Who is responsible?

Ms. AGUIRRE. Thank you. We all work together, I would say. Dr. Lauer has been working a tremendous amount and passes on daily, really, a tremendous amount of information to all the entities you mentioned. So, it is ONS, OIG, FBI, all the—it is a very large amount of information sharing.

Everything he does, which is a huge volume, gets passed to the others. Likewise with the rest of us, as far as I can tell. If something comes across our radar, we pass it on. And then same with

the law enforcement entities to the extent that they can based on their investigation.

Senator BURR. I understand if it comes across our radar, but I am going to go to Ms. Wright's testimony where she said in our December 2020 report, NIH officials stated that they rely on universities to identify and monitor financial conflicts of interest and I believe confidently that we have got a mechanism in place or protocol in place to follow through when we think there is a problem.

The question is, what do we have to identify the problem? Because when Senator Warren and I met with institutions, they basically said, we believe that when the U.S. Government gives a visa to these researchers that we have got on a research branch, they have already completed the security clearance form, which is 100 percent false.

Institutions have told us, in many cases, these same individuals who we might have concerns about are their top researchers, so they are going to be the least likely to turn in their top researchers. How do we solve this?

Ms. AGUIRRE. Well, there are several avenues we are working on in collection—in conjunction with the NIH and the law enforcement and other agencies to raise awareness. Extramural, I mentioned. In the last year, we have had an ONS liaison from the FBI out there talking to academia, private institutions, other Government agencies. But we are also working with the National Counterintelligence Task Force to come up with an awareness program that extramural entities can understand.

You mentioned about security clearances and how it is really—it is very hard to understand the real issue without having a clearance and having access to that information. And so, we are trying to come up with an unclassified way to get that message across that. That is one way. We also coordinate with other agencies. For example, you mentioned the visa process.

We do coordinate, for example, with other—with the IC, with CBP on their J1 visa when it is relevant to our activities. And that scientists coming in, for example, to NIH entities, there is a coordination program there. So, it is about enhancing our cooperation within HHS, outside of HHS, and an awareness program.

Senator BURR. Thank you, Madam Chair.

The CHAIR. Thank you.

Senator Casey.

Senator CASEY. Thank you, Chair Murray. I want to thank our panelists for their testimony and for their presence at the hearing. I want to start with Acting Director Aguirre, and I hope I am pronouncing your last name correctly. Aguirre?

Ms. AGUIRRE. That is fine. I go by Aguirre, but Aguirre is fine.

Senator CASEY. Aguirre, I am sorry. Sorry about that. But Director Aguirre, in recent testimony by the American Hospital Association before the Senate Homeland Security and Governmental Affairs Committee revealed that the expansion of network connected technologies to manage pandemic response has increased vulnerabilities in the hospital networks.

The Hospital Association described concerns they have about cyber-attacks that steal COVID-19 related research, including both treatment protocols as well as vaccine data. Can you please de-

scribe the unique threat that both hospitals and health care systems face when it comes to cyber-attacks, especially those which are a nation-state sponsored which seek to steal both medical research and innovation?

Ms. AGUIRRE. Sir, I am not an expert in that area. We do coordinate heavily with our Office of the Chief Information Officer who is, in my understanding, the lead for that for us. And so, we support them from our angle of a counterintelligence support angle. But I am not an expert in the area that you are talking about.

Senator CASEY. Well, we will do some follow-up. Thanks very much for the work that you do, because we have heard a good bit about this in Pennsylvania and I know other states as well. I wanted to turn next to Dr. Lauer. I know we don't have a lot of time. I want to make sure I at least get my question for Dr. Lauer. There is a long predicate to this question. Doctor. I want to start by thanking you for your work and the work you do to provide both outreach and guidance on best practices to research institutions.

The January 2021 report by the—I am sorry, in the January 2021 report, the Joint Committee on the research environment, they recommended that universities within the biomedical research enterprise bolster their cybersecurity, put teams in place to enhance protection of sensitive material, and provide training to their faculty. However, the December 2020 GAO report on agencies foreign influence policies recommends relieving the burden on universities and universities themselves have spoken out about the need for consultation, consultation in developing both directives and recommendations.

I worked successfully in the process where the National Defense Authorization Process, I worked to designate an academic liaison within the Defense Department to provide both training and guidance on sensitive but unclassified data to academic research institutions that carry out critical defense research. So, there is no doubt that there is overlap between the universities that are part of the biomedical research enterprise and those that conduct DOD research.

