

# Revisiting the Framework for Reviewing Global Engagements October 20, 2021

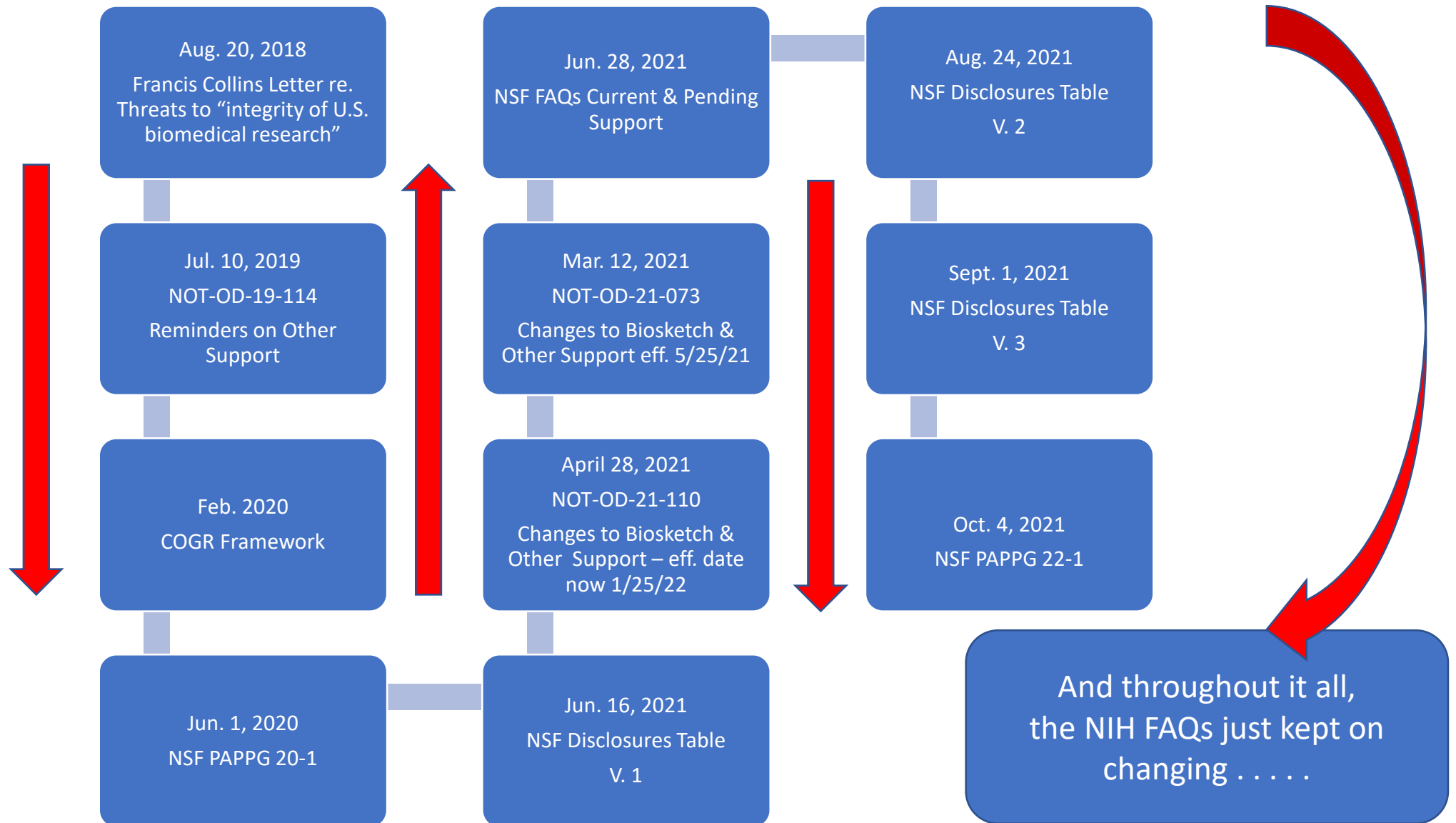
## **Moderator:**

- **Naomi Schrag, Vice President for Research Compliance, Training & Policy, Columbia University**

## **Guest Speakers (in order of appearance):**

- **Rob Rutenbar, Sr. Vice Chancellor for Research, University of Pittsburgh**
- **Tracey Westervelt, Director, Research Finance, Harvard University**
- **Craig Reynolds, Assist. Vice President for Research-Sponsored Projects, University of Michigan**
- **Stacy Pritt, Asst. Vice President, Conflict of Interest & IACUC, Faculty Associate, Export Control Officer, University of Texas Southwestern Medical Center**

