The Honorable Charles E. Grassley  
Chairman, Committee on Finance  
United States Senate  
Washington, DC 20510

Dear Mr. Chairman:

I am writing in response to your letter of January 17, 2019, referencing your ongoing concern about the threats foreign entities pose to the integrity of taxpayer-funded medical research. In your letter you asked us to respond to six questions to provide you with a deeper understanding of the efforts of the Department of Health and Human Services Office of Inspector General (OIG) to identify, mitigate, and take enforcement action against these threats. Responses to your questions are enclosed.

My staff will contact you to schedule the briefing you requested to discuss the work and activities referenced in our response. If you have any questions, please contact me, or your staff may contact Christopher Seagle, Director of Congressional Affairs, at 202-260-7006 or Christopher.Seagle@oig.hhs.gov.

Sincerely,

Daniel R. Levinson
Inspector General

Enclosure
Question 1: Please describe in detail the process by which the Health and Human Services Inspector General interfaces with NIH, the Justice Department and other relevant agencies to protect the integrity of medical research from foreign threats.

Answer: Upon receiving an allegation from the National Institutes of Health (NIH), the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) evaluates the allegation and determines whether our Office of Investigations (OI) will open an investigation; refer the matter to another agency with appropriate authorities, such as the Federal Bureau of Investigation (FBI); or, where appropriate, refer the matter back to NIH for administrative review. When evaluating referrals, OIG is sensitive to the fact that academic and professional reputations could easily be damaged by erroneous allegations.

When a violation of criminal law is identified during an investigation conducted by OIG, the facts are presented to the U.S. Department of Justice (DOJ) for prosecutorial consideration. To protect the integrity of medical research, OIG liaises with the HHS Office of Security and Strategic Information (OSSI), the entity within HHS providing oversight, policy direction, standards, and performance assessments in the areas of intelligence, counterintelligence, insider threat, cyber threat intelligence, information security, national personnel security, homeland security, and the safeguarding of classified information. In some instances, OIG works on matters with the FBI’s Joint Terrorism Task Forces and National Cyber Investigative Joint Task Force, the U.S. Department of Homeland Security, the United States Computer Emergency Readiness Team (US-CERT), and components at FBI Headquarters and local field offices. OIG also interacts as appropriate with representatives of the intelligence community and HHS’s Office of Research Integrity.

In addition to our investigations and enforcement activities, OIG conducts oversight of NIH through audits and evaluations, some of which relate to protecting the integrity of NIH-funded research. In fiscal year 2019, OIG received $5 million in appropriations for oversight of grant programs and operations of NIH, including agency efforts to ensure the integrity of its grant application evaluation and selection processes. We have recently initiated evaluations to assess NIH’s vetting and oversight of its peer reviewers, including its efforts to prevent or detect inappropriate sharing of information by peer reviewers, and an evaluation of how NIH monitors the financial conflicts of interest (including foreign financial interests) reported by grantees.

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1 OIG is currently completing an audit focused on NIH’s controls to permit and monitor access to sensitive data. We anticipate that this final report will have a restricted distribution due to its sensitivity. OIG Work Plan, W-00-17-42020, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000186.asp.
2 The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245). As directed by this law, OIG submitted a comprehensive NIH oversight plan to the Committee on Appropriations of the House of Representatives and the Senate, the Senate Committee on Health, Education, Labor and Pensions, and the House Committee on Energy and Commerce.
institutions. OIG is also initiating audits that will assess NIH’s Institutes and Centers to review their (1) pre-award process for assessing risk of potential recipients of Federal funds; (2) policies, procedures, and controls in place for ensuring that both foreign and domestic grantees disclose all relevant affiliations, sources of support, and financial interests, including intellectual property interests; (3) internal controls for identifying and addressing potentially duplicative grant funding and overlap; (4) testing of select cybersecurity controls within the NIH Electronic Health Records system; and (5) controls to ensure that NIH has an accurate inventory of hardware, software, and Internet Protocol (IP) resources.

Question 2: In the past five years, how many institutions have been referred by NIH to HHS OIG for noncompliance issues related to medical research? In your response, please include data on referrals for the institution’s failure to take corrective action after learning researchers received contributions from foreign governments and did not disclose it, and referrals for institutions that failed to adequately perform background checks on researchers involved in taxpayer-funded research. For each referral, please provide the reason for which the referral was made, the institution in question, and the resulting action taken by HHS OIG.

Answer: OIG recently received 12 referrals from NIH with such allegations. OIG is currently conducting a review of these referrals to determine whether the allegations warrant the opening of investigations. These new referrals appear to primarily involve Principal Investigators on NIH grants conducting medical research at U.S. universities who allegedly have failed to disclose foreign affiliations on their grant applications. Outside of the recent referrals, OIG has examined a total of 51 complaints in the past 5 years from NIH. Four of these complaints were related to potential research fraud, and none involved foreign contributions. The other 47 complaints were not germane to the issues raised by your inquiry.

Question 3: In the past five years, how many investigations has HHS OIG conducted of researchers who participated in federally funded research and allegedly failed to disclose their receipt of foreign government funding?

Answer: In the past 5 years, OIG conducted one investigation involving failure to disclose foreign government funding.

Question 4: In the past five years, how many investigations has HHS OIG conducted of researchers who were allegedly agents of a foreign government?

Answer: In the past 5 years, OIG did not conduct any investigations involving researchers who were allegedly foreign government agents. The identification of an individual as an “agent of a foreign government” as outlined in current law is a matter that has historically been reviewed by the FBI and other Title 50 agencies. Given that OIG does not possess statutory authority under the laws covering foreign agents, we have not traditionally investigated matters solely related to such violations.
Question 5: In the past five years, how many investigations has HHS OIG conducted of researchers who allegedly stole intellectual property created by taxpayer-funded research?

Answer: In the past 5 years, OIG conducted one specific investigation involving this type of allegation.

Question 6: In the past five years, how many referrals has the HHS OIG made to the Justice Department for potential prosecution relating to researchers who participated in federally funded research and allegedly failed to disclose their receipt of foreign government funding; researchers who were allegedly agents of a foreign government; and researchers who allegedly stole intellectual property created by taxpayer-funded research? How many referrals were accepted for prosecution and what was the result of each?

Answer: OIG has made two referrals to DOJ for potential prosecution in the past 5 years responsive to this question. One referral related to researchers who participated in federally funded research and allegedly failed to disclose their receipt of foreign government funding, and the other involved researchers who allegedly stole intellectual property created by taxpayer-funded research (this is the same matter referenced in our response to question 5). DOJ declined to pursue action in both matters. No other matter referred to DOJ in the past 5 years met the additional criteria listed. Additionally, researchers who were allegedly agents of a foreign government would fall under statutory authority beyond OIG’s purview. Given that OIG does not possess statutory authority under the laws covering foreign agents, we have not traditionally investigated matters solely related to such violations.

In cooperation with the FBI, OIG continues to expand its efforts in this area and will continue to do so as authority, resources, and funding allow.