



December 21, 2018

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

Dear Mr. Chairman:

Thank you for your October 23, 2018, letter to Dr. Francis Collins, Director of the National Institutes of Health (NIH), on threats to the integrity of U.S. biomedical research. Enclosed please find NIH's responses to your questions.

If you have any questions, please ask your staff to contact Lauren Mullman in the NIH Office of Legislative Policy and Analysis at Lauren.Mullman@nih.gov or (301) 496-3471.

Sincerely,

A handwritten signature in black ink, which appears to read "Lawrence A. Tabak", is written over a horizontal line.

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director
National Institutes of Health

Enclosure

NIH Responses to the Questions in Chairman Charles E. Grassley's
October 23, 2018 Letter

- 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.*

NIH employees, contractors, and affiliates who are U.S. citizens and working in the intramural program undergo background investigations conducted by the Office of Personnel Management National Background Investigation Bureau (NBIB) commensurate with their position designation (Tier 1-5). Prior to initiating a background investigation by NBIB, a Special Agency Check (SAC) is conducted requiring an individual's fingerprints to be compared against the FBI's criminal databases including terrorist watch lists. Once the fingerprint results are analyzed and adjudicated the background investigation process begins.

All foreign nationals working in the NIH intramural program undergo screening by NIH to ensure they meet NIH policy requirements. These include reviews of educational credentials, curriculum vitae and bibliography, funding letter from the outside organization if not fully funded by NIH, and immigration documents.

Extramurally, grantee institutions are responsible for the personnel designated on their awards, not NIH. The agency, however, requires that authorized organization representatives certify—in accordance with relevant law—that all information provided in grant applications is accurate. NIH determines if grant applicants are eligible to receive grant awards but does not conduct background checks, per se.

To determine eligibility, NIH conducts a pre-award risk assessment by checking multiple Federal-wide systems used for management and oversight of Federal funding recipients. This includes the Federal System for Award Management (SAM), which includes ineligible recipients, such as those that have been suspended or debarred; the Federal Awardee Performance and Integrity Information System (FAPIIS) to review past performance information; and audit concerns issued by the National External Audit Review Center.

NIH grants are awarded to the institution, not the investigator. Given that, the recipient institution is responsible for the actions of its personnel and other research collaborators, including third parties involved in the project.¹ Recipients are required by the uniform grant regulations to have systems, policies, and procedures in place by which they manage Federal funds and grant-related activities. The NIH Grants Policy Statement (NIH GPS),² which is a term and condition of all NIH awards, details these responsibilities and the respective roles of the institutions and individuals.

Prior to making an award, NIH requests updated "other support" information for the program director/principal investigator (PD/PI) and other key personnel identified in the grant

¹ <https://nexus.od.nih.gov/all/2018/05/29/waitits-not-my-grant/>

² <https://grants.nih.gov/policy/nihgps/index.htm>

application to ensure that updated information on all financial resources, whether Federal or non-Federal, foreign, commercial or institutional, available in direct support of an individual's research endeavors, are known and considered prior to award. This information is used by NIH to ensure that only the funds necessary to the approved project are included in the grant award.

NIH requires institutions, as the applicants for and recipients of NIH funding, to ensure that individual investigators make all appropriate disclosures to their institution regarding other support, affiliations, and financial interests, whether or not they are employees of the institution. Institutions, in turn, must ensure that all applications and reports submitted to NIH are complete and accurate.

Among other obligations, the applicant organization must certify, and in some cases, submit assurances that they comply with the public policy requirements provided in the NIH GPS. These requirements are intended to ensure that recipient organizations handle their Federal awards responsibly. While NIH maintains oversight of our awards, we entrust our recipient organizations with the responsibility and accountability for successfully administering their grant award, including prudent fiscal management and other requirements spelled out in the NIH GPS.

With regard to grant funding, in general, domestic or foreign, public or private, non-profit or for-profit organizations are eligible to receive NIH awards, including academic universities, hospitals, small businesses, and other for-profit entities. NIH may limit eligibility for certain types of grant programs, such as limitations to small business applicants, or other limitations on eligibility consistent with relevant law and/or policy. The qualifications of the investigators designated by the applicant institution are evaluated during peer review to ensure they have the appropriate expertise and skills to serve on the leadership team and execute the project.

NIH expects everyone involved in NIH-supported research—both domestic and foreign—to promote scientific integrity. Breaches of trust and confidentiality are unacceptable and inconsistent with the relevant legal and policy framework and with NIH's guiding principles of scientific excellence, scientific integrity, and fair competition.

- 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.*

It is difficult to quantify the specific amount of staff time and budget dedicated to reviewing potential violations of the rules concerning foreign affiliations and financial contributions, as this is only part of NIH's larger compliance and oversight responsibilities. The NIH Extramural Research Integrity Liaison Officer, the Division of Grants Compliance and Oversight, and the NIH Office of Management all coordinate to review these issues, along with other areas of compliance, and coordinate with the HHS Office of Inspector General (OIG) and other agencies and offices, as needed.