# Guidance Timeline





# Improving Disclosure Mechanisms at Pitt

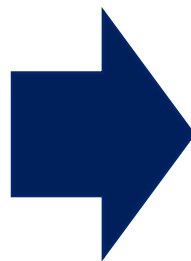
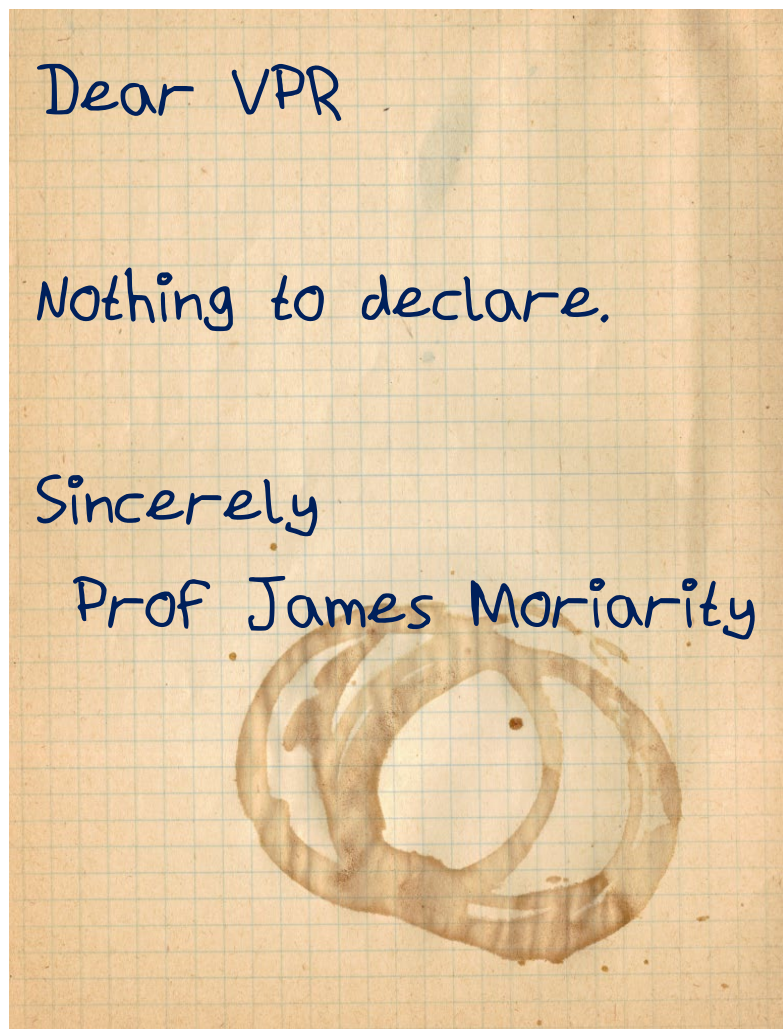
**Rob A. Rutenbar**

Senior Vice Chancellor for Research  
University of Pittsburgh

Pitt **Research**



# Disclosures@Pitt: 2019→2020



## Integrated, unified, online

1. Disclosures under review:

View/Edit	Organization	Relationships	Disclosure Types	Total Value	Total Days	Last Updated	Remove
There are no items to display							

2. Previously reviewed disclosures: (click 'Modify' to enable editing)

Modify	View	Organization	Relationships	Disclosure Types	Total Value	Total Days	Last Updated	Remove
	<a href="#">View</a>	American Physiological Society	Self	<ul style="list-style-type: none"><li>Reimbursed and/or Sponsored Travel</li><li>Consulting and Other Professional Services (including but not limited to advisory, speaking, employee, independent contractor, editorial and expert witness services)</li></ul>	\$15,000.00	20	6/26/2020 7:14 AM	
	<a href="#">View</a>	Springer Publishing Company LLC	Self	Reimbursed and/or Sponsored Travel	\$0.00		6/26/2020 7:14 AM	
	<a href="#">View</a>	Americans for Medical Progress	Self	Management, Officer or Board of Directors Positions (e.g.: President, CEO, CTO, CMO, CSO)	\$0.00	2	6/26/2020 7:14 AM	
	<a href="#">View</a>	Japan Aerospace Exploration Agency	Self	<ul style="list-style-type: none"><li>Reimbursed and/or Sponsored Travel</li><li>Consulting and Other Professional Services (including but not limited to advisory, speaking, employee, independent contractor, editorial and expert witness services)</li></ul>	\$10,500.00	1	6/26/2020 7:14 AM	

