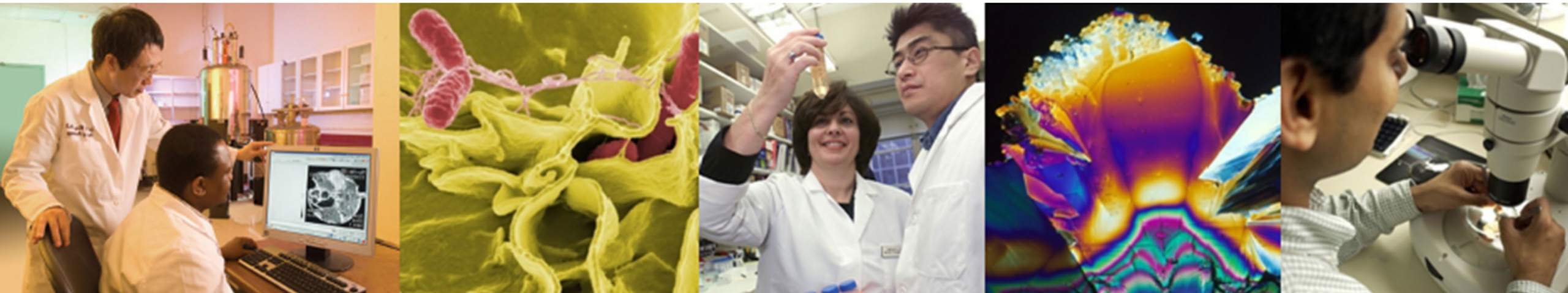


Foreign Influences on Research Integrity

117th Meeting of the Advisory Committee to the Director

December 13, 2018



Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH

M. Roy Wilson, MD, MS
President, Wayne State University



Introduction: Statement of the Problem

- NIH has identified:
 - Undisclosed foreign financial conflicts
 - Not fully and accurately disclosing other financial support during grant application, award, and implementation processes
 - Undisclosed conflicts of commitment
 - For example, other affiliations and positions that often come with resources and equities
 - Peer review violations

False Reporting: Withholding Information

For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED
PHS 398 OTHER SUPPORT

Provide active and pending support for all senior/key personnel. **Other Support includes all financial resources, whether commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

There is no "form page" for reporting Other Support. Information on Other Support should be provided in the *format* shown below.

For information pertaining to the use of and policy for other support, see [NIH Grants Policy Statement, Section 2.5.1: Just-in-time](#) information on the application under consideration nor the current PHS award for this project should be listed as Other Support.

Effort devoted to projects must be measured using "person months." NIH and other PHS agencies use the concept of "person months" to determine the percent of effort. For more information about calculating person months, see NIH's [Frequently Asked Questions](#).

Format

NAME OF INDIVIDUAL <u>ACTIVE/PENDING</u>	
Project Number (Contact Principal Investigator) Source Title of Project (<i>or Subproject</i>)	Dates of Approved/Proposed Project Annual Direct Costs
The major goals of this project are... <u>OVERLAP</u> (<i>summarized for each individual</i>)	

Other Support includes **all financial resources ...**
 available in direct support of an individual's research endeavors, including but not limited to ...