Given that much of the research carried out by universities is both unclassified but sensitive, what support does NIH and HHS offer that is tailored specifically to academic institutions?

Dr. LAUER. Thank you, Senator. So, we are working closely—we recognize these tensions. On the one hand, assuring security, assuring protection of innovation, assuring intellectual property, both big IP and small IP, but at the same time keeping administrative burden to a minimum. And we recognize that there is a balance. And the difficult part is to try to find the right balance. We are working very closely with OSTP. And as you say, I am very happy that you noted the report.

We are working very closely with OSTP to do this in as coordinated and cohesive way as possible, and also to achieve the level of consultation and interaction, exactly as you say. We have engaged in a number of outreach programs that are targeted toward biomedical research institutions and biomedical researchers.

We had a very successful one at the University of California that involved over 2,000 people. We had a more recent one in upstate New York. We had another one in Utah. And we anticipate having

a number of these types of outreach events, among other things, in the months ahead.

Senator CASEY. Thanks very much.

The CHAIR. Thank you.

Senator Marshall.

Senator MARSHALL. Good morning, Chair. Thank you for having us today. And I want to just start by thanking Chair Murray and Ranking Member Burr for holding this hearing and emphasizing the importance to protect biomedical research and federally funded intellectual property. And if I could just make one point.

I hope that both sides of the aisle apply the same principles here to private property, intellectual property of U.S. innovation in pharmaceutical and medical device manufacturing in that same regard, especially with our trade agreements and policies we develop in this prestigious chamber, and my concern about waiving intellectual property and just protecting our FDA approved innovation, I have always said that innovation will do more to drive the cost of health care down than any legislation we can ever write if we just keep the Federal Government out of the way.

My first question would be for Ms. Aguirre. Aguirre—Ms. Aguirre. Sorry, I got that right. And we recently learned that an Ohio man was sentenced to 33 months in prison from stealing valuable research from a children's hospital for his own financial gain incentivized by the Chinese Communist Party. This is just one example. We certainly have had similar examples in Kansas and at Kansas State University was stealing of our intellectual property. How is HHS partnering with the private sector to develop new solutions?

Ms. AGUIRRE. Thank you. From our perspective, we—I mentioned the extramural awareness program that we are working, and so over the last year, we have been out there, a member of our staff who is on detail from the FBI has been out there with other Government entities, academia, private institutions, within our agency, other agency partners in an awareness campaign, safeguarding science awareness and bio-economy awareness.

We are also, I mentioned, working on an interagency way with the National Counterintelligence Task Force, which is headed by the FBI, but it is multi-agencies involved, to come up with a larger plan to be able to spread awareness out there outside of Government. And I don't know—apologize, Dr. Lauer may have something to add as well.

Senator MARSHALL. Dr. Lauer, my follow-up question is probably kind of the same part of this, but in 2018, Dr. Collins, Director of the NIH, basically made a plan. He said this is what we need to do, a plan of action. And I guess maybe just an update on that plan of action and how are we measuring success? What metrics are we following to say that we are being successful, and we are going in the right direction?

Dr. LAUER. Thank you, Senator. Yes, we have absolutely followed through on what Dr. Collins said in his letter. One way that we measure success is by results that we have seen when we identify concerns and see whether or not there are consequences. There have been over 100 scientists who have been removed from the NIH ecosystem through a variety of ways, resignations, termi-

nations, premature retirements, or internal Departments. Also 34 or so referrals to the OIG. Mr. Cantrell mentioned some successful prosecutions and several settlements that have been made.

Another measurement of success is self-disclosures. We are now seeing a number of institutions that are discovering problems on their own because they know that this is a problem that they are looking. Perhaps the one that is most well-known publicly was Moffitt Cancer Center. They discovered that their own CEO had a talents' contract and that led to his resignation, as well as the resignation of five other senior people.

Over 10 percent of the cases that we are aware have come to our attention because of self-disclosure. So, I think that is another important metric of success.

Senator MARSHALL. Well, the Moffitt Cancer Center sure takes me back in memories of place I trained at. And Dr. Dennis Cavanaugh was one of my great mentors as well. I guess this question is also, probably back to the NIH, is culturally in this country, medical research, I am a physician, if people were stealing someone else's research, you would be ashamed.

You would lose your professorship. Just—in other countries is just the culture that it is okay to steal intellectual property. Is there a big cultural difference why people keep trying to rob the bank from us? I just don't even understand it culturally. And what countries are kind of leading the charge here and trying to steal our intellectual property?

