• **Topic:** The focus of this session will be on how research institutions are approaching this evolving area to date in such areas as communication, awareness, policies, procedures, etc. Information will be shared from 2-3 institutions in order to spark discussion around examples and current practices as well as what role FDP might play or activities that FDP could undertake to best support its members and the research community.
Agenda

• Welcome and introduction of the issue and objective of the session

• Overview of the new FDP Working group and objectives

• University overview
  • Harvard, Univ. of North Carolina, Northwestern

• Discussion and Q&A
Welcome and Introduction of the Issue and Objective of the Session
Welcome and Introduction of the Issue and Objective of the Session

• Key Environmental Factors
• Complexity, Breadth and Depth of Topics
• Pace of Change → Uncertainty
So What’s the Real Issue?

“Foreign Influence”

- Economic Implications
- Outside Activities (Appts & Affiliations)
- Intellectual Property
- Data Theft
- Open Science

- Over-Commitment

- Conflict of Interest
- “CRIS” Countries (China, Russia, Iran, Saudi Arabia)
- Talent Programs

- Other Support / Current & Pending
- Biosketches
- Publications
- Export Controls
- FBI
- DOJ
- Universities
- Sponsors
- Congress
- OSTP
“Foreign Influence”

- Diversion of intellectual property (IP) in grant applications
- Sharing of confidential information during peer review
- Failure to disclose substantial resources

August 2018

October 2018 - Present

July/August 2019

NIH Letter
“Foreign Influence”

August 2018

NIH Letter

- Diversion of intellectual property (IP) in grant applications
- Sharing of confidential information during peer review
- Failure to disclose substantial resources

October 2018 - Present

Foreign Component / Foreign Influence

- “Significant”
- Outside of United States

- NIH: Letters to Universities & ACD
- Congress: Sen. Grassley / Rubio, etc.
- NDAA, DoD, DOE, FBI

July/August 2019
“Foreign Influence”

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July/August 2019

Disclosure (NIH / NSF)

- Affiliations & appointments
- Include non-financial support
- Talent Programs
- Other Inclusions?
“Foreign Influence”

August 2018

NIH Letter

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July/August 2019

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- Affiliations & appointments
- Include non-financial support
- Talent Programs
- Other Inclusions?
New FDP Foreign Influence Working Group

• Overview and objectives
  • Inter-FDP committee to promote coordinated response
  • Foreign influence requirements identification
  • Confirmation of the accuracy/clarity of definitions (other support, appointments, etc.)
  • Plus understanding agency expectations (beyond simple requirements, what is needed)
  • Institutional responsibilities versus investigator responsibilities
  • Address issues that require input/dialogue
    • Restricted NOAs
  • Documentation of burden and suggestions for burden reduction
  • Promotion of harmonization across agencies where possible
  • Coordination with COGR and other interested parties
Membership

- Michelle Masucci (Faculty)
- Robert Nobles (Faculty)
- Lori Schultz (ERA)
- Susan Anderson (ERI)
- Pamela Webb (Research Administration)
- Jim Luther (Finance/Audit/Costing)
- Doug Blackman (Export Controls/Research Compliance)
- Mary Lee (COI/Research Compliance)
- Robin Cyr (At-Large)
- Pamela Caudill (At-Large)
- Kim Moreland (At Large)

Interested? Please email Pamela (pwebb@umn.edu) and Jim Luther (james.luther@duke.edu) so we can email you when the group needs additional input or help.
University Overview
Harvard, Univ. of North Carolina, Northwestern to include:

• Yesterday → Today → Tomorrow
• Obstacles Overcome
• Remaining Challenges

Faculty & Institutional Implications
University Overview

Harvard University

• Yesterday → Today → Tomorrow
• Obstacles Overcome
• Remaining Challenges

Faculty & Institutional Implications
University Overview

University of North Carolina

• Yesterday ➔ Today ➔ Tomorrow
• Obstacles Overcome
• Remaining Challenges

Faculty & Institutional Implications
University Overview

Northwestern University

- Yesterday → Today → Tomorrow
- Obstacles Overcome
- Remaining Challenges

Faculty & Institutional Implications
Polling Question #1:

What is your institution’s awareness?
- Faculty
- Leadership
Polling Question #2:

Has the pace of change/communication challenged your institution’s ability to provide adequate funding, leadership support, technical and administrative support to address these issues?
Polling Question #3:

Have there been unintended consequences of the national or your institution's response to these issues?
Polling Question #4:

What is your institution’s biggest concern as you address this?