Failure to disclose other support at multiple opportunities

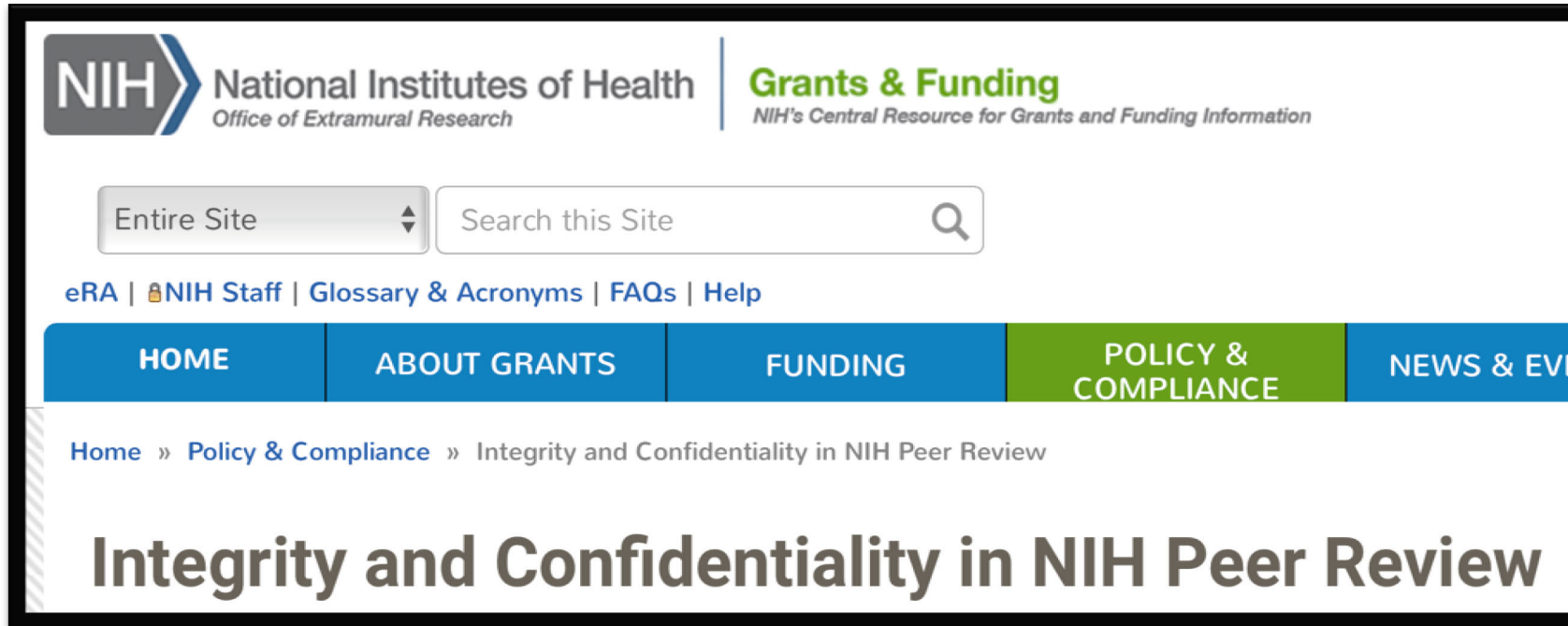
17. By signing this application, I certify (1) to the statements contained in the application to be true, complete and accurate to the best of my knowledge. I also provide the relevant information in the terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or information will constitute a criminal offense under 18 U.S.C. 1001 and may result in administrative penalties. (U.S. Code, Title 18, Section 1001)

I agree

[See the NIH Grants Policy Statement for more information on the NIH Grants Policy Statement at https://www.nih.gov/grants/policy-statement](https://www.nih.gov/grants/policy-statement)

*The list of certifications and assurances, or an internet site where you may obtain this list, is contained in the PHS 398 application form.