Dr. LAUER. Senator, that is a great question. There was a couple of interesting articles in Nature just this past month, or I think it was in March about problems in China with scientific research integrity and how our leaders in China recognize that they have a problem. One example are these paper mills that generate hundreds of fake papers later and have to be retracted. And unfortunately, some of those papers are written by physicians who are eager to achieve academic advancement without doing real work. And so, it should be noted that the leadership there is recognizing that they have a very serious problem, and they need to work on it.

Senator MARSHALL. Thank you so much and I yield back.

The CHAIR. Thank you very much. And I would just ask any Senators who do want to ask questions today to either come to the Committee hearing room or let us know online as quickly as possible. We want to make sure anybody who does want to ask a question makes themselves available fairly quickly here.

With that, Dr. Lauer, NIH and the HHS Office of Inspector General have investigated an increasing number of cases of potential undue foreign influence over the past few years. The HHS Office of Inspector General has issued several reports on its findings. How have the recommendations that are outlined by the HHS OIG and adopted by NIH help the agency reduce foreign influence in biomedical research?

Dr. LAUER. I think they have helped a great deal. We have a very strong working relationship with OIG, both on the audit side as well as on the investigation side. Mr. Cantrell mentioned a couple of the investigations that led to success, the doctor who lied on his applications and was essentially siphoning money to support

his laboratory in China, or siphoning expertise, and also the research institute that lied and had to settle in a False Claims Act.

I think that our discussions between our respective agencies, OIG and NIH, have helped us both to be more successful in addressing this problem and understanding the nature of the risks, and also leveraging each other's expertise and resources.

The CHAIR. Thank you. And Mr. Cantrell, what further steps do you feel we still need to be taking to reduce foreign influence on our biomedical research?

Mr. CANTRELL. Thank you for the question. As mentioned, NIH has taken our recommendations and made significant progress and virtually all of them toward adopting and implementing our recommendations, but I think there is still work to do. There is still progress to be made on some of the recommendations.

This is a continuous—this has to be a continuous monitoring and learning situation so that all the different facets of responsibility and oversight that need to be built into the system, whether it be at NIH, whether it be research—academic institutions, or whether it be at the level of the peer review or the principal investigators, each layer has to be both educated about the issue, as we have discussed already in this hearing, as to understand clearly what the requirements are, and there has to be transparency in that reporting of potential conflicts of interest foreign or otherwise.

I think it is a big job with multiple actors requiring action. But I think it is critical that NIH and our office and ONS continue to look toward solutions that both protect the research in the physical world through our work, but also in the cyber world. That is another area where there is definitely a need for a continued focus to protect our data from theft via cyber.

The CHAIR. I think we have lost your sound, Mr. Cantrell.

Mr. CANTRELL. I apologize, can you hear me now? My Internet connection—I am in the office, but unfortunately it must have—it is going down.

The CHAIR. Okay, I think we will let your connection get reestablished and well, while you are doing that, I am going to turn to Senator Hassan for her questions.

Senator HASSAN. Well, thank you, Madam Chair, and to Ranking Member Burr, and thank you to our witnesses for being here today. I wanted to start with a question to Dr. Lauer. In 2019, you appeared before another panel on which I sit, the Homeland Security Committee's Permanent Subcommittee on Investigations to speak about securing the U.S. research enterprise from China's talent recruitment plans. That hearing was part of our ongoing bipartisan work to prevent bad foreign actors from exploiting loopholes in our laws to steal U.S. based research and intellectual property.

I am encouraged to hear that there has been some progress since 2019, including the January report you mentioned on practices for strengthening the security and integrity of America's research enterprise. Can you expand on some of the key elements of that report? And I also want to just follow-up on what Senator Murray was asking about with regard to conflicts. Can you talk about the recommendations around disclosing conflicts of interest, including with foreign countries?

Dr. LAUER. Thank you, Senator. That particular—I do remember that hearing and that report, and I want you to know that report was extremely helpful, and we have distributed that report quite widely because we think that the information in there is quite pertinent. So, several things.

There were, I think, 21 identified recommended practices in the report, and obviously for different institutions with different kinds of interests, which ones would be most appropriate to them may vary. But there are recommendations. Some of them, perhaps the most important is that there should be strong communications within institutions, and also between institutions and in Federal agencies.

We provide a number of suggestions for how that specifically should be done. The report also described in detail, as you describe what is meant by different types of problems, conflict of interest, conflict of commitment, the problems of budgetary and scientific overlap, what is a foreign intelligence recruitment program, and why is a foreign intelligence recruitment program a problem. And we do address those in great detail. Thank you.

