

#### FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

### Foreign Influence Management – Enhancing the Security and Integrity of America's Research Enterprise

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..and the members of the FDP Foreign Influence Working
Group

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- Current State Overview
  - OSTP JCORE Foreign Influence
  - NDAA 223: Disclosure of Funding Sources in Federal Funding Applications
  - MITRE Report: Improper Influence in Federally Funded Fundamental Research
  - GAO Report: Agencies Need to Enhance Policies to Address Foreign Influence

Overview as Context

- "Connecting the Dots" Foreign Interference and Associated Risks to the Integrity of Research
  - Listening Session Discussion
- Q&A

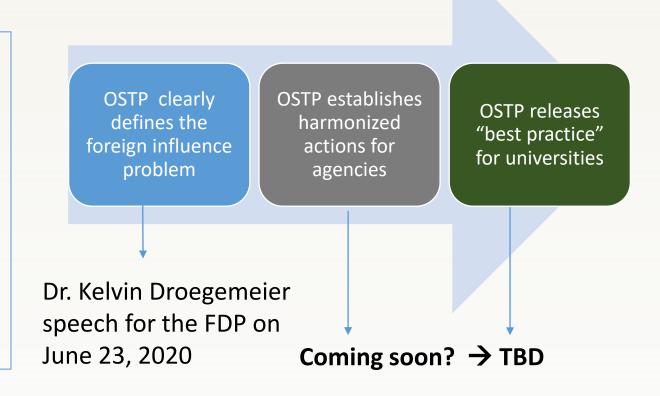


### OSTP – JCORE Report and Actions

OSTP: Office of Science & Technology Policy

JCORE: Joint Committee on the Research Environment – White House Summit

JASON Report: Fundamental Research Security





### NDAA: Section 223 Disclosure of Funding Sources in Federal Funding Applications

- 2021 National Defense Authorization Act (NDAA): sets spending and policy priorities for the Department of Defense
- Section 223: Disclosure requirements: Each individual listed in the application for federal funding must
  - Disclose amount, type, and source of all current and pending research support,
  - Certify that the disclosure is current, accurate, and complete, and
  - Entities applying must certify that the covered individuals in the application have been made aware of the requirement to report their current and pending research support
  - Enforcement: Non-compliance with disclosure requirements may result in
    - Application rejection // Suspension or termination of the active award,
    - Institutions that knowingly allow their researchers to hide sources of funding could likewise be permanently barred





# MITRE Report on Improper Influence in Federally Funded Fundamental Research – December 2020

#### Objective

- <u>Identify improper foreign government influence risks</u> to federally funded fundamental research.
- Employ effective tools and processes to counter improper foreign government influence.
- <u>Take an integrated approach</u> to resist improper foreign government influence on federally funded fundamental research while balancing it with the need to maintain the core principles and values of the enterprise, and continue to attract the best and brightest students and researchers to the U.S
- MITRE conducted interviews with 157 individuals in 65 sessions over an eight week period during the summer of 2020
- Participants represented a variety of stakeholders in the federally funded fundamental research enterprise (F3RE) including 19 universities and eight federal agencies
- Principal Findings (excerpts):
  - There is a <u>broad understanding of the negative impacts</u> of improper foreign influence
  - Ensuring openness and the ability to attract the best scientist internationally are top priorities and any action must be balanced against maintaining these priorities
  - Indication are that the existing courses of action are not completely effective
  - Individual PIs continue to perceive a <u>large gray area</u> when presented with specific international collaboration opportunities
  - Many universities feel that they are <u>unable to make informed decisions</u> regarding particular opportunities for international collaboration
  - Existing processes focus on disclosures made as part of a grant application, but many risks arise at later points in the grant and research lifecycle.
  - Enforcement efforts focused on specific countries create a hostile environment for valuable talent in the F3RE



### MITRE Report on Improper Influence in Federally Funded Fundamental Research

#### Academic stakeholders want

- Greater consistency across agencies with respect to disclosure requirements and the extent to which universities should scrutinize their faculty, students, and visitors
- Timely access to data about new emerging foreign influence risks
- Coordination of information regarding the behavior of foreign collaboration partners