# Problem: Open Ended Q&A

**INSTITUTION:**

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**COUNTRY:**

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**TITLE/ROLE:**

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**DISCUSS:**

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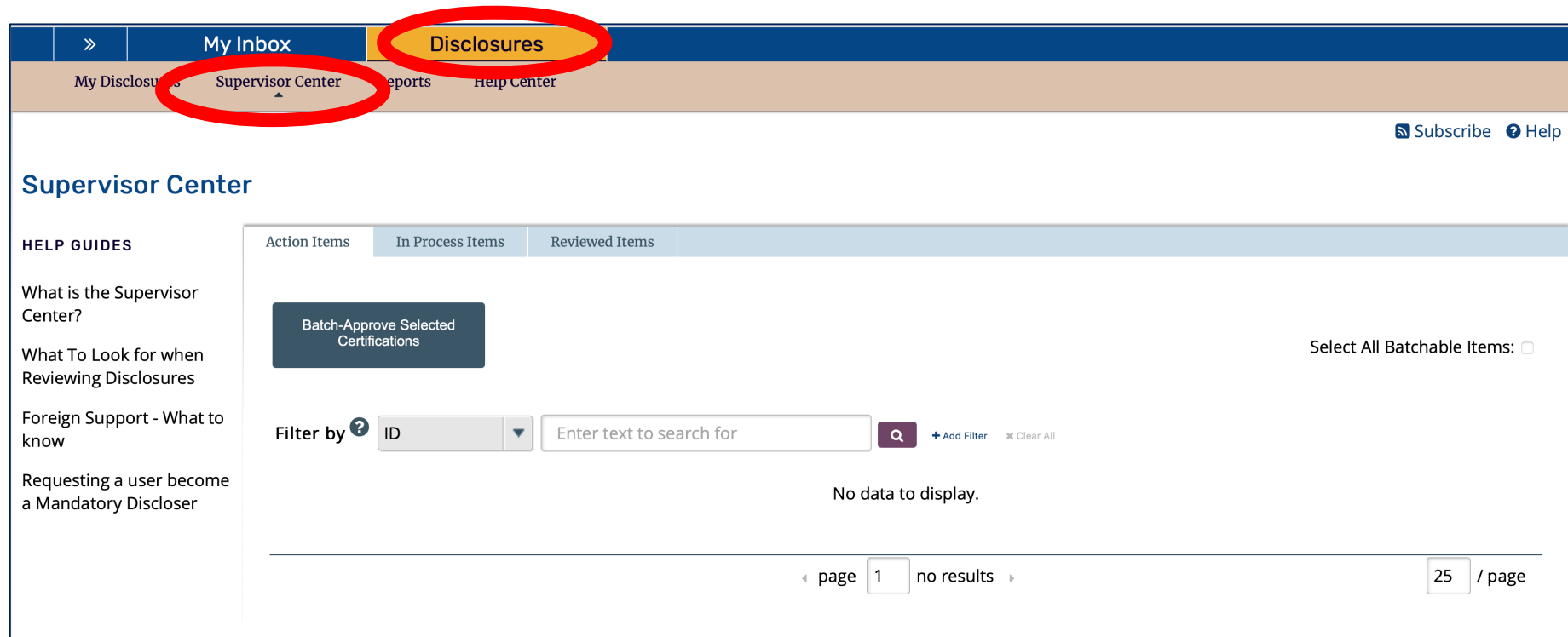


# Solution: Yes/No Question Decision Tree

QUESTION	RESPONSE FORMAT
Name of Institution	TEXT BOX
Country:	DROP DOWN MENU
Title or Role:	TEXT BOX
<b>Do you conduct research, scholarly activities or teach (in person or remotely) at this Institution or in collaboration with them?</b>	YES/NO If YES – TEXT BOX
<b>Have you applied for any grants on behalf of this institution? Are you included as effort on any grant associated w/ this institution?</b>	YES/NO If YES – DROP DWN MENU
<b>Is your appointment or affiliation listed on this institution's website or other promotional materials?</b>	YES/NO
<b>Do you acknowledge this position in your CV, your publications, in other research communications, or on your faculty webpage?</b>	YES/NO
<b>Have you disclosed this position to your funding agency according to their requirements?</b>	YES/NO/NOT-REQ