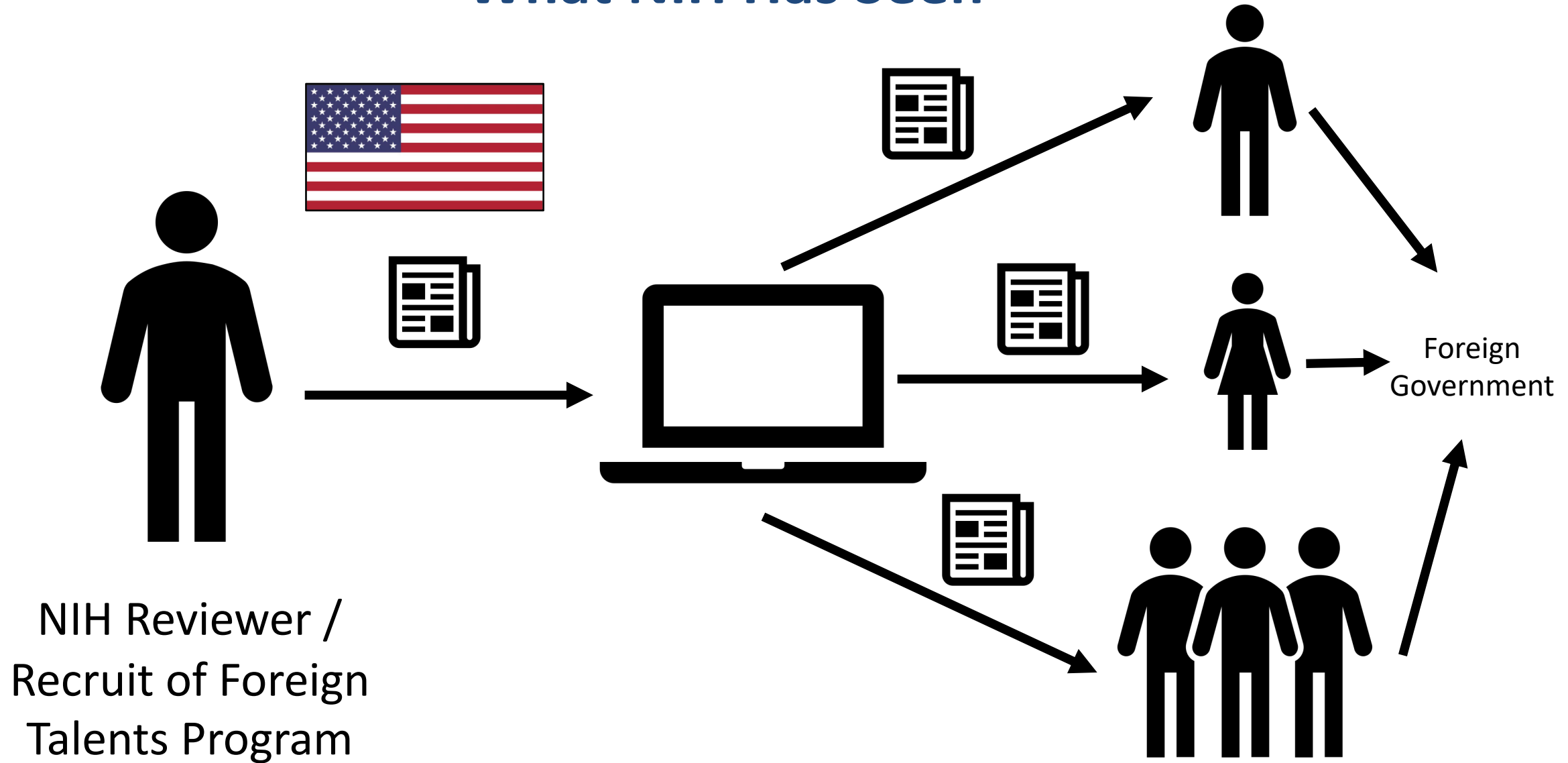
Inappropriately Transmitting Information: Peer Review



The screenshot shows the NIH Grants & Funding website. The header includes the NIH logo and the text "National Institutes of Health Office of Extramural Research" and "Grants & Funding NIH's Central Resource for Grants and Funding Information". Below the header is a search bar with a dropdown menu set to "Entire Site" and a search button. A navigation menu is visible with tabs for "HOME", "ABOUT GRANTS", "FUNDING", "POLICY & COMPLIANCE" (which is highlighted in green), and "NEWS & EVENTS". Below the navigation menu is a breadcrumb trail: "Home » Policy & Compliance » Integrity and Confidentiality in NIH Peer Review". The main heading of the page is "Integrity and Confidentiality in NIH Peer Review".

“Confidentiality in NIH peer review *prohibits* a peer reviewer member from: Sharing applications, proposals, or meeting materials with **anyone who has not been officially designated to participate** in the peer review process.”