#### Recommended Courses of Action

- Extend consideration to the entire grant and research cycle
- Replace the rule and compliance approach with risk reduction approach
- To the greatest extent possible, align the policies, data and disclosure requirements, online forms, and guidance regarding research integrity of the major federal grant-making agencies
- Create an information sharing and analysis center that would enable all parts of the F3RE to share up-to-date information on evolving risks, threats, and risk-mitigation strategies.
- Create and make use of metrics and indicators related to agreed upon courses of action, impact, effectiveness, improvement of PI understanding of where to draw the line, and how well we are ensuring openness, and the ability to attract the best scientist internationally



### GAO-21-30: Agencies Need to Enhance Policies to Address Foreign Influence

- The GAO states "To protect U.S. investments in scientific research from undue foreign influence, federal agencies should have conflict of interest policies and require researchers to disclose foreign interests."
- To this end, the GAO reviewed NIH, NSF, NASA, DoD, and DoE and found that only the first three had agency wide COI policies but none had agency wide policies that address non-financial COI
- "In the absence of agency-wide COI policies and definitions on nonfinancial interests, researchers may not fully understand what they need to report on their grant proposals, leaving agencies with incomplete information to assess the risk of foreign influence"
- GAO found that, regardless of whether an agency has a conflict of interest policy, all five agencies require researchers to disclose information—such as foreign support for their research—as part of the grant proposal that could be used to determine if certain conflicts exist.



### Conflict of Commitment Questions POC: Amanda R. Humphrey & Dr. Alice Young)



- If agencies ask institutions to collect information on all professional activities, what is the expected review scope?
  - Faculty are expected to engage in outside professional activities as part their institutional appointments, thus the pool of investigators that would require additional review, management and coordination would increase substantially.
  - Such changes in approach will add administrative burden and extraordinary costs to institutions.
  - There have been reports that the incoming administration will be looking to expand participation in research by a more diverse body of institutions, including MSIs and HBUCs. Given the likely disproportionate impact of increases in administrative burden on institutions enhancing their research activities, how will agencies ensure sufficient clarity and limit burden to maintain alignment with each agency's stated equity goals?
- Currently, there are large inconsistencies among agencies in the scope of the information they would like institutions to collect, how and where to transmit it, and clarity about their expectations for institutional assessment of that information.
  - Could the agencies create a matrix of the information to be collected by the institution?
  - With respect to the assessment portion, what are their expectations for assessment by the institution, for assessment by the federal agency itself, and for coordination between the two?
  - What will harmonization among and across agencies look like (perhaps some sort of CoI/CoC "Common Rule")?



#### Conflict of Commitment Questions



POC: Amanda R. Humphrey & Dr. Alice Young)

- The enforcement activities point to concerns over research security as being a key driver in clarifying and amending expectations around disclosures. Research security concerns would be difficult for institutions to assess because the vast majority of the business relationships appear legitimate. Several enforcement actions highlight intentional obfuscation by the indicted individual.
  - What is the expectation in terms of institutional responsibility in this area?
  - What tools will our federal partners make available to institutions?
- When we talk about disclosures of all potential conflicts of interest, there are many disclosures expected to be assessed, some currently not going through research offices and therefore the breadth of the changes poses significant challenges.
  - Example: Information about professional service is generally held within a PI's academic department, and many institutions will need major revisions in processes.