NIH staff also ensure compliance with the public policy requirements provided in the NIH GPS. These requirements are intended to ensure fairness, equity, fiscal stewardship, and other protections in activities that receive NIH support. They include measures to promote objectivity in research, civil rights protections, human subjects protections, consideration of environmental impacts, animal welfare, compliance with Public Health Service (PHS) policies on research misconduct, maintaining a drug-free workplace, prohibitions on lobbying with Federal funds, and many others.

Numerous staff from across NIH review applicant and recipient compliance with the laws, policies, and regulations guiding the NIH grant award process. This includes, but is not limited to, those from the NIH Center for Scientific Review (CSR) who receive applications; staff in CSR and the funding institutes and centers (ICs) who manage the peer review of applications; and program and grants management staff within the funding NIH ICs, who review and monitor the financial and administrative aspects of grant awards as well as its scientific progress. Officials within the NIH Office of the Director also ensure and evaluate the efficient and effective management of extramural resources.

Together, all of these staff ensure that NIH grant awards are managed responsibly as part of our overall stewardship and accountability role. As this is a multi-factorial process across the entire NIH, it is difficult to quantify the specific amount of time or budget dedicated solely to the oversight issue raised in the question.

- 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.*

The HHS OIG Office of Audit Services conducts independent audits of HHS programs and/or HHS grantees and contractors.

When NIH becomes aware of potential noncompliance concerning a grant award, and/or when NIH wants to review or confirm compliance issues, the Office of Extramural Research, within the NIH Office of the Director, contacts the recipient institution to determine the facts and address any issues associated with active or pending NIH awards. This may include instituting specific award conditions or enforcement actions.

- 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.*

At the discretion of NIH, tens of thousands of reviewers volunteer each year to review grant applications, with more than 25,000 serving in Fiscal Year 2017 alone. Individuals may be designated as “Do Not Use” for future peer review service for reasons other than violating NIH policies and procedures, e.g., if they are on an extended leave status or otherwise are

not available or appropriate for peer review service at a given time, as initiated by the reviewer or by NIH. Therefore, providing a list could be misleading and/or misinterpreted, especially since the status could change, i.e., placement on the list does not necessarily indicate “a ban on performing peer reviews.” For those being assessed by their institution regarding a particular allegation, they may be on a “Do Not Use” list for a limited time at NIH but may be asked to provide peer review service on a future occasion depending on the outcome and circumstances. Additionally, past service on peer review is no guarantee of future service.

With that said, in order to protect the confidentiality and security of the review process, and consistent with NIH policy, e.g., NIH Guide Notice NOT-OD-18-115, NIH may terminate review service for an individual if NIH determines that a situation involves a breach of review integrity. Examples referenced in that Guide Notice are attempts to influence the outcome of the review or the reviewer(s), or to access information or materials related to the review by any other means.

- 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?*

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH is not a law enforcement agency.

NIH will take action where appropriate under its authority to address such concerns as part of its proper oversight, compliance, and stewardship roles. As an example, when NIH identifies noncompliance with the terms and conditions of award, it may take actions consistent with the regulatory requirements found in 45 CFR 75.207 and 75.371 for grants and FAR 52.227-11 for contracts. For NIH Contracts, 48 CFR 27.305-4, 48 CFR 27.302(j) and 5 CFR 45(b)(1-4) provides confidentiality protection for information submitted under a contract and for inventions made under a contract.

Depending on the severity and duration of the noncompliance, NIH may decide to take one or more actions, which are also described in the NIH GPS, Section 8.5, Specific Award Conditions and Remedies for Noncompliance, including imposing specific award conditions, disallowing costs, withholding future awards for the project or program, suspending the award activities, making a referral for suspension or debarment, terminating the award, or revoking or taking title to the inventions made with the Federal support and pursuing patent protection or licensing the invention itself.

NIH also can take action when peer reviewers violate the confidentiality of review, as outlined in the NIH Confidentiality and Nondisclosure Rules.³ These actions may include but are not limited to notifying or requesting information from the reviewer's institution,

³ https://grants.nih.gov/grants/peer/guidelines_general/Confidentiality_CertificationsPR.pdf

terminating a reviewer's service, facilitating referral to the HHS OIG, or pursuing a referral for government-wide suspension or debarment.

As stated in Section 2.3.12 of the NIH GPS,⁴ recipients of NIH funds are reminded of their vital responsibility to protect sensitive and confidential data as part of proper stewardship of federally funded research, and take all reasonable and appropriate actions to prevent the inadvertent disclosure, release or loss of sensitive personal information. In addition, Section 8.1⁵ states that recipients shall immediately notify the awarding agency of developments that have a significant impact on award-supported activities. This includes problems, delays, or adverse conditions that may impair the ability to meet the objectives of the award.

Intellectual property is defined as a work or creation of the mind such as an invention or a literary or artistic work, and is protected by international laws, including patent, copyright, trade secret, and trademark laws. An owner of a trade secret may bring a claim in federal court under the Defend Trade Secrets Act of 2016 for misappropriation of trade secrets. Economic espionage involving the misappropriation of trade secrets for the benefit of a foreign government, agent or instrumentality is a criminal act under 18 U.S.C. 1831. International and U.S. patent laws, including the Patent Act, provide remedies for patent infringement disputes and those related to ownership and inventorship of inventions.