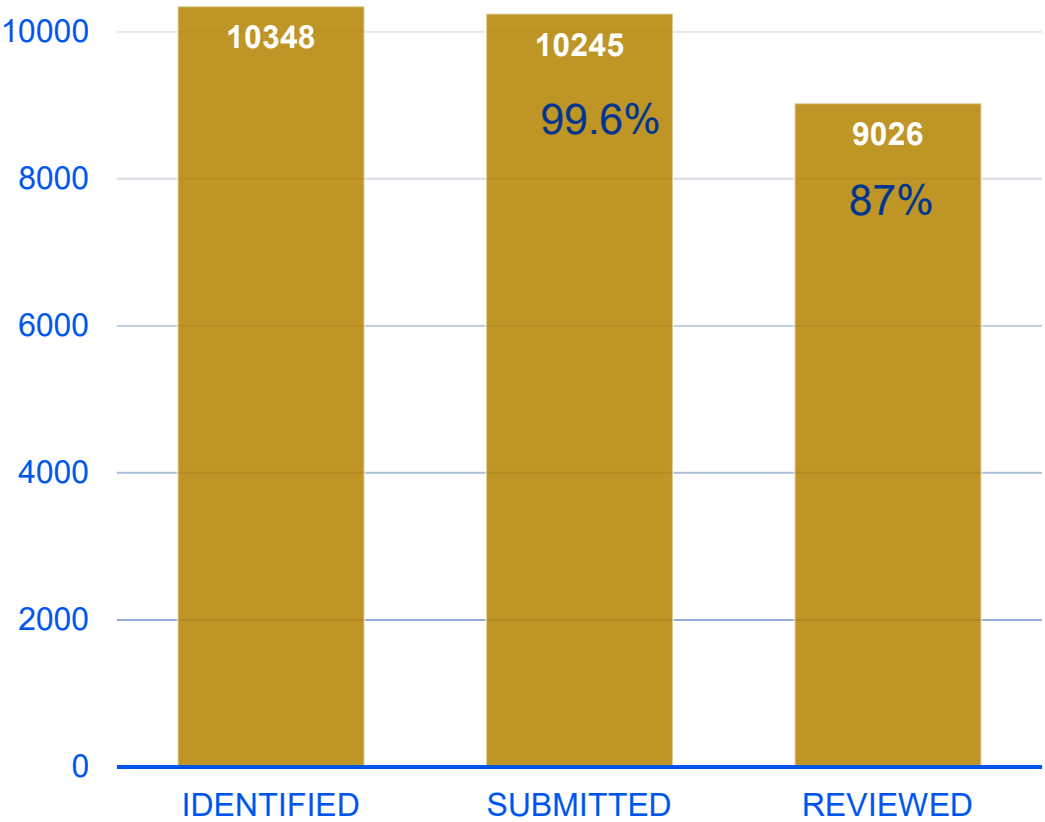
# More Improvements: Supervisors

- Added **training** for research supervisors, and **simplified** the Disclosure Tracking page for their disclosing staff

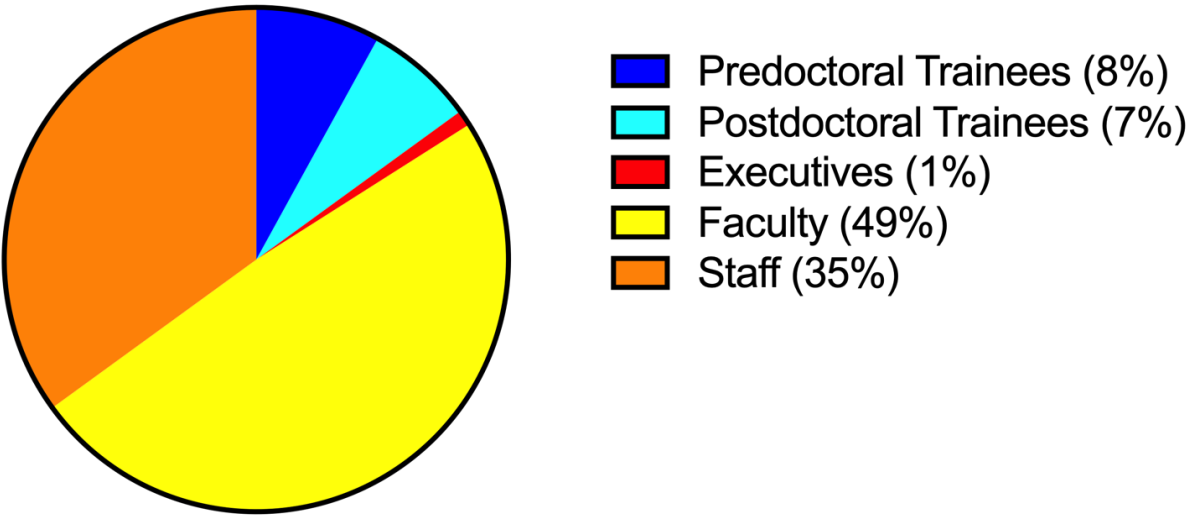


# 2021 Results: 10x More Foreign Disclosure

## Snapshot +2mo After Deadline



## Disclosers by Employment Category





# Improving Processes for Disclosures Concerning International Activities

Tracey Westervelt

Director, Research Finance

Office of Sponsored Programs, Harvard University



# Where Harvard Started: International Focus

## Respond to increased focus by federal agencies and sponsors

- Identify the impact and potential influence of international connections
- Ensure sponsored programs are compliant with existing agency requirements

## Consolidate the University's collection of information

- New GMAS functionality to capture details already imbedded in the proposal and awards

## Support requests by agencies and Harvard leadership

- Fulfill reporting requirements, enhance monitoring capabilities
- Substantiate University's compliance obligations

# The 10 International Components in GMAAS



International Sponsor



International Subaward



International Travel



International Collaboration



Establishment of New  
International Site



Use of International Facilities/  
Instrumentation at an International Site



International Shipment/Transfer/Exchange  
of Research Materials, Data and/or  
Equipment



International Human Subjects  
and/or Animal Research



Foreign National



Impact on U.S. Foreign  
Policy

Only Applies to Specific Sponsors



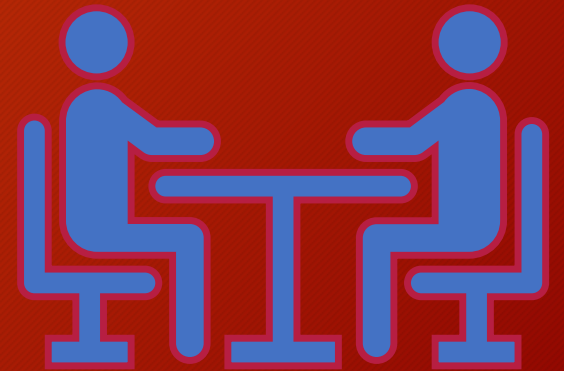
# Fast Forward 12 Months: NIH Notice(s)

- NIH issues three notices [NOT-OD-21-073](#), [NOT-OD-21-107](#), [NOT-OD-21-110](#)) that update its submission requirements, specifically related to Faculty Disclosures, and the Grants Policy Statement with a staggered timeline.
- Some requirements are clarifications while others are changes.
- Pivot to update policy, systems, and business processes related specifically to faculty disclosures