What NIH Has Seen



Ongoing NIH Efforts

- Seek to mitigate and prevent (more than criminalize)
- Work with institutions and organizations
 - Dr. Collins letter to recipient organizations (August 21, 2018)
 - Communications to specific institutions: employment actions
- Work with partners across the government (including FBI)
- Peer review
 - Invitation to serve at agency discretion
 - Reporting to institutions and OIG
 - Enhance security

Talents Recruitment



RECRUITMENT
PROGRAM OF GLOBAL EXPERTS

“CHINESE TALENT PROGRAM”

Tens of thousands of recruits¹,
including at least 6,000 top-
tier recruits²

Key qualification:
Access to intellectual property


Most recruits receive federal
funding (NIH and other
agencies)

1. 1000 Talents website: <http://www.1000plan.org/en/history.html>
2. China's Plan to Recruit Talented Researchers, Nature, 2018:
<https://www.nature.com/articles/d41586-018-00538-z>

The Talents Program

NEWS

Photo by Ha Nguyen | The Chronicle



How one graduate student allegedly stole Duke research to create a billion-dollar Chinese company

New book describes how foreign intelligence can manipulate American universities like Duke

Education or espionage? A Chinese student takes his homework home to China

Ruopeng Liu believes his work at a Duke lab was simply "fundamental research" that he brought back to China. His former professor thinks otherwise.

by Cynthia McFadden, Aliza Nadi and Courtney McGee / Jul.24.2018 / 7:49 AM EDT

ACD Working Group for Foreign Influences on Research Integrity



Sam Stanley, MD
President, Stony Brook University



Jeff Balser, MD, PhD
President & CEO, Vanderbilt
University Medical Center



Michael Drake, MD
President, Ohio State University



Larry Tabak, DDS, PhD
Principal Deputy Director,
NIH (Co-chair)



Maria Zuber, PhD
Vice President for Research, MIT



Ana Mari Cauce, PhD
President, Washington
University



Wallace Loh, PhD, JD
President, Maryland University



M. Roy Wilson, MD, MS
President, Wayne State
University (Co-chair)

Working Group Charge

- Identify approaches for NIH and applicant/grantee organizations to partner to ensure that research support, affiliations, and financial interests are accurately reported
- Propose approaches to facilitate appropriate collaboration with scientists across the globe, while helping to safeguard intellectual property in NIH applications or developed in whole, or in part, with support from the U.S. government
- Propose additional steps to protect the integrity of the peer review process
- Address the issue in ways that
 - Reflect tradition of partnership between NIH and grantee institutions
 - Emphasize the value of foreign nationals in the American scientific enterprise

Foreign Nationals in American Research

- The number of people involved in inappropriate activities is small, but the issues are significant, and therefore must be addressed
- The vast majority of foreign nationals make important contributions to American institutions and to science
 - 24% of U.S. Nobel prizes have been awarded to foreign-born scientists
- The challenge is to find ways to build and continue important and successful relationships with foreign scientists in all countries while simultaneously protecting the Nation's research integrity
- The focus of current concern is China - but this issue is not unique to China

Recommendations: Considerations and Overview

- Act with care and consideration of the important relationships and collaborations with foreign scientists and organizations
- Work together and with AAU, APLU, ACGE, AAMC, ACE and other prominent educational organizations on outreach
- Should they be accepted by the ACD and Dr. Collins, the extent to which recipient organizations can implement the recommendations will vary across recipient organizations
- Recipient organizations and NIH should work together to identify and allow for best practices to allow for institutional variation in implementation

Organization of Recommendations

NIH

Communication and Awareness

Risk Mitigation

Consequences and Actions

RECIPIENT ORGANIZATIONS

Communication and Awareness

Risk Mitigation

Ongoing Monitoring

NIH Should

NIH: Communication and Awareness

- Implement a broad education campaign to raise awareness about the need to disclose other foreign support, international affiliations, international collaborations, and financial interests
 - Help universities develop best practices for how to handle these challenges
 - Collaborate with other federal and security agencies
- Develop communications materials, additional training guidelines, policy updates, and changes to reporting requirements in collaboration with other government agencies, especially key funding agencies, to streamline and unify requests and requirements
- Re-evaluate existing policies and forms and to expand the requirements and make the requirements explicit as to what must be reported as other support
- Foster trusted relationships with universities and organizations in foreign countries
- Contact and work with recipient institutions to address concerns if made aware of new threats or information