- Other Support/Current & Pending, COI, Export Controls, Export Controls, IP Management, Data, Economic Concerns, Something Else
Discussion and Questions
University Activities Related to Non-Disclosure and Loss of Intellectual Property Concerns

Ara Tahmassian, Ph.D.
Chief Research Compliance Officer
Office of the Vice Provost for Research

Federal Demonstration Partnership Meeting
Foreign Influence Implementation Discussion
September 24, 2019
Framing the Issues

From our perspective the concerns can be summarized as:

• **Integrity of Peer Review Process**: Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and

• **Failure to Fully Disclose Information**: Failure by some researchers to fully disclose substantial resources from other organizations, including foreign governments, financial conflicts of interest; appointments at foreign institutions, etc. in their grant proposals or institutionally required disclosures.

• **Compliance with Regulatory Requirements**: U.S. Export Control laws and regulations establish a set of requirements for transfer of technology and data to foreign countries and/or foreign national in the U.S., in addition sanctions from the Office of Foreign Assets Control (OFAC) restrict interactions with individuals or entities on the sanctions list.

• **Loss of Intellectual Property (IP)**: There have been a number of reported instances of unauthorized removal of data from research laboratories resulting in loss of intellectual property including publication of the inappropriately obtained data before U.S. scientists.
Framework

The Advisory Committee to the Director Working Group for Foreign Influences on Research Integrity Recommendations

Organization of Recommendations

NIH

- Communication and Awareness
- Risk Mitigation
- Consequences and Actions

RECIPIENT ORGANIZATIONS

- Communication and Awareness
- Risk Mitigation
- Ongoing Monitoring
Communication and Awareness

ACD Recommendation:

“implement 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”.

Action: 80-90 informational sessions on the subject for various stakeholders.

The audience for these briefings has included the institutional leadership (e.g. Board Members, key Board Committees, President, Provost, Deans, Vice Presidents), faculty, school and central research administrators, University Development Officers, Technology Transfer Officers, the University Risk Management and/or Audit Committees as well as various university research oversight committees.
Faculty Disclosures

• Communication from OVPR on the importance of full disclosures
• Developed comprehensive Guidance and FAQ for the faculty on the requirements addressing major issues with guidance on each.
• Basic Principles
  ▪ Harvard University recognizes its important role in the advancement of legitimate national security needs and the protection of the intellectual property developed as a result of its research and scholarly activities.
  ▪ Harvard University’s stewardship of research funding, both from federal government agencies and from private funders, is a core institutional responsibility, and Harvard has developed policies and adopted rules to ensure that its activities are conducted with integrity and with due regard for the health, safety, and privacy of everyone concerned.

• Integrity of Peer Review Process
Faculty Disclosures

- Compliance with Regulatory Requirements
- Protection of Intellectual Property (IP) – includes pre-publication data
- Transparency & Disclose of Information
- FAQ with answers to specific questions from faculty and administrators received during the presentations and those sent to OVPR.
- Established a process for quick focused communications sent to impacted faculty as agency specific policy or guidance is issues (e.g. DOE Talent Program Memo, NIH Reminder Notice).
Section on Faculty Disclosure Guide and FAQ

FAQs

GUIDANCE ON RESPONSIBILITIES REPORTING & DISCLOSURE REQUIREMENTS

1. Integrity of Peer Review Process
2. Transparency & Disclosure of Information
3. Compliance with Regulatory Requirements
4. Protection of Intellectual Property (IP)
Communication and Awareness

Guidance for Researchers in Addressing Faculty Disclosure & Intellectual Property Protection

(As of 7/15/2019)

Agencies continue to issue updates, modification or clarifications to existing requirements. The Office of the Vice Provost for Research is continuing to monitor the communications from the agencies and will update this site and the FAQs as appropriate.