# Committees, committees and more committees

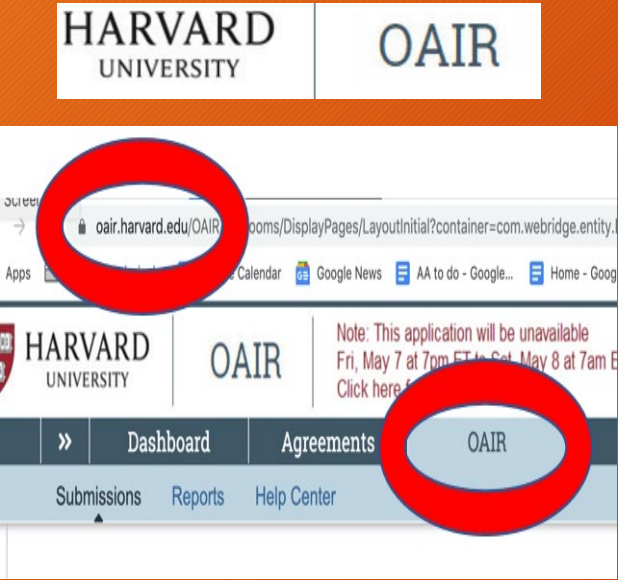
Six Committees working through issues and business process:

- 1) Faculty Disclosure Working Group
- 2) Faculty Disclosure Systems Subgroup
- 3) NIH Contract Review Working Group
- 4) **Faculty Disclosure Executive Committee**
- 5) Faculty Disclosure Process Group
- 6) Faculty Disclosure Training and Communication Group

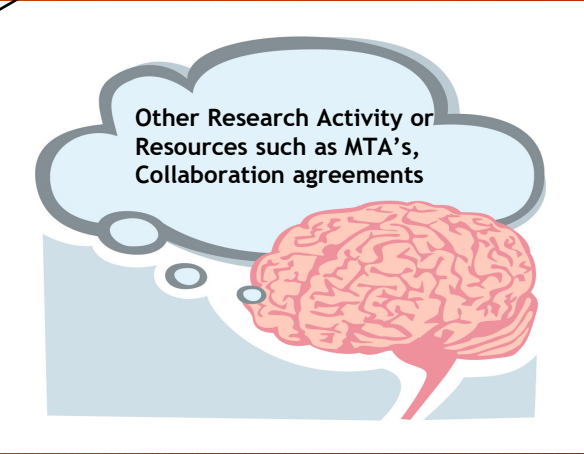




# Sources of Information for Other Support



Agreements - DUA



Harvard GMAS

Other Support – Project/Proposal

\*Title:  
Major Goals:  
\*Status of Support:  
Project Number:  
Name of PD/PI:  
\*Source of Support:  
\*Primary Place of Performance:  
Project/Proposal Start and End Date: (MM/YYYY) (if available):  
\* Total Award Amount (including Indirect Costs):  
\* Person Months (Calendar/Academic/Summer) per budget period.

# HARVARD INITIATIVES UNDERWAY

- Enhanced Guidance and FAQs for Faculty Disclosures
- Establishing a University-wide Research Compliance Policy Review Committee
- Systems Enhancements
- Mandatory training for faculty and grants administrators



# CHALLENGES TODAY

- Specific workflow for NIH Just in Time and RPPR's
- Consolidating data and overcoming faculty concerns regarding privacy
- Subaward Disclosure Process
- PI signature process on Other Support
- Process for review of Other Support
- External foreign contracts involving research (storage, review)

UNIVERSITY OF MICHIGAN

# SUPPORTING INTERNATIONAL RESEARCH AT MICHIGAN

The Latest Challenges and Questions to Ponder

Craig Reynolds, Assist. Vice President for Research  
Sponsored Projects



# Efforts To Date (a non-exhaustive list)

- Policy

- Standardized applicability of COI policy

- Tools

- Added new questions on international engagement in our eResearch systems
  - COI disclosure form
  - Proposal Approval Form (PAF)
  - Certifications of PI/Co-I when electronically signing PAF

- Processes

- Instituted Other Support Review compliance checkpoint



# Challenge #1

## Review of Faculty “Outside Agreements” with Foreign Entities

# Challenge #1: Review of Faculty “Outside Agreements” with Foreign Entities (per NOT-OD-21-073)

- Getting the agreements is the easy part
- How do we know there is an agreement that must be reviewed?
- How do we know that an agreement has been reviewed?
- Who is responsible for reviewing agreements and for monitoring remediation?
- When should we review agreements (at time of disclosure or JIT)?
- Who is responsible for translations?
- Must translations be certified?
- Where should agreements be electronically stored?
- Who should have access to the agreements?