NIH Should

NIH: Risk Mitigation

- Update policy to require disclosure of foreign collaborations and affiliations
 - Expand current regulatory approach concerning conflicts of interest to expressly account for interest in which no financial remuneration is indicated but which overlaps with scope of NIH award
- Collaborate with the Office of Research Integrity or appropriate oversight authority to determine if and when material nondisclosures to the NIH regarding funding (and overlap in effort) should be considered as research misconduct
- Reexamine and consider clarifying the ownership of NIH grant-funded research data, to make clear that these non-commercialized data, resources, and tools are the property of the recipient organization
 - NIH Grants Policy Statement:
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.1_rights_in_data_publication_and_copyrighting_.htm?Highlight=data
 - Sharing among the scientific community should be subject to the oversight of the recipient organization and not the PI
- Add to grant terms and conditions a statement addressing nondisclosure of other financial support or affiliations, or peer review violations

NIH Should

NIH: Risk Mitigation

Considerations to address Peer Review violations:

- Improve system controls at NIH
- Limit reviewer ability to download, print, or otherwise share materials
 - Consider making the Internet Assisted Review scoring process a closed ecosystem
- Add a pop-up message at log-in that reminds users materials are confidential and log-in can be tracked
- Notify designated official at recipient organizations promptly of allegation and resulting findings related to peer review violation
 - Recipient organization can meaningfully assist the NIH with resolution
- Make new training on review integrity for Scientific Review Officers, study section chairs, and reviewers available to Recipient Organizations as soon as possible

NIH Should

NIH: Consequences and Actions

In cases where peer review is violated:

- Determine extent of the compromise
 - Did affected applications have pre-patent and pre-licensing-relevant information? Could the material have been incorporated into unrelated grant or patent applications?
- Determine under which circumstances applicants will be notified

In cases where NIH identifies violations (e.g., not reporting foreign support or affiliations):

- Alert the recipient organizations and work them to rectify issues
 - NIH actions and resulting consequences are determined through communication with the recipient organization and depend on the extent of the violation

When institutions have multiple violations of peer review or investigators not reporting other support or affiliations, and are not receptive to adjudicating concerns regarding undue foreign influences, consider an institution-wide assessment of the recipient organization

Recipient Organizations Should Consider

Recipient Organizations: Communication and Awareness

- Implementing a broad education campaign about the needs to disclose other foreign support as part of disclosure processes for NIH, and international affiliations, international collaborations, and financial interests to home recipient organization
 - Incorporate these messages into regular Responsible Conduct of Research training
 - Increase training and awareness for new faculty who are foreign nationals
 - Ask investigators to document in writing conversations and decisions about what each student and post-doc will take when leaving a laboratory
- Educating leadership, officials, and investigators regarding the scientific topics that are more prone to interest by untoward actors
 - Recipient Organization should identify all key stakeholders (PDs/PIs, Peer Reviewers, visiting scientists and scholars, hosting/ sponsoring faculty, laboratory administrators, and faculty administrative support) and tailor the communications plans accordingly

Recipient Organizations Should Consider

Recipient Organizations: Communication and Awareness

- Discussing how to safely *host* laboratory and VIP medical visits which can be potential entry points for unwanted information gathering
 - Be aware of activities like adding unrelated additional visitors with little advance
- Developing guidelines for securely hosting visiting scholars or students
 - Encourage additional vetting or discussions regarding project ownership and appropriate data exchange
- Initiating pre-travel ‘safety briefings’ to educate investigators and encourage precautions for international travel

Recipient Organizations Should Consider

Recipient Organizations: Risk Mitigation

- Assessing the physical, technical, and administrative controls frameworks employed by Recipient Organizations that host foreign scientists for the risk of data misappropriation and exfiltration
 - There are many controls frameworks, such as the controls within the National Institute of Standards and Technology (NIST) Special Publication 800-53 (rev. 4), that can be mapped directly to the research laboratory environment to reduce the risk of data misappropriation.
- Providing independent certification of full adherence to and compliance with specific control and security frameworks