Senator HASSAN. Thank you very much for that answer. I want to move on to another question now to both Ms. Aguirre and Dr. Lauer. When the pandemic first hit, global sharing of the COVID-19 genomic sequence data helped to jump start the development of life saving vaccines and therapeutics.

More recently, sharing sequencing information has become critical to identifying and tracking new COVID-19 variants. This is just one example of how sharing scientific data can bolster our response to public health emergencies and accelerate research.

Ms. Aguirre and Dr. Lauer, how do we balance the need to share scientific data to improve public health on a global scale with the importance of mitigating National Security risks? And we can start with you, Ms. Aguirre.

Ms. AGUIRRE. Thank you. So, from our perspective as the counterintelligence lead, we rely on people like Dr. Lauer and the others to help us with that balance. You know, we are focused mostly on the risks and concerns, and it can look like everything is a problem. So, I don't want to take too much time here because I think Dr. Lauer will have the most thorough answer.

But from our perspective, we rely on those with that view, who know the importance of the large picture that not everyone is a bad actor, that we have to do this collaboration, that the science is very important. And so, from our perspective, we try to make sure that we don't get pigeonholed into thinking everything is bad, especially in the awareness programs. We want to raise awareness in the right way. And I will defer to Dr. Lauer now.

Senator HASSAN. Thank you.

Dr. LAUER. Yes, thank you. So genomic data sharing has been a critical part of science for at least the last 30 years. In 2015, NIH issued a genomics data sharing policy in which we deal with exactly this balancing the benefits of data sharing with the risk and particularly protecting the risks of research participants, individuals, groups, and the public trust. We have a very extensive and thorough process at NIH by which we review all data sharing requests. All data are identified. We have a process for making sure

that is being done correctly and that there is appropriate data quality.

Then every data request that comes in goes through an extensive review. Not every data requested that comes in gets approved. And then we have a follow-up process to make sure that there is no problem with compliance. As Ms. Aguirre would say, our data management problems, our data management incident, when we have a serious problem has only occurred in 0.1 percent of the projects that we have handled. So, I think this is a testimony to how well the process is working.

Senator HASSAN. Well, thank you very much. Thanks to all the witnesses, and thank you, Madam Chair.

The CHAIR. Thank you.

We will turn to Senator Braun.

Senator BRAUN. Thank you, Madam Chair. This question is for Ms. Wright. HSGAC Committee issued a report in 2019, Threats to The U.S. Research Enterprise, China's Talent Recruitment Plan, after the Committee examined China's propaganda efforts in U.S. colleges and universities. The report focused on foreign gift reporting and the lack of data collection that should be done by the Department of Education and other agencies.

While we have made progress in reporting, there still exists inadequate data sharing between these agencies and intelligence agencies posing a National Security threat. Do intelligence agencies receive the data they need in order to ensure National Security?

Ms. WRIGHT. Thank you, Senator Braun. So, I will say that is not an issue that GAO has explicitly looked at in terms of foreign gifts and what may be reported or tracked and monitored by the intelligence community. That being said, in terms of the work that we have looked at with regard to disclosures of financial conflicts and resources, we think that is really an important thing to be able to identify what resources researchers may be getting that could then pose these potential conflicts.

I will also perhaps just note that identifying the source of funding can be a challenge. We have certainly seen that in other work that GAO has done. And so, there is the importance of ensuring that there is broad information sharing and access to tools, and information and data bases that can be used to not just identify but perhaps also verify information that may exist with regard to gifts.

Senator BRAUN. Very good. One other question. The DOD and NIH make up the largest percentage of federally funded research, 41 percent and 26 percent, respectively. NIH is the largest public funder of biomedical research in the world and is a leader in medical discovery, globally. Researchers often apply for and receive both NIH and DOD grants for the same research.

Why doesn't the DOD require grant applicants and recipients to fully disclose those collaborations or affiliations with foreign entities or individuals, including the exchange of staff, data, or funding, a foreign employment appointment, or providing funding for a laboratory space and materials?

Ms. WRIGHT. On that issue, we certainly identified in our work that DOD, across the agency, across the Department, excuse me, did not have a policy in place to guide disclosures of conflicts of interest. Certainly, there is a lot of information, or focus I should say,

on financial conflicts but we also think nonfinancial conflicts are really important. One of the things that we heard from the Department at the time that we were doing our work is that they were waiting for the guidance from the Joint Committee on the Research Environment with regard to what steps the agency should be taking to make sure that there is proper disclosure of information, also what their conflict-of-interest policy should include.