# Review of Faculty “Outside Agreements (cont’d.)

- What should we be reviewing for?
  - Per [NIH Foreign Contracts FAQ 4](#), “NIH will review contracts, grants or any other agreements to confirm that all information provided in the Other Support submission is accurate and complete.” Is that all?
  - Commitment overlap (yes)
  - Scientific and budgetary overlap (theoretically yes, but how? Is investigator’s certification sufficient?)
  - Allocation of intellectual property rights (maybe)
  - Confidentiality provisions (maybe)
  - Publication and affiliation requirements (maybe)
- How do we advise faculty without providing legal counsel?

# Review of Faculty “Outside Agreements (cont’d.)

- How do we handle problematic agreements?
  - Require faculty renegotiate their agreement?
  - Reduce faculty appointment to avoid effort overlap?
  - Turn down funding?
- How do we address faculty claims of contract interference?
- What constitutes acceptable evidence that faculty have satisfactorily renegotiated their problematic agreements?
- How do we ensure that faculty understand what terms and conditions they should and should not accept in future agreements with foreign entities?

## Challenge #2

# Review and Mitigation of Conflicts of Commitment and Non-financial Interests



# Challenge #2: Review and Mitigation of Conflicts of Commitment and Non-financial Interests

- Unlike FCOIs, regulatory requirements for Conflicts of Commitment ill defined and evolving
  - [Agency Actions Needed to Address Foreign Influence, GAO Report 22-105434](#)

“In the absence of agency-wide COI policies and definitions for non-financial 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... We recommended defining non-financial conflicts in agency policies...”
- Unlike FCOIs, schools/colleges have historically been responsible for handling Conflicts of Commitment at U-M

# Challenge #2: Review and Mitigation of Conflicts of Commitment and Non-financial Interests

- Most urgently, U-M policies need updating to give Office of Research a role in adjudicating COC's
  - Regents By-laws
  - Standard Practice Guide (U-M “policy book”)
  - Faculty Handbook
  - Policy for the Identification and Management of Conflicts of Interest Related to Research, Sponsored Projects, and Technology Transfer
- How broad or narrow should the updates be? Will other agencies follow suit?

# Challenge #2: Review and Mitigation of Conflicts of Commitment and Other Non-financial Conflicts

- Policy needs more precision in its application
  - “A potential conflict of commitment exists when a faculty or staff member’s external relationships or activities have the possibility (either in actuality or in appearance) of interfering or competing with the University’s educational, research, or service missions, or with that individual’s ability or willingness to perform the full range of responsibilities associated with his or her position.”
  - What does this mean in context?
    - 12 month, 10 month, and 9 month appointments
    - Allowance for faculty to engage 1 day / week in “outside activities”
- How do we effectively interface with Deans and Chairs?
- Can we fold COC reviews into existing COI processes?

## The Grand Challenge

Success will require socializing with our faculty the reality that NIH policy requires U-M to review their private, independent outside activities and agreements with foreign entities if they have or are seeking support from NIH

Craig A. Reynolds, Assistant Vice President for  
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# Connecting the Dots