Recipient Organizations Should Consider

Recipient Organizations: Risk Mitigation

- Examining the robustness of their internal processes to identify potential breaches
 - Initiate or amplify cybersecurity approaches that may identify possible data breaches or inappropriate use of authorization credentials to access systems, or inappropriate sharing of information
 - Evaluate and implement mechanisms for identifying and verifying financial support, for example, using ORCID number to disambiguate individuals, or asking companies for lists of researchers working in foreign universities with company support
 - Have other support/foreign support and cybersecurity monitoring reported and tracked centrally (e.g., Office of Sponsored Research) using a single, accessible database

Recipient Organizations Should Consider

Recipient Organizations: Risk Mitigation

- Providing faculty or staff traveling to certain regions to use loaner computers and electronic equipment
- Vetting potential employees prior to hiring through unclassified searches, review of any agreements they have with businesses, organizations, and institutions; check their FCOI and conflicts of commitment
- Adding to existing scientific misconduct or other similar policies:
 - That employees must disclose other funding support (i.e., financial conflicts)
 - That employees must disclose positions and affiliations at other universities or institutions (i.e., conflicts of commitment)
 - Language explicitly addressing the need to uphold peer review integrity and consequences of violations of NIH peer review

Recipient Organizations Should Consider

Recipient Organizations: Risk Mitigation

- Developing review and adjudication processes that are appropriate for examining potential misconduct related to foreign influences
- Implementing systematic audits to ensure FCOIs and conflicting commitments are accurately reported
 - May be random checks or initiated by ‘flags’ (see below), or a combination of both approaches

Recipient Organizations Should Consider

Recipient Organizations: Risk Mitigation

- Developing review and adjudication processes that are appropriate for examining potential misconduct related to foreign influences
- Implementing systematic audits to ensure FCOIs and conflicting commitments are accurately reported
 - May be random checks or initiated by ‘flags’ (see below), or a combination of both approaches
- Always proactively notify NIH about peer review violations and inaccurate or undisclosed foreign support or affiliations with outside organization

Recipient Organizations Should Consider

Recipient Organizations: Ongoing Monitoring

- Working with professional organizations to obtain guidance for developing processes for ongoing monitoring that are consistent with the risks associated with the research on the campus
- Developing a list of 'flags' that may trigger a university to conduct an audit, particularly if inconsistent with funding
- Initiating post-travel follow-up questionnaires for research-related trips to select countries
 - Track at the department level international travel that triggers questionnaire completion
- Working with OSSI and other security agencies to gather lessons learned and best practices for identifying potential threats
 - Receive guidance regarding access to unclassified databases used by the FBI and the federal Office of Personnel Management

Acknowledgements

- Michael Schmoyer, Ph.D., Assistant Deputy Secretary, HHS
- Michael Lauer, M.D., Deputy Director for Extramural Research, NIH
- Laurie Locascio, Ph.D., VPR, University of Maryland
- Dr. Peter Pisters, President, MD Anderson Cancer Center

In-person meeting speakers/experts

- Constance Taube, Deputy Director, National Counterintelligence and Security Center
- Teresa Domzal, Ph.D., Assistant Director, Corporate Strategy Integration, National Counterintelligence and Security Center
- Susan Saunders, Deputy Assistant Director, National Intelligence Manager, Counterintelligence, National Counterintelligence and Security Center
- Noni Byrnes, Ph.D., Acting Director, Center for Scientific Review, NIH
- Scott Kennedy, Ph.D., Deputy Director, Freeman Chair in China Studies, and Director, Project on Chinese Business and Political Economy, Center for Strategic & International Studies

NIH folks who provided expertise/info on internal processes

- Ken Bridbord and Jackie Officer, Fogarty International Center at NIH
- Patricia Valdez and Diane Dean, Office of Extramural Research, NIH
- IMOD staff & Executive Secretaries Nicole Garbarini, Ph.D., and Jessica Mazerik, Ph.D.

DISCUSSION