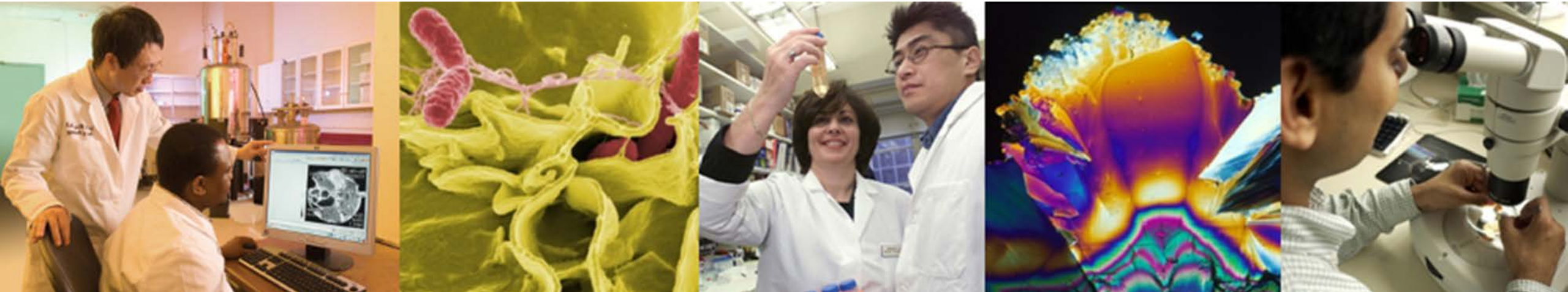


# Foreign Influences on Research Integrity

117th Meeting of the Advisory Committee to the Director

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# 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

# 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](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

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

- 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

# 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

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## 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
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# DISCUSSION