### "Connecting the Dots" – Foreign Interference and Associated Risks to the Integrity of Research

• "Listening Session" offered by FDPs Foreign Influence Group to key NIH and NSF partners re: challenges associated with gathering, integrating and reporting foreign influence disclosure information across our institutions



### Jan 6th Meeting Participants

- Foreign Influence Working Group (FIWG) Description: This Working Group will focus on and act as the key points of contact related to this emerging and evolving topic, how it is affecting the FDP member organizations; activities that FDP could undertake; assist in keeping members updated as well as provide for afor discussion with federal representatives.
- FIWG Members:
  - Pamela Webb (Res Admin) Co-chair
  - Jim Luther (Finance/Audit/Costing) Co-chair
  - Alex Albinak (FDP Co-Chair)
  - Susan Anderson (ERI)
  - Lynette Arias (Research Administration)
  - Doug Backman (Export Controls/Research Compliance)
  - Pamela Caudill (At-Large)
  - Robin Cyr (At-Large)
  - Mary Lee (COI/Research Compliance)
  - Michelle Masucci (FDP Co-Chair / Faculty)
  - Laura McCabe (Faculty)
  - Kim Moreland (At Large)
  - Robert Nobles (Faculty)
  - Lori Schultz (ERA)
  - Shandra White (At Large)

#### Federal Partners:

- Michelle Bulls, NIH
- Jean Feldman, NSF
- Rebecca Keiser, NSF

#### Other Participants:

• Wendy Streitz (COGR President)



#### Two primary topics have been discussed with FIWG

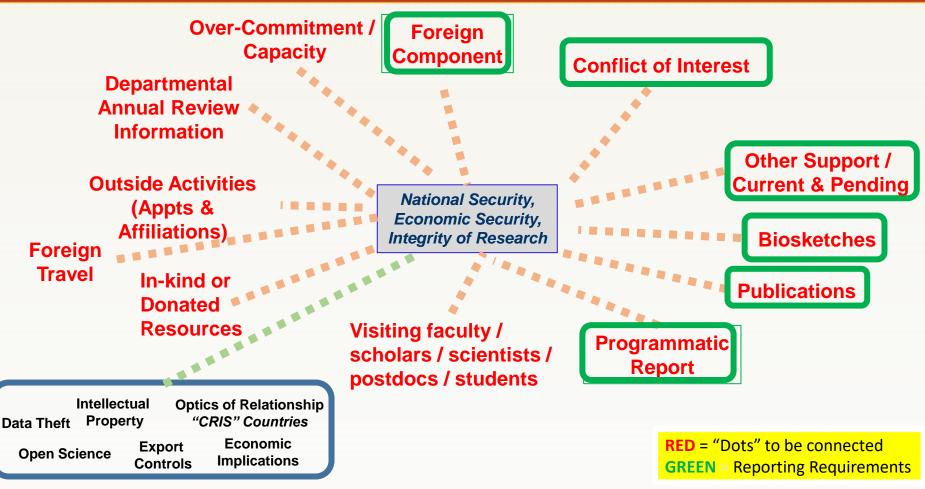
- How difficult is it for your institution to leverage processes, internal controls, technology and offices to comply with NSF and NIH's recent guidance?
- On the continuum of accountability, where are your thoughts coalescing with regard to who will ultimately be accountable for inaccurate reporting: the PI or the institution (knowing that it is NOT this clear cut)?

- Timeframe for Enforcement
- Clarity on Responsibilities and Expectations / Harmony & Consistency and Definitions

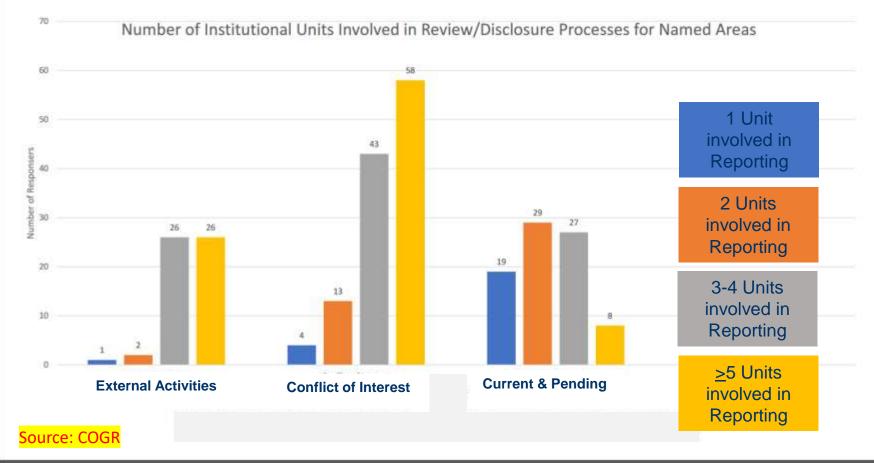
Note: Universities are committed to addressing the risk identified by agencies. This is a discussion about how to do most effectively in the least burdensome way and in an enforcement timeframe that is reasonable for institutions and federal partners