GUIDANCE FOR RESEARCHERS IN ADDRESSING FD & IP PROTECTION

1. Introduction
2. Basic Principles
3. Integrity of Peer Review Process
4. Transparency & Disclose of Information
5. Compliance with Regulatory Requirements
6. Protection of Intellectual Property (IP)
7. Definitions

Office of Vice Provost for Research
Integrity of Peer Review

Confidentiality of information obtained during peer review is critical to the integrity of the review process. The Office of Research Integrity (ORI Introduction to RCR: Chapter 10. Peer Review) explains:

“[I]nformation that is shared during peer review is shared confidentially, that is, with the understanding that it will not be shared with anyone else without permission. Confidentiality is generally required during grant reviews, manuscript reviews, and personnel reviews.

During grant and manuscript reviews, confidentiality helps protect ideas before they are funded or published. In personnel reviews, confidentiality is important to protect personal privacy.”

NIH's Peer Review: Grants and Cooperative Agreements lists eight (8) core values of the peer review process: expert assessment, transparency, impartiality, fairness, confidentiality, security, integrity, and efficiency. The Confidentiality section articulates this as follows:
Guidance for Administrators

• Developed a comprehensive Guidance for Review of Faculty Disclosures for administrators
  • Includes list of disclosures made and information disclosed
    ▪ Offices holding the information
    ▪ Examples of how/what to look for
    ▪ Essentially a guide for “connecting the dots”!

• Increased training for research administrators on developing landscape.

• Greater coordination through “Sponsored Administration Leadership Committee”.

• Exploring systems enhancements to assist with reviews.
Disclosed Information

- Collaboration Agreements: Research collaboration agreements with lab and/school
- Appointment Letters: Listing Specifics on duties, %-appointment, pay, any restrictions, etc.
- Biosketches: Information on faculty positions, appointments, memberships, honors, publications
- Other/Current and Pending Support: Listing of all faculty current and pending awards, effort, funding, foreign component, overlap, effort, etc.
- fCOI Disclosure: Listing of all faculty interests outside of the university and payments
- Outside/Professional Activity Report: Listing of all faculty outside activities - teaching, research activities, appointments, awards, honorary memberships, etc.
- Research Performance Progress Report (RPPR): Information on, accomplishments, publications, conference papers, and presentations, inventions, participants and Other Collaborating Organizations, etc.
- OTD Disclosures: Potential IP, start-up information and any positions, licensing, industry agreements
School: Disclosure

Responsible Office

- OTD Disclosures
- Collaboration Agreements
- Appointment Letters
- Biosketches
- Other/Current and Pending Support
- fCOI Disclosure
- Outside/Professional Activity Report
- Research Performance Progress Report (RPPR)
Risk Management - Sensitive Negotiations

- Established a University Committee for Review of Sensitive Collaborations to review international activities such as:
  - Contractual Agreements for Research (Funded or Unfunded), Services, Procurement or Related Activities
  - Gifts
  - Technology Transfer Agreements
- Process includes reviews of the activity, potential risk, and development of risk mitigation measures if appropriate.
Risk Management - Sensitive Negotiations

• Forms developed for each group
• Completed forms submitted to OVPR
• Review and assessment of risk (similar to existing Provostial Review)
• Determine if:
  ▪ Low risk - develop mitigation plan
  ▪ Higher Risk – review consult with Chairs of Committee, if necessary send to the Committee for review.
Sensitive Negotiation Flow-Chart

- Initiating Office Submits Form
- Review form received by OVPR
- Risk analysis questionnaire completed

- Risks Identified
  - NO Approve
  - YES Mitigation Measures Developed
    - YES Approve with Mitigation measures
    - YES- Modified Approve with modified mitigation
    - NO Committee Agrees

- Forward to committee for review
  - NO Disapprove
  - YES Committee Agrees
    - YES Approve with modified mitigation

Developed in consultation with appropriate offices (e.g. HIO, OGC, OTD, OSP, School Deans/Administrators, UDO, Federal Relations, etc.)
Risk Management- Visiting Appointments

Developed Guidance for oversight of visiting appointments of non-US researchers

• Question on the candidate (who, where, what)
• Hosting Research Unit (research portfolio, funding sources)
• Cybersecurity- what access, connections, etc.

