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United States Senate

COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510-6275

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October 23, 2018

VIA ELECTRONIC TRANSMISSION

The Honorable Dr. Francis Collins
Director
National Institutes of Health

Dear Dr. Collins,

In an August 20, 2018, letter to NIH grantee institutions, you called attention to a series of threats posed by foreign entities to the integrity of U.S. biomedical research.¹ In that letter, you warned that foreign actors have “mounted systematic programs to influence NIH researchers and peer reviewers,” may have worked to divert intellectual property produced by NIH-supported research to other countries, and may have contributed resources to NIH-funded researchers in ways which could impact the integrity of the research. I appreciate your office providing a briefing to my staff on October 17, 2018, regarding these matters. The briefing was informative; however, additional questions remain.

As you are aware, the foreign threats described by your August letter are not new. In a 2013 case, foreign researchers were charged with conspiring to steal research funded by a multi-million dollar NIH grant for the benefit of a Chinese governmental entity and a direct competitor of the American university where the research was conducted.² On August 23, 2018, you reportedly stated that the NIH is currently investigating several cases in which researchers supported by federal grants may have failed to disclose financial contributions from foreign governments.³ According to one report, the NIH has not released details about the entities that are under investigation.⁴

¹ Letter from Francis S. Collins, Director, National Institutes of Health, to NIH Grantee Institutions (August 20, 2018) Available at: <http://www.sciencemag.org/sites/default/files/NIH%20Foreign%20Influence%20Letter%20to%20Grantees%2008-20-18.pdf>; Similar concerns were expressed in subsequent testimony before the Senate Committee on Health, Education, Labor and Pensions. See: *Prioritizing Cures: Science and Stewardship at the National Institutes of Health, Hearing before the Senate Committee on Health, Education, Labor and Pensions*, 115th Cong. (2018) Transcript available at: <http://www.cq.com/doc/congressionaltranscripts-5378816?2>

² Department of Justice “Manhattan U.S. Attorney and FBI Director-In-Charge Announce Criminal Complaint Against Three New York-Based University Researchers for Conspiring to Receive Bribes From A Chinese Company And A Chinese Government-Supported Research Institute” Press Release (May 20, 2013). Available at: <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-and-fbi-assistant-director-charge-announce-criminal-complaint>

³ Lev Facher “NIH is investigating researchers who might have failed to disclose contributions from foreign governments” *STAT* (August 23, 2018). Available at: <https://www.statnews.com/2018/08/23/nih-is-investigating-researchers-who-might-have-failed-to-disclose-contributions-from-foreign-governments/>

⁴ Jocelyn Kaiser, David Malakoff, “NIH investigating whether U.S. scientists are sharing ideas with foreign governments” *Science* (August 27, 2018) Available at: <http://www.sciencemag.org/news/2018/08/nih-investigating-whether-us-scientists-are-sharing-ideas-foreign-governments>

These cases raise important questions about the effectiveness of NIH's vetting process for grant recipients. In March 2018, NIH reminded its extramural community about conflict of interest regulations and their requirement to disclose all financial interests received from foreign institutions of higher education, as well as foreign governments.⁵ However, it is not clear that these disclosure requirements adequately address the significant and pervasive threats posed by foreign entities to our research institutions and the integrity of taxpayer funded studies. Critical points in the grant evaluation process need additional clarification, including NIH's application review procedures, its background check or other investigatory processes, and any other methods used to verify the disclosures made on grant applications. Further, many of the grant recipients arrive in the U.S. on a variety of visas, yet the information about the true nature of the recipients' intent or identity is often withheld from the government, or simply not adequately collected by consular officials.

Congress requires a better understanding of these processes and the steps NIH has taken to ensure their integrity, as well as the integrity of resulting studies and protections for any intellectual property produced by taxpayer funded research. Accordingly, please answer the following no later than November 6, 2018:

1. Please describe in detail the process by which NIH, or any affiliated entity, conducts background checks of researchers and institutions prior to awarding NIH grants. Please describe these processes in both the intramural and extramural program at NIH.
2. How many staff and how much taxpayer money per year is budgeted to identify and investigate potential violations of the rules concerning foreign affiliations and financial contributions? Please provide a copy of the budget and all other supporting documentation for the past five years.
3. With respect to the recipients of NIH funds, how many systematic reviews, or audits, have been performed of those entities in the past five years for potential violations concerning foreign affiliations and financial contributions? Please list each entity and the results of the review.
4. At the October 17, 2018, briefing, your staff noted that NIH places individuals on a "do not use" list if they violate certain policies and procedures and placement on that list results in a ban on performing peer reviews. Please provide a copy of that list.
5. What enforcement mechanisms are available to NIH to protect NIH-funded intellectual property and punish foreign agents for violating NIH policies and rules? Does NIH require additional authorities to effectively punish and deter wrongdoers? If so, what are they?

⁵ NIH Notice Number: NOT-OD-18-160 "Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests (March 30, 2018) Available at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html>

6. Please provide the committee a list of all entities currently under investigation for employing individuals that failed to disclose contributions from foreign governments. Do you plan to make that list public? If not, why not?
7. In addition to HHS' Office of Security and Strategic Information, does NIH regularly work with the Justice Department, State Department, and the Intelligence Community to properly track, assess, and analyze potential threats to the integrity of the grant process and their impact on national security? If so, please describe those relationships. If not, why not?
8. With respect to the following, please provide a list of all instances in the past five years in which the following occurred: (1) foreign actors mounted systematic programs to influence NIH researchers and peer reviewers; (2) foreign actors worked to divert intellectual property produced by NIH-supported research to other countries; (3) foreign actors contributed resources to NIH-funded researchers in ways which could impact the integrity of the research. For each instance, please describe in detail the nature of the violation and whether a referral was made to the Health and Human Services Inspector General or the Justice Department.

Thank you in advance for your prompt attention to these matters. Should you have any questions, please contact Josh Flynn-Brown of my Judiciary Committee staff at (202) 224-5225.

Sincerely,



Charles E. Grassley
Chairman
Committee on the Judiciary

cc:

The Honorable Mike Pompeo
Secretary
U.S. Department of State