**Stacy Pritt**  
Vice President,  
Conflict of Interest &  
IACUC Faculty  
Associate, Export  
Control Officer



**UT Southwestern**  
Medical Center

Grants

Tech  
Development

Travel  
Oversight

External  
Activities

# The Dots

Information  
Security

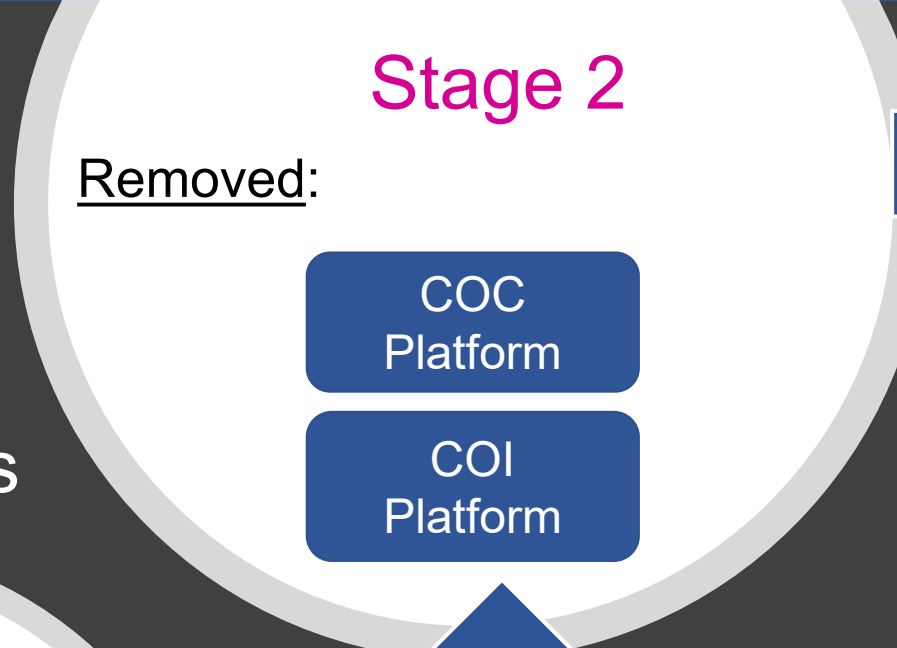
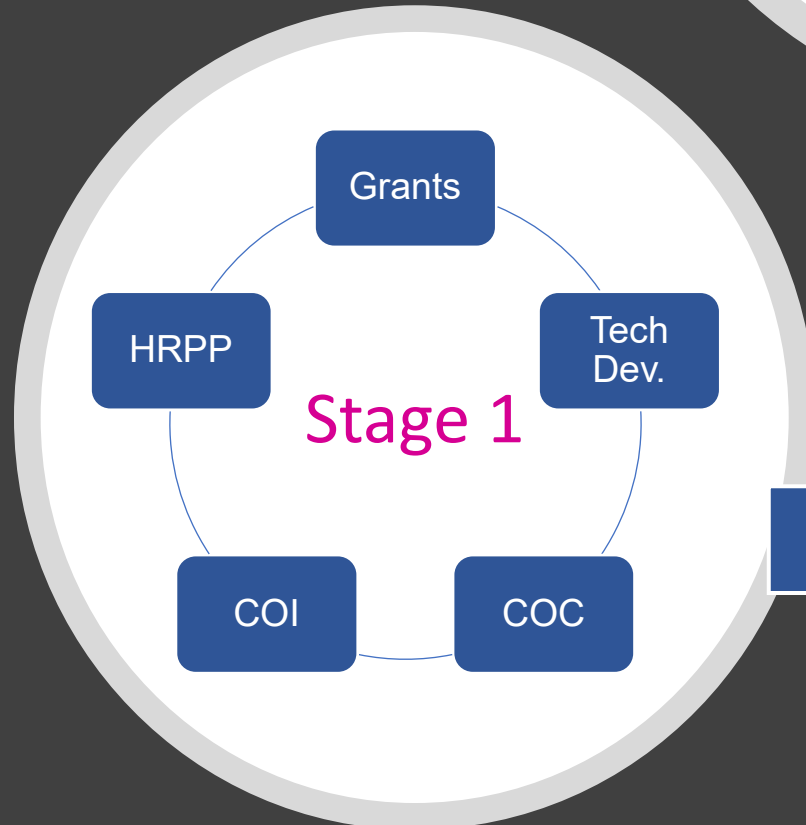
COC

Export  
Controls

International  
Affairs

COI

# Progressive Development of Research Administration Software Platforms

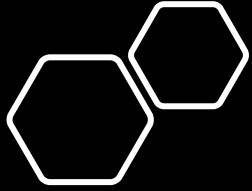


## Stage 3

- New System:
  - New integrations
  - Combine COC & COI in one portal
- New Structure: Include COC, COI, & Export Controls in one department
  - Improved Disclosure Forms
  - Revamped Training
  - Enhanced Data Collection
  - Enhanced Screening

# New Opportunities: “Research at a Glance”

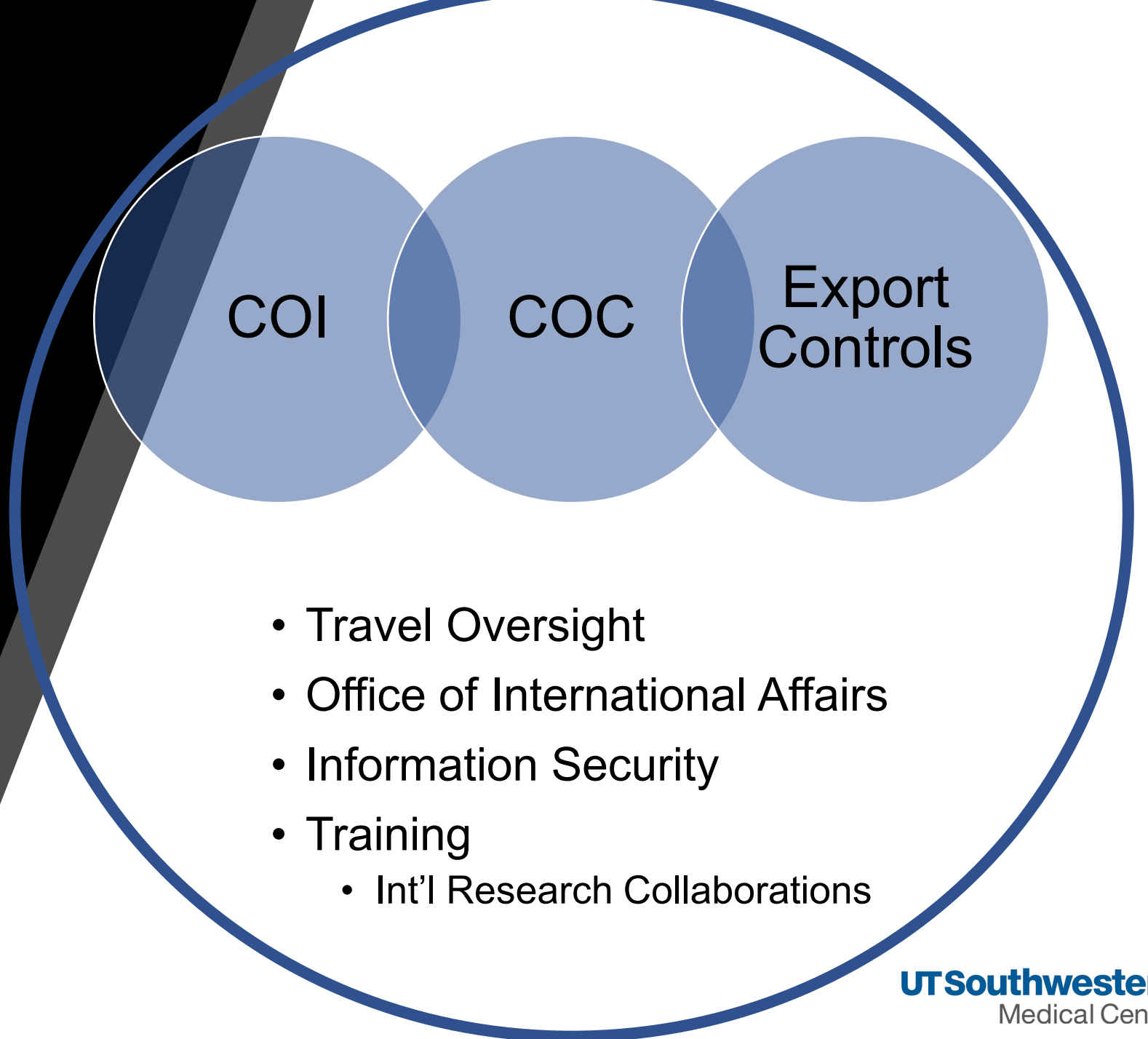
- Display:
  - PI Name
  - IRB Protocols
  - IACUC Protocols
  - Grants
  - Agreements
- Next Steps:
  - Access to Information Security