We made a recommendation to the Department that they needed to ensure that they did develop an agency wide conflict of interest policy. We have not yet heard from them what steps they have taken since that report. They did concur with the recommendation and noted that they plan to take action, but we are waiting on the guidance or recommendations that came out of the Joint Committee on the Research Environment. We will continue to monitor that, as we do with all of our recommendations, and look to see what actions they take.

Senator BRAUN. Thank you.

The CHAIR. Thank you.

Senator Hickenlooper.

Senator HICKENLOOPER. Yes, thank you. I think I got myself on mute there by accident. Thank you all for being on this panel and clearly think this is of vital importance. I strongly believe that we need to prioritize research into automation and artificial intelligence, machine learning, go down the list. We do need to prioritize research into these issues to remain competitive, along obviously with the incredible progress we have made in our life sciences.

But this obviously is all of great interest to other companies as well, and in particular China. Ms. Aguirre, as we move forward and continue to prioritize these areas, what more do we need to do to, I don't know, to fortify, that is the right word, to fortify our federally funded research to ensure that our competitiveness, to assure our competitiveness and to secure our intellectual property as much as we possibly can?

Ms. AGUIRRE. Thank you. From my perspective, and I agree with what Dr. Lauer said earlier, I would say our largest challenge is the volume. I think, I see so much motivation in the various offices, in mine, in NIH, interagency, and it is the resources. I think there are great ideas in various ways for approaching this from many angles in an interagency way. And so, to me, it is, keep doing what everyone is doing, do more, and resources can be a constraint.

Senator HICKENLOOPER. Yes. I wholeheartedly concur. Does anybody else want to chime in on that? You don't have to. The other part of that is the other side of the coin there. I just finished reading Walter Isaacson's wonderful book on Jennifer Doudna called *The Code Breaker*. And it really is an exciting description of science and how it can cross international boundaries to great beneficial effect.

As we become very aware of the strategic responsibilities around these frontiers of science, how do you—how do we safeguard this intellectual property for our country, but at the same time not lose that essential—the innovation and the excitement that comes from international collaboration? I guess—and any of you can answer that, I am sorry.

Dr. LAUER. Alright. Well, I will start. So, I previously was a practicing scientist and a practicing physician, and I had the great pleasure of participating in international research. And I completely agree with you, Senator. So, I think that part of this is keeping in mind there is a difference between dishonesty and collaboration.

Collaboration is not secret offshore bank accounts. It is not stealth employment. It is not duplicative grants. It is not telling to disclose important financial conflicts of interest. It is not having two jobs at once. It is not breaking the rules on peer review. None of that is collaboration. That is cheating, dishonesty, lying, call it what you want.

I think this is an important part of our messaging here, which is that legitimate international collaborations are great. I have experienced them myself. This is something that is extremely important for science and medicine to move forward, but that is different from lying, cheating, and stealing.

Senator HICKENLOOPER. Anybody else want to chime in on that?

Ms. WRIGHT. Certainly, I will just jump in by saying that I think it is really important too to understand and emphasize the importance of scientific integrity principles and making sure that everybody is really coming to this issue with those same values and principles in mind. We have done certainly quite a bit of work at GAO looking at scientific integrity across Federal agencies and have some other work ongoing.

I really just think embracing and emphasizing those kinds of principles that talk about the foundations that are important, like trust, like transparency, as was mentioned earlier, are really key to espousing those values so that you can have that balance between collaboration, but also making sure that we are protecting research. Thank you.

Senator HICKENLOOPER. I agree completely. Great. You guys are terrific, and I want to thank each of you for your public service, because you are right at the core of so much of what is really important, so much of what is happening. Anyway, I will yield the rest of my time. Thank you so much.

The CHAIR. Thank you.

Senator Cassidy.

Senator CASSIDY. I apologize if I am asking questions others have asked. Splitting between three committees. Dr. Lauer, the All of Us Precision Medicine Initiative collecting data from 1 million U.S. residents for genetic diseases, it is my understanding that a lot of this research, a lot of the genetic testing is done in China. Similarly, I am told that like 23 and Me and others, I don't know if it is 23 and me in particular, but some of those that do direct consumer marketing again have their genetic testing done in China, and then universities are getting their genetic testing done either in China or by a company with Chinese links.