*Note: All visitors to Harvard research programs must sign a Visitor Participation Agreement.*
Risk Management – Prospective Review

Developed prospective review procedures for the identification and enhanced risk management of challenging research portfolios. These reviews are intended to verify that the award management meets the funders criteria and that there are no changes (e.g. foreign component, conflict of interest management, etc.) that have been introduced since the award was accepted that may pose a compliance risk or the need for agency notification.

*Example: 90-10-3*
Risk Management – Other

- Faculty with joint appointments- process for greater oversight and receipt of regular information.
- Greater scrutiny of practices for providing access to resources (e.g. IT systems) to non-university persons (e.g. contractors, outside collaborators, etc.).
- Enhancing Research Data Security practices and policies.
Foreign Influence in Research

Robin L. Cyr, CCEP
Associate Vice Chancellor for Research Compliance
Research Compliance Officer
As UNC continues to strengthen existing international collaborations and pursue new opportunities that benefit our faculty, students, and research objectives, we ask that faculty and all principal investigators remain mindful of and adhere to guidance on foreign influence, which is available on the

**UNC Research Compliance Webpage**
# What should you do if you are engaged in sponsored research activity?

## Expectation Guidance Chart

<table>
<thead>
<tr>
<th>What</th>
<th>When</th>
<th>How</th>
<th>Why</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclose/ Report financial interests and relationships</td>
<td>Prompted by system COI disclosure, or within 30 days of acquiring new interests</td>
<td>AIR, the University's Activities, Interests and Relationships Management System (COI)</td>
<td>Policy on Individual Conflicts of Interest and Commitment</td>
</tr>
<tr>
<td>External professional activities for pay</td>
<td>At least 10 Days prior to beginning activity</td>
<td>AIR, the University's Activities, Interests and Relationships Management System (EPAP)</td>
<td>Policy on External Professional Activities of Faculty and Other Professional Staff &quot;EPAP Policy&quot;</td>
</tr>
<tr>
<td>Review and update Other Support, as needed</td>
<td>Now – for use in upcoming applications and progress reports</td>
<td>OSR, School of Medicine SPO</td>
<td>NIH: Biosketch Format, Instructions, and Samples NSF: Current and Pending Support. NSF: Biographical Sketch(es) – Synergistic Activities NSF: Collaborations and Other Affiliations</td>
</tr>
<tr>
<td>Ensure appropriate disclosure of foreign components</td>
<td>Prior to commencement of work with a foreign entity whether or not grant funds are expended</td>
<td>OSR, School of Medicine SPO</td>
<td>Grants to Foreign Organizations, International Organizations and, Domestic Grants with Foreign Components</td>
</tr>
<tr>
<td>Disclose recruitment or participation in a ‘foreign talent’ program (ex. 1000 Talents Program)</td>
<td>Immediately</td>
<td>Office of Research Compliance</td>
<td>No formal policy, additional information will be posted soon</td>
</tr>
<tr>
<td>Investment in a start-up company or technology</td>
<td>Before sending or receiving proprietary information about the related technology and/or investing funds</td>
<td>Office of Technology Commercialization</td>
<td>University’s Patent and Invention Policy</td>
</tr>
<tr>
<td>International travel</td>
<td>Prior to travel</td>
<td>UNC Global Travel Registry</td>
<td>UNC CH Policy Concerning Global Study, Travel, and Research.</td>
</tr>
<tr>
<td>Consult with export control officer, as needed</td>
<td>Consult shipping overseas, engaging in international collaborations, research related travel abroad</td>
<td>Export Compliance Office</td>
<td>U. S. Export Control Regulations</td>
</tr>
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</table>
Achieving export, trade and OFAC compliance is more than simply screening for denied and restricted parties—it involves an assembly of numerous export-related processes to get the job done and Visual Compliance has a full suite of versatile components that fit seamlessly into those processes.