# New Opportunities: “COI at a Glance”

- Display:
  - Training Status
  - Disclosure Submissions
  - Disclosure Category
  - Entity Name
    - U.S. or Non-U.S.
  - COI related documents, e.g., management plans
  - Approval Status
    - COI
    - Supervisor
- Access:
  - Authorized users in COI, Grants, Tech Dev. & HRPP units
- Future “Export Control at a Glance”:
  - Export Control Documentation, e.g., Technology Control Plans (TCPs), Licenses

# Synergistic Combination





# Poll Questions to Set the Stage for Our Case Study

1. In the past year has your institution made changes to its processes or systems to address NIH and/or NSF support/affiliation disclosure requirements?
  - Yes
  - No
  - Changes are currently being considered
2. Does your institution review faculty consulting agreements before the faculty members sign them?
  - Yes
  - No
  - It depends
3. If you answered yes to Q.2, who reviews the agreements?
  - a. The school or department
  - b. COI/Research Compliance office
  - c. Sponsored Programs Office
  - d. Office of General Counsel
  - e. Tech Transfer Office
  - f. Someone else
  - g. I did not answer “yes” to Q.2
4. Does your institution require faculty to obtain approval before hosting a visiting scientist?
  - Yes
  - No
  - It depends



# Case Study

- Prof. A. is a pharmacologist at Star University, a private institution. Prof. A has grant funding from NIH that covers 60% of his salary and grant funding from NSF that covers 30% of his salary. He is a tenured, full-professor with a 12-month appointment. He works only on fundamental research.
- Star U. permits faculty to consult one day per each five-day week. Star does not require disclosure or review of faculty consulting agreements except as required under NIH and NSF COI rules. Prof. A. has been following all the news coverage about government investigations into Inappropriate foreign influence. Prof. A. is concerned, and he sends his department chair his three current consulting agreements and asks him “Are these OK?”
- **Consulting agreement #1** is with a U.S. pharma company to review safety data for an FDA-approved drug. It requires that Prof. A. attend two one-day meetings and pays \$1,500 per meeting plus reimbursement of travel expenses.
- **Consulting agreement #2** is with a Canadian pharma company to provide advice on the development of a new research protocol. It pays \$10,000 and must be completed in a month. Prof. A. signed an NDA agreeing to keep the terms of the agreement confidential
- **Consulting agreement #3** is with a university in China and requires Prof. A. to provide advice on setting up a new degree program in pharmacology. It names Prof. A. as an adjunct faculty member and pays him \$30,000 per year. The agreement requires him to make 3, separate, month-long visits to the Chinese university each year. It also requires Prof. A to host Prof. B., a pharmacologist from the Chinese U., in his lab for 3 months to help Prof. A with his research and learn how his lab is set up. Prof. A and Prof. B are excited about this chance to collaborate. They think they will be able to publish a paper together, and they have already started exchanging compounds and data.

# Poll Question

- What do you think about Prof. A's consulting agreements?
  - Nothing that can't be handled – I've seen worse
  - Agreements 1 and 2 look Ok, but Agreement 3 is a bit worrisome
  - Looks like I'll need to cancel that vacation I've been planning -- I'll be working late for a LONG time!!!!!!



## Additional Points for Discussion

- What if Prof. A had a 9-month appointment? Would that change the analysis regarding any of the consulting agreements?
- Would your analysis differ if Prof. A also had a laboratory at the Chinese university?
- What if Star Univ. determined by looking at Prof. A's publications and websites that he has been working on setting up the new pharmacology program at the Chinese University for the past two years?