Again, I apologize if someone else has asked this, but can you kind of give me a flavor of what we are doing to keep this incredibly sensitive data from being misused or even absorbed by those folks in China?

Dr. LAUER. Senator about the specific programs, I would have to follow-up with you, because I don't know the exact details of where

the genomic sequencing is being done. We do have an extensive genomics sharing, genomics science policy, which has evolved over the decades and most recently was put out in 2015, where we try to balance exactly what the tensions that you are suggesting.

On the one hand, we want to enhance scientific progress. On the other hand, we want to make sure that there are no—there is no misusing the data. That data is being used for exactly what it is supposed to be used for. That is not being shared inappropriately with others. And that individuals, groups, U.S. public trust are appropriately protected.

Senator CASSIDY. Do you agree that if knowing that the NIH—I gather the NIH is doing all of your genomic testing onsite?

Dr. LAUER. Again, I would have to follow-up with you on the details. Some of the genomic testing is onsite. Some of it is happening at specific sequencing centers around the United States that have expertise in doing this. I would say, it is fair to say it is a mix.

Senator CASSIDY. But none of it is done abroad, I guess the thrust of my question. Would you also agree, though, that if some of this is being done in China, say University, X, Y, Z University is having, is outsourcing their genetic testing, or if a direct-to-consumer entity is outsourcing their genetic testing to China, that this could be problematic?

Dr. LAUER. It might be. What we do is any time that a significant part of NIH funded research is occurring outside of the United States, we call that a foreign component and we go through a formal process to make sure that appropriate steps are being taken.

Senator CASSIDY. That is what I am asking, though. It is not necessarily the results of the testing, but rather the testing itself. In this case, as we both know, if you correlate genetic material with others, it gives you a big leg up in terms of the future of medicine, the future of understanding an individual's health status, and in fact, their blood relatives health status. So, I am asking not so much the results of the testing, but rather the actual test itself, if my genetic code is being deposited in some place which does not have protections of privacy that the U.S. takes for granted.

Dr. LAUER. Yes, I hear you, Senator, I think that is part of the reason why we want to make sure, for example, that all the data that we use as part of our genomic data sharing is de-identified because the protection of the individual is something that is of key importance.

Senator CASSIDY. Let me go back to my question. For some reason, I guess I am not making it clear. Would it be problematic if universities, hospitals, etc., direct consumer marketers are having their testing done in China or with an entity which shares information with the Chinese Government?

Dr. LAUER. Well, it depends upon what we consider the risks to be. We are particularly concerned about the risk to the individuals, the research participants, and that is why we have a variety of steps in place to protect them. One of the most important is identifying their data. We don't see genetic data in and of itself as being a National Security risk. But I would say that we work very closely with our experts and colleagues in other parts of Government, including OIG and ONS to make sure that we are doing this as best as we can and doing it right.

Senator CASSIDY. I have been told that there really, there is no data that which cannot be re-identified. There may be a function such as the data link, but in terms of truly de-identifying of medical records or some aspect of medical records, almost always it can be re-identified. Would you disagree with that?

Dr. LAUER. We are watching this quite closely, and you are right that there have been instances where it appears that researchers have been inappropriately re-identifying people. One of the key steps that we take whenever we share data is to discuss exactly what steps will be made to make sure that no attempt will be made to re-identify participants.

Senator CASSIDY. Then it goes back to, I guess, my question. If we are concerned about foreign interference on our medical research, everybody you are describing is subject to the jurisdiction, authority, and potential for penalties from the NIH or the U.S. Government. But if we are dealing with an entity overseas, which is not subject to that, does not fear that, etc., then if they have that same material, they could handle it differently with all the nefarious consequences that we fear. That would be correct?

Dr. LAUER. Yes. So, this is the reason why we don't just automatically process a data sharing request. All the data sharing requests that we get go through a very extensive vetting process and we, in fact, reject a fair number of them, including requests that are coming in from foreign entities. Because we are worried about that. We are worried about misuse of the data.

Senator CASSIDY. With that, I yield back, Madam Chair. Thank you.

The CHAIR. Thank you.

We will turn to Senator Rosen.

Senator ROSEN. Thank you, Chair Murray and Ranking Member Burr. Thank you for holding this very important hearing. Appreciate the witnesses being here and for all the important work that you are doing. I would like to build a little bit of what Senator Casey was talking about earlier, university research partnerships, because as we have seen from the current pandemic collaboration among researchers, of course, it is more important than ever as we race to find solutions. And there is no doubt we can overcome more diseases and medical conditions through partnerships together than we can ever do in silos.

