

Changes to Institutional Research Disclosure Practices in the Era of Foreign Influence

October 21,
2020

Moderator:

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Panelists:

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Texas MD Anderson Cancer Center

COGR's Survey on Institutional Disclosure Practices: Summary of Results and Analysis

COGR Membership Meeting
October 2020

Overview of Presentation

- Survey Methodology & Response Rate
- Major Themes from the Survey
- Notable Results
- Areas for Further Consideration

Survey Methodology & Response Rate