Under the Bayh-Dole Act, an ownership interest in an invention made under a non-profit's funded research award may not be assigned without the permission of the funding agency.

Under the Act, NIH's funding recipients retain ownership of their inventions and, throughout the patenting and licensing process of an invention, they are required to report their efforts to patent and license the invention. As noted herein, any transfer or assignment of ownership from a funding recipient to a third party by a non-profit requires NIH's approval. If the funding recipient fails to disclose or elect title to an invention made with Federal funds within specific timeframes set forth in the Bayh-Dole Act, NIH may take title to the invention. If a funding recipient decides not to pursue or maintain protection of an invention, it is required by statute and regulation to waive its rights in the invention to the NIH.

The funding recipient, typically an institution, not a person, is responsible for the actions of its employees and other research collaborators, including third parties involved in the project. Funding recipients are required by uniform regulations to have systems, policies, and procedures in place by which they manage Federal funds and research-related activities. If a funding recipient takes administrative action against senior/key personnel on an NIH award that impacts the ability to carry out the approved research at the location of, and on behalf of, the recipient institution, the institution is obligated to notify NIH. NIH reminded its grantee institutions in Spring 2018 about their responsibilities in the management and administration of their awards and sent further guidance to all grantee and applicant organizations on August 22, 2018. If NIH concludes that senior/key personnel on an

⁴https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.3.12_protecting_sensitive_data_and_information_used_in_research.htm

⁵https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.1_changes_in_project_and_budget.htm?tocpath=8%20Administrative%20Requirements%7C8.1%20Changes%20in%20Project%20and%20Budget%7C8.1.2%20Prior%20Approval%20Requirements%7C6

NIH-funded award are no longer qualified or competent to perform the research objectives, NIH can take several actions, including approving a new principal investigator recommended by the grantee if scientifically appropriate, or terminating the grant. Generally, NIH views a replacement of the senior/key personnel as the best course of action, when possible, to allow progress of meritorious science, and in consideration of all involved in the project.

- 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?*

NIH is not in a position to comment on the investigations or reviews underway within the HHS OIG, Department of Justice, or institutions that have employment or other arrangements with individuals who failed to disclose contributions from foreign governments. We closely work and coordinate with our federal partners in such regard, as NIH does not conduct law enforcement investigations. As we continue to assess the issue as part of our normal stewardship activities, NIH is focused on established U.S. scientists who serve as peer reviewers and principal investigators on grants issued to U.S. institutions.

When concerns arise, however, NIH requests that institutions review disclosures and provide details of any identified instance of non-compliance along with a detailed description of the corrective actions taken by the institutions. Institutions that fail to take corrective actions may be subject to administrative actions which can include a referral to the HHS OIG for further consideration.

- 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?*

NIH closely works with and fully cooperates with its federal partners, including but not limited to the HHS OIG and the Department of Justice, during their reviews and investigations. In cases where NIH becomes aware of violations, NIH consults with these agencies to support a specific and systematic approach to addressing foreign influence on the U.S. biomedical research enterprise.

NIH works with other government agencies and the broader biomedical research community to identify steps that can help mitigate these unacceptable breaches of trust and confidentiality that undermine the integrity of U.S. biomedical research. The Director of the NIH Office of Policy for Extramural Research Administration, who is the Chief Grants Management Officer for NIH, participates in the Executive Committee on Grants Administration Policy, which brings together senior grants managers from across HHS. NIH uses this forum to communicate NIH's efforts in this area and to facilitate discussion on strategies and opportunities to coordinate to protect the integrity of research across the agency.

NIH is exercising its due diligence to address these issues if and when they arise. NIH seeks to continue engaging the broader community on this issue and mitigate the risks within our authority. For example, NIH established the Advisory Committee to the NIH Director (ACD) Working Group on Foreign Influences on Research Integrity⁶ to promote research integrity across biomedical and behavioral science. On December 14, 2018, the Working Group's recommendations were presented to the full ACD for discussion. NIH is currently reviewing and considering the recommendations presented in their report.

- 8) *With respect to the following, please provide a list of all instances in the past five years in which the following occurred. 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.:*
- a. Foreign actors mounted systematic programs to influence NIH researchers and peer reviewers;*
 - b. Foreign actors worked to divert intellectual property produced by NIH-supported research to other countries;*
 - c. Foreign actors contributed resources to NIH-funded researchers in ways which could impact the integrity of the research.*

NIH cooperates and collaborates with the HHS Office of Inspector General (OIG) and the Justice Department (DOJ) regularly on matters which may appear to have a foreign nexus of potential concern. To ensure the integrity of OIG and DOJ ongoing activities, we ask that you request more detailed information from those offices directly.

⁶ <https://acd.od.nih.gov/working-groups/foreign-influences.html>