We have to foster and protect those partnerships among universities or valuable research institutions. So, for example, the University of Nevada, Reno School of Community Health Sciences, we partner with other universities and organizations in a number of countries so the students can receive a variety of research and direct public health experience. At the University of Nevada Global Health Initiative, they focus on research to help reduce health disparities, again, around the world.

For me, ensuring adequate security protocols, some of the things Senator Cassidy was talking about too, is training amongst researchers and the students who work with them. It is challenging to keep up with because they have so many other things on their plate. So, what federally supported training is available for the researchers and for their students who assist and conduct with this research? And I will ask everyone to respond to this.

Ms. Aguirre, can you please speak first? And Ms. Wright and Dr. Lauer.

Ms. AGUIRRE. Sure. I talked—this is Lisa. I talked a little bit before about an extramural training program. So, we worked and have been working initially from an internal, intramural perspective to have awareness training plan and program. And in terms of a large interagency effort to come up with sort of a more comprehensive extramural training awareness plan and program. But that doesn't mean it hasn't been happening already.

I mentioned that one of our staff members who is on detail from the FBI, has done numerous training and awareness interactions over the last year, along with the interagency and other partners. And so, we hope to just have a more comprehensive program to get the messaging out there to the—in an extramural way. And I will defer to Dr. Lauer.

Senator ROSEN. Yes. And I would also see if you would like to add particularly about audits of some of this. So you are getting the training and we know students are coming in and out every quarter, every semester, and so how would you—I am particularly interested if you go in once, but how often are you going in, how are you auditing that the information is staying up to date. So, I guess Dr. Lauer, maybe you want to or if somebody else wants to answer, but that seems problematic to me as well.

Dr. LAUER. Oh, I am sorry—

Senator ROSEN. No, that is Okay. Whoever would like to answer that, it is fine. It is hard to—we are all here on the zoom screen, so—

Dr. LAUER. Senator, I thought you addressed that one to me, but as an example of the best practice, there are some institutions now that because they are concerned about loss of data, they no longer allow thumb drives and everything, therefore, it is a network.

They can see, for example, if an unusually large amount of data is suddenly disappearing in the middle of the night and they can immediately put a stop to it. They can also identify certain kinds of data that they do not want to leave their institution, and because people cannot use portable drives anymore, they are able to handle that. And we are talking about some very large research institutions around the country that are doing exactly this. And this is just one example of a practice that might help.

Senator ROSEN. Wonderful. Ms. Wright, I didn't mean to—sorry about that. Sometimes in the zoom screen I don't see everyone, so I didn't mean to cut you off.

Ms. WRIGHT. Not a problem. Perfectly understandable. So, I was just going to add that from GAO's perspective, we certainly reached out to the university community and talked a lot with principal investigators as well as administrators. And one of the things that we heard certainly is a need for more information sharing, the need for more training, more guidance, particularly in terms of identifying foreign talent recruitment programs.

We heard from certainly a number of the principal investigators that many of them either were not aware of foreign talent recruitment programs or just simply didn't even know how they would go about identifying such programs. And so, for them, there is certainly this desire and this need to have more training and have

more continuous information being provided about what are the threats, what are the things that they need to be aware of and be on the lookout for.

A lot of the training may be happening at the principal investigator level, but the extent to which that is done, flowing down to other people involved in the research, I think that is something that is really important as well to consider.

Senator ROSEN. I think you are right, not just in this area, but in all others, being sure we have that good cyber hygiene, that we understand whatever the mission of our job is, how we protect the information, how we protect our information and ourselves and those we serve are extremely important. Thank you all. My time has expired.

The CHAIR. Thank you very much, Senator.

I will turn to Senator Burr.

Senator BURR. Thank you, Madam Chair. I should have said this at the beginning of the question period. I believe all of you who are testifying today take this very seriously. Here is my concern. There is no single entity that is in charge of identifying either falsification of the applications or violation of the rules. This seems to almost be a system that is reliant on somebody to uncover information that is either false or somebody's actions that break the rules.

I am going to turn to what Dr. Marshall's questions centered around and point to just a release from the Department of Justice yesterday where they have now indicted a mathematics professor a university in Illinois because of a violation under his NSF grant. And it said in the indictment that he was actually on faculty with a university in China from 2018 to 2023 under a contract. Now, he had worked at this institution in Illinois since 2000. And I personally met with institutions, and as I said earlier, they don't believe it is their responsibility to continually update this information. It is voluntary on the part of the grantee to the university.