### "Connecting the Dots"









## "White Paper" Topics to Guide Discussion

- 1) Institutional / Cultural challenges related to Managing & Reporting Outside Activities
- 2) Management of FCOI data
- 3) The Inherent Complexity and Breadth of the "Dots" Makes it Difficult to Comply
- 4) Pitting Institution against individual faculty Guilty until proven innocent
- 5) Technical Barriers
- 6) Faculty Perspective
- 7) Accountability: PI or the institution

#### **Discussion Structure**

- Issue/Background
- Challenges
- Recommendations\*

#### **Process**

- Foundation for future discussion
- Brief (5 minute) coverage of each topic
- Questions from feds only

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<sup>\*</sup>Recommendations in this context means ideas that we can collectively explore for next steps; FDP's role does not include making formal recommendations to agencies



## 1. Institutional / Cultural challenges related to Managing & Reporting Outside Activities

- Differing definitions of what needs to be reported
- Historically, institutions have not included reporting of an investigator's outside professional activities except for COI
  - "Consulting" activities are not considered related to an investigator's research endeavors because they are the provision of contracted services intended to benefit a third party
- 9-month employees likely don't have obligations to their institution during the summer
- Change may involve adjustments in tenure and faculty governance
- Institutions and investigators have limited ability to track and establish monetary value of unique materials or data sets



## 1. Institutional / Cultural challenges related to Managing & Reporting Outside Activities

#### **Recommendations**

- 1. Ensure requirements and enforcement align with institutional ability
- 2. Harmonize requirements across agencies so that rules are consistent and able to be clearly articulated
- 3. Institutions will vary with respect to how they approach this centrally or reliance on faculty's accurate disclosure
- 4. Federal agencies should have resources to assist in advising throughout the grant lifecycle and making determinations of compliance



#### 2. Management of FCOI Data

- Agencies currently have inconsistent requirements; it is difficult to institute and enforce rules with inconsistent FCOI policies
- Outside commitments were not necessarily considered FCOI and therefore not consistently reported
- Many institutions treat FCOI compliance separately and distinct from pre-award staff and systems and it will be a challenge to integrate them
- Confidentiality FCOI disclosures and determinations are typically treated confidentially and shared with a limited number of systems
- FCOI reporting cycles and systems do not always align with grant reporting requirements or timelines



#### 2. Management of FCOI Data

#### Recommendations

- 1. Recognize privacy issues that institutions will face; clearly articulate purposes for use of information that is disclosed
- 2. Establish clear, unambiguous definitions/descriptions that all parties understand
- 3. Consider the complexity of evaluating unpaid positions, affiliations, etc. which are outside the FCOI requirement
- 4. Harmonize requirements across agencies
- 5. Understand timeline needs for new or substantially altered systems



## 3. Inherent Complexity and Breadth of the "Dots" Makes it Difficult to Comply

- No national standards exist about data, definitions, and practices relative to C&P/Other Support, COI, COC, Faculty Annual Reporting
- Culture varies tremendously from "I own you lock, stock, and barrel" to "just do your duties"
- Who receives data varies significantly
- The format of data varies significantly and data collection sites do not intersect with each other



## 3. Inherent Complexity and Breadth of the "Dots" Makes it Difficult to Comply

#### Recommendations

- 1. Award one or more grants to help create an in-depth understanding of the challenges involved in consolidated data collection and reporting
- 2. Clearly and unambiguously define the scope of reporting expectations
- 3. Clearly articulate what data elements belong to what purpose, and limit their use accordingly
- 4. Seek to identify good models that could be re-purposed or re-used
- 5. Consider timing of data collection and sharing; allow sufficient time for adaption to updated standards/requirements
  Group

