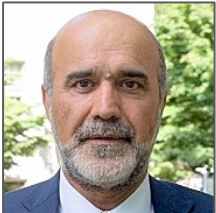


# Higher Education Compliance Issues



**Paul J Coleman**

Compliance Consultant, Retired NSF Investigator



**Ara Tahmassian**

Chief Research Compliance Officer, Harvard University



**Moderated by Lisa Mosley**

Executive Director, OSP, Yale University



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Manger, Huron Consulting Group



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# Current Compliance Issues

- Foreign Influences on Research
- Compliance Programs
- Self Disclosure
- Effects of a Government Investigation or Audit



# Foreign Influences on Research

- Foreign entities
- Media Reporting
- Investigating Researchers and Foreign Students
- Effects to Sponsored Programs & Visa Programs



# Foreign Influences: Current State Overview

## Federal Focus

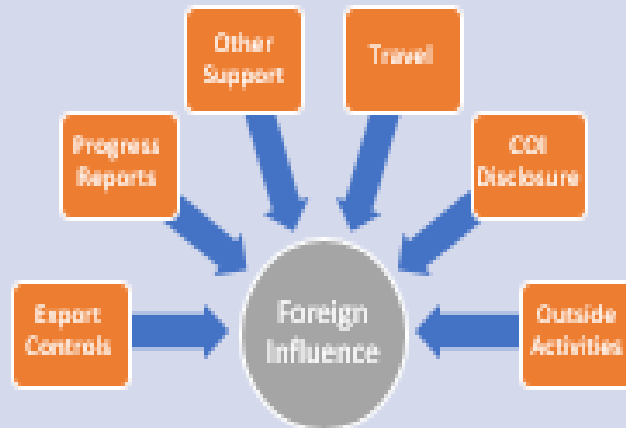
- Federal intelligence, security, and science agencies and members of Congress have expressed increasing concern regarding various forms of foreign interference on research
- Starting in August 2018, NIH has been taking action to address the concern:
  - Issued “Dear Colleagues” letter to grantee institutions
  - Released the Advisory Committee to the Director Report on Foreign Influence in Research in December 2018
  - Referred several allegations regarding foreign influence in biomedical research to federal investigators
- NSF, NIH and DOD have all issued varying communications that address foreign influence

## Industry Response

- Industry policy and advocacy groups have been coordinating responses to agencies to express their concern about the impact that the clarifications will have on institutions
- Key Policy and Advocacy Groups:
  - Association of American Universities (AAU)
  - Council on Governmental Relations (COGR)
  - Federal Demonstration Partnership (FDP)

## Institutional Challenge

- Institutions are challenged to figure out how to gather information from multiple sources, across typically disparate units within an institution to obtain the complete picture of foreign influence risk



# Foreign Influence + Other Support: Agency Guidance

## NIH

- Expansion of reporting requirements:
  - Unpaid appointments that provide access to lab space, research materials, and staff
  - Startup packages
  - Domestic research collaborations with scientists whose work is supported by an institution that is not the NIH grantee
  - Consulting that is in "any way" related to a faculty member's research endeavors
  - Research conducted outside of a faculty member's appointment period
  - Participation in a "talent" program

## NSF

- Biosketch requirements:
  - All appointments whether or not remuneration is made
- Current and Pending Support:
  - Information must be provided for all current and pending support irrespective of whether such support is provided through the proposing organization or directly to the individual
  - All project and activities, regardless of remuneration, that require a time commitment must be included.

## DOD

- DOD is required to:
  - Protect IP, controlled information, key personnel, and information about critical technologies relevant to national security
  - Limit foreign influence
  - Support efforts toward development of domestic talent in relevant scientific and engineering



# Addressing Foreign Influence

Research institutions across the country are considering various mechanisms to address foreign influence. Items to consider when implementing other internal controls are outlined below:

BACKGROUND CHECKS	VISITING PROTOCOLS	FOREIGN GIFTS & PARTNERSHIPS	SYSTEMS AND SPACE ACCESS	DATA SECURITY
<ul style="list-style-type: none"><li>• Consider expanding background checks for visitors and employees who may work on research projects</li></ul>	<ul style="list-style-type: none"><li>• Review and update Visiting Scientist agreement templates to capture technology and space access, IP restrictions, disclosure requirements, etc.</li></ul>	<ul style="list-style-type: none"><li>• Identify gifts received from foreign entities or individuals and ensure IP protection, as applicable</li><li>• Implement processes for escalated review of foreign agreements and/or agreements with companies subject to US sanctions</li></ul>	<ul style="list-style-type: none"><li>• Ensure identity management when provisioning access to systems</li><li>• Ensure access to physical space containing sensitive data is restricted</li><li>• Monitor access logs for unusual activity</li></ul>	<ul style="list-style-type: none"><li>• Determine strategies to protect against data exfiltration</li><li>• House sensitive databases using secure data centers and/or on restricted networks</li><li>• Prohibit the use of personal equipment on restricted networks</li><li>• Require use of loaner equipment during foreign travel</li></ul>



# Compliance Programs

- Most programs are based on federal sentencing guidelines
- Is compliance a required program or effective business practice?





# Compliance Programs

The **seven** elements identified in the federal sentencing guidelines are the primary indicators of the Federal Government's **expectations** for effective compliance activities



# Self Developed vs Government Required

- Self Developed - reduced risk in resolution of prosecution
- Government Required – often overly burdensome



# Self Disclosure

- Why? Required by Contract or Grant Conditions
- When? Significant evidence has been uncovered
- Who? Contracting & Program Officer, Your Cognizant Auditors,
- What? Clearly state issues identified by internal review and plan of action
- How? Official letter, preceded by and/or follow-up phone conversations



# Effects of a Government Investigation or Audit

- Resources, Relationships, Reputation
- Additional burdens
- Reduced morale and trust



?



# Other Issues?

COI – Corporate Gifts – Expenditure analysis - ICOI