Visual Compliance Offers:

- Restricted Party Screening
- Audit and Resolution
- Export classification
- Controlled Technology Management
- Export Automation
- Regulations Tips & Tricks

Email exportcontrol@unc.edu and ask to get access to Visual Compliance. This is free to all UNC employees with a valid email address.
UNC National Security Working Group

Chair – AVCR /Research Compliance Officer
Co-Chair – Director of Federal Affairs

- Professor and Chair of Biochemistry and Biophysics
- Senior Associate Dean for Research and Innovation, Professor of Physics and Astronomy
- Chief Audit Officer
- Director of Business Development, Industry Relations (Development Office)
- AVC for Campus Safety and Risk Management
- Executive Director of EH&S and Risk Management and the Biosafety Officer
- Executive Director of the Office of Sponsored Research
- Conflict of Interest Officer (Research Division) and the Assistant Provost for Academic Personnel (Provost’s Office)
- Interim Director of the International Student and Scholar Services
- International Liaison Officer and the Director of Global Relations (UNC Global)
- AVC for Human Resources
- Internal Controls Reporter, Enterprise Financial Accounting and University Controller
- CFO, Executive Director of Payroll and Materials Management
- Chief Audit and Compliance Officer for UNC Health Care System
- AVC for Institutional Privacy and Chief Information Security Officer
- Director of University Relations – Office of University Communications
- Director of Licensing and Innovation Support (Office of Technology Commercialization)
- AVC for Student Affairs and Senior Operating Officer
- Associate University Counsel
<table>
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<tr>
<th>UNC National Security Breakout Groups</th>
</tr>
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<tbody>
<tr>
<td>• Faculty and Employees</td>
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<tr>
<td>• Vendors</td>
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<tr>
<td>• Travel and Ambassadorship</td>
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<tr>
<td>• Grants and Gifts</td>
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<tr>
<td>• Students</td>
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<tr>
<td>• Physical Security</td>
</tr>
<tr>
<td>• Materials</td>
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<tr>
<td>• Disclosures COI and EPAP</td>
</tr>
<tr>
<td>• Cyber Security (DHS Cyber Security Review)</td>
</tr>
<tr>
<td>• Campus Communications</td>
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</tbody>
</table>
Breakout Groups – The Charge

- Review of foreign gifts, grants, contracts and collaborations
- Review process for faculty to disclose foreign financial interests and affiliations
- Each group is looking into how to leverage Visual Compliance – vendors, new hires, sponsored projects (interface with OSR database will be first to implement, HR and Finance – hopefully)
- Facility access and materials management and security
- Protections of data and cybersecurity
- Protection of intellectual property and the use of technology control plans
- Foreign travel safeguards and protections for students and faculty
- International visitors to campus – visiting scholars, students and delegations (including those coming in via the UNC Health Care System)
- Relationships with foreign entities and persons
- Communication, communication, communication
Quotes from an email I received recently from a student:

• “I want to appreciate you and want you to know that we’ve got your back, as well.”

• “You serve an important role, you are in a position that might be able to understand and make important impact to solving the problem. I, as well as many, want to understand the problem.”

• “The University has made me grow, as well as the US. I grew up being educated to be a global citizen.”

• “We also want to help.”

• “When there is a problem, it is not someone else’s problem, we’d like to contribute and shoulder it together. And I believe this is deep inside every researcher’s heart that motivates our work/position, deep down in your heart, and in everyone’s heart.”

REMEMBER

Not everyone is a bad actor.

According to the FBI, they are less than 1% but, the cost of lost IP can exceed $600 billion a year
MANAGING FOREIGN INFLUENCE ISSUES AT NORTHWESTERN UNIVERSITY

FDP Meeting, September 24, 2019

RICHARD M. LUEPTOW
Senior Associate Dean

Northwestern University
What do faculty think about foreign influence issues?