Input



## 4. Pitting Institution against Individual Faculty – Guilty until Proven Innocent

- Understanding the rapidly changing requirements and clearly communicating the to faculty is a challenge
- "Sea-change" mindset that is moving universities away from a supportive and facilitative environment to one of mistrust/assumption of possible wrong-doing
- Inconsistent, or vague requirements makes it difficult to identify non-compliance; retrospective reviews based on new rules exacerbate this
- Agencies and institutions are not fully equipped to quickly and decisively handle the repercussions of non-compliance.
- Investigating claims can cause significant disruption to the lives of investigators and their labs, and can have significant negative implications even if there are no ultimate findings



## 4. Pitting Institution against Individual Faculty – Guilty until Proven Innocent

#### Recommendations

- 1. Harmonize and clarify the requirements and the investigative and adjudicative process across agencies, with timelines
- 2. Partner in designing processes and approaches low-risk issues should allow faculty to continue research during an investigation
- 3. Recognize that differences in size, type (private/public), and IHE/industry will result in varying ability to enforce or investigate



#### 5. Technical Barriers

- Many institutions today have separate systems and offices to track grants, gifts, appointments, FCOIs, faculty activity, and COC
- Significant investments in technology will be required to integrate systems, data, and processes
- Technology resources at institutions are severely constrained, even more so due to COVID and associated budget cuts
- No comprehensive system exists in the commercial marketplace
- Many data points are still paper-based



#### 5. Technical Barriers

#### **Recommendations**

- 1. Ensure that expanded reporting requirements are consistent across agencies so that institutions can develop a single workflow and system that will enable compliance for all agencies
- 2. Provide grants to institutions (similar to the way IRB systems were handled) to allow for development and sharing of reusable "demonstrable-dots-connected" systems
- 3. Allow adequate lead time for implementation
- 4. Acknowledge different pathways to effectiveness



#### 6. Faculty Perspective

- Faculty get "mixed messages" science encourages "open science", there are many international students; institutions encourage faculty to be actively engaged outside the U/outside the US but less and less clear that these engagements continue to be welcome
- Deliberate avoidance of rules is rare; confusion about what is normal, allowed and needed is common
- Faculty need to thoroughly understand rules to be able to train the next generation of scientists
- Faculty see these rules through the lens of "academic freedom"; compliance activities that directly impact them are likely to have a shared governance review requirement



#### 6. Faculty Perspective

#### **Recommendations**

- Harmonize definitions and requirements across agencies so they are easy to understand/seek faculty input for clarity
- Provide agency support to faculty so that questions/concerns can be promptly addressed
- Allow for timely assessments long enough to get the right facts; short enough to not unduly endanger reputations. Allow for faculty response.
- Avoid reporting violations or imposing penalties until the matter has bee adjudicated
- Establish national norms for enforcement that institution can adopt
- Allow research to continue while most investigations are underway



#### 7. Accountability: Pl or the Institution

- Institutional signatures should have meaning all parties should be clear about what approval means and what obligations accrue with a signature
- Any obligation that requires an institution to sign-off without the ability to validate that information inherently detracts from the value of the signature.
- Approvals lose meaning and value when they are forced, imprecise or impractical
- Data today is limited, imprecise, and subject to interpretation; additional clarity and precision is critical for all parties.



#### 7. Accountability: Pl or the Institution

#### **Recommendations**

- Institutions should be held accountable for that which is realistically under their control
- Institutions should not be help responsible for inaccurate information if they have policies in place that require full and accurate disclosure and have trained appropriately
- Respective roles of institutions, agencies, and investigators should be clearly stated
- Implications of failures should be clearly articulated and aligned with the party(ies) who failed
- Investigators should be helped personally responsible for information that must come directly from them
- Institutions and agencies should join forces to provide educational tools about reporting obligations and expectations.



Q&A (Time Permitting)