To some degree, I am hearing from all of you that there is no reporting—there is no requirement, and I say that loosely, because there is no penalty an institution faces if, in fact, they don't report these things. And so, I guess I would turn to you, Dr. Lauer, first and say how many cases are currently under investigation for possible grant concerns at NIH?

Dr. LAUER. Right now, it is over 500, and what you described is exactly what we have seen.

Senator BURR. Go ahead.

Dr. LAUER. Yes, I would also say that we have required for a very long time, I would say even decades, that researchers have to disclose all support that they are receiving to help their individual research endeavors. And that includes support from other institutions, not only the institution from which they are applying.

We have clarified that more recently. And as Ms. Wright mentioned, we put out a new set of forms, we are putting out right now, which makes it even more clear that scientists are responsible for disclosing all forms of support that they are receiving. Universities are ultimately responsible because we give grants to institutions, not to individual scientists.

There have been consequences, as Mr. Cantrell said. The Department of Justice reached a \$5.5 million settlement with a research

institute that failed to disclose properly. So, you are absolutely right, and we are doing everything we possibly can to make those requirements even more clear and to address them when problems come up.

Senator BURR. Well, Dr. Lauer, you and Mr. Cantrell, the most recent National Defense Authorization Act provided the Federal Government with clear enforcement authorities to take actions on cases related to foreign influence. How are NIH and the OIG using these new authorities and, or any additional enforcement tools needed to ensure that cases of foreign influence are addressed appropriately and in a manner that sends a message that this will not be tolerated?

Dr. LAUER. We are working very closely with OSTP and also with our other colleagues to move that forward. As it has also been mentioned, I am part of the National Counterintelligence Task Force, part of the executive committee, and that is being run by FBI. FBI and OSTP are working in close coordination. So, we are moving forward with the implementation of the NDAA, exactly as you say.

Mr. CANTRELL. If I could add—

Senator BURR. Yes, sir.

Mr. CANTRELL. Yes, we are taking these cases, which we receive oftentimes from Dr. Lauer and his team, and we have great cooperation and support from his team as well as ONS and the FBI. So, these cases are a priority for us. We have gotten great support from U.S. Attorneys Offices when there is a matter that we can prove, and we use the tools, all the tools available to us when there is criminal conduct to pursue prosecution.

I think, and some of these cases serve as examples. And I know that through our training seminars that we participate in, providing examples of these unlawful conduct where individuals have been convicted can be a wakeup call for those in the community to serve as a hopefully a deterrent and maybe an opportunity for self-disclosure, as Dr. Lauer was discussing earlier, so that we can address these things proactively without the reactive approach of a criminal prosecution.

Senator BURR. One last question, and probably Dr. Lauer this probably is you, and it feeds off of Dr. Cassidy's question, is it currently legal for a U.S. company like 23 and Me to sell the genetic data that they accumulate from the customers that they process?

Dr. LAUER. Senator, I don't know the answer to that because that is out of my area of expertise, but I am happy to follow-up.

Senator BURR. I would appreciate it if you would, if there is action that we need to look at from a standpoint of the protection of genetic data. If that genetic data is actually being sold, at a minimum, that is something that I think needs to be disclosed to the millions of Americans that utilize that service from a standpoint of the jeopardy that it may put the United States or other places in the world in. I think Dr. Cassidy raises a great question. And it seems that China has been rather aggressive at trying to get the genetic data that they need within the system of innovation there. I thank the Chair.

The CHAIR. Thank you very much, Senator Burr. That will end our hearing today, and I really want to thank all of our colleagues

for a really thoughtful discussion. And I want to thank all of our witnesses, Dr. Lauer, Director Aguirre, Inspector General Cantrell, and Director Wright, for sharing your time and expertise with us. For families across the country, our leadership on biomedical research is not only a source of pride, but of hope for them and their loved ones battling diseases.

I look forward to working in a bipartisan way to take action based on what we have heard today to make sure we are protecting this important work. With that, for any Senators who wish to ask additional questions, questions for the record will be due in 10 business days on Thursday, May 6th, at 5 p.m.

The hearing record will also remain open until then for Members who wish to submit additional materials for the record. The Committee will next meet on Tuesday, April 27th, at 10 a.m. for a hearing on childcare and supporting children, workers, and families. With that, the Committee stands adjourned.

[Whereupon, at 11:35 a.m., the hearing was adjourned.]