• “Never heard of it.”
• “I’ve heard about this, but I don’t know how it affects me.”
• “It doesn’t matter to me. My research isn’t that interesting.”
• “It doesn’t matter to me. My research isn’t that kind of research.”
• “It will change with the next administration.”
• “They can’t abridge my academic freedom!”
• “How will this affect my students/post-docs?”
• “How will this affect my overseas collaborations?”
• “Don’t tell me what to do!”
• “Just tell me what to do.”
What can be done?

- Educate faculty and staff
- Educate administrators how to educate faculty (e.g. what does “talent” programs mean to faculty?)
- Modify procedures (examples next)
- Keep track of what is going on (AAU, APLU)
- Update Conflict of Interest reporting
- Maintain academic freedom (e.g., recent DARPA grant)
- Meet with officials (FBI, agencies, OSTP)
- Track changes in what is considered non-fundamental research
What is Northwestern doing?

- FAQ’s: [https://www.research.northwestern.edu/foreign-influence-faqs/](https://www.research.northwestern.edu/foreign-influence-faqs/)
- Vetting visitors [Research Visitor Vetting Checklist](https://www.research.northwestern.edu/vetting-checklist)
- Limiting numbers of visitors (engineering only)
- Follow AAU and APLU recommendations
- VPR: “Guidance Regarding Foreign Influence and Involvement in University Research”: [https://research.northwestern.edu/guidance-regarding-foreign-influence-and-involvement-university-research](https://research.northwestern.edu/guidance-regarding-foreign-influence-and-involvement-university-research)
  - Transparency in disclosure
  - Export compliance
  - Policies for engaging visiting collaborators
  - Proper security of materials, data, and confidential information
  - Protection of intellectual property
  - Peer review
- Update NIH and NSF research administration checklists
- Presentations at departmental faculty meetings
- Engaging with federal officials
- Update annual COI disclosure questions as needed
What are the specific concerns regarding “foreign influence” in the academic setting?

What are “foreign talent recruitment programs” and why is there concern about them?

What is the federal government doing to address concerns about foreign talent recruitment programs?

What steps must I take in response to these concerns?

Do I need to end my foreign collaborations and/or stop welcoming foreign students and visitors into my lab?

I have a visitor in my lab who is supported by his/her home foreign institution. S/he is not funded by any of my federal grants. Do I need to account for this visitor in proposals or progress reports? If so, how?

How do I know if a company, university, or other entity creates risk? Do you have examples of entities that I should not work with or that invite extra scrutiny?

https://www.research.northwestern.edu/foreign-influence-faqs/
Vetting Visitors

- Awareness

- Common sense

- Checklist:
  
  The sponsoring PI has spoken to the prospective visitor on __________________ (DATE)
  
  □ in person
  □ by telephone
  □ by video conference

  □ The sponsoring PI confirms that the prospective visitor is competent and will provide a meaningful contribution to the PI’s research or educational program.

  □ The sponsoring PI can accommodate the prospective visitor in terms of space, lab support, and other expenses.

  □ The sponsoring PI has done appropriate due diligence and is not aware of any matters or problematic issues, including activities that are incompatible with Northwestern polices and values, that should be considered in the decision to invite the prospective visitor.
What is Northwestern NOT doing?

- Surveilling faculty or students
- Discouraging or shutting down collaborations developed with universities abroad
- Turning away students, postdocs or other scientists by virtue of the nationality
• “Northwestern is committed to being an inclusive and welcoming place for all international students. We cannot fulfill our mission to produce the highest caliber of research and solve problems of global significance without attracting the best talent in the world.....”

• “At Northwestern, knowledge knows no borders, and everyone at the University benefits from the presence of talented international students, faculty and staff. We recognize that these individuals play a powerful role in shaping our community, and we value them deeply.”

--Provost Jonathan Holloway, June 7, 2019
https://news.northwestern.edu/stories/2019/06/northwestern-message-to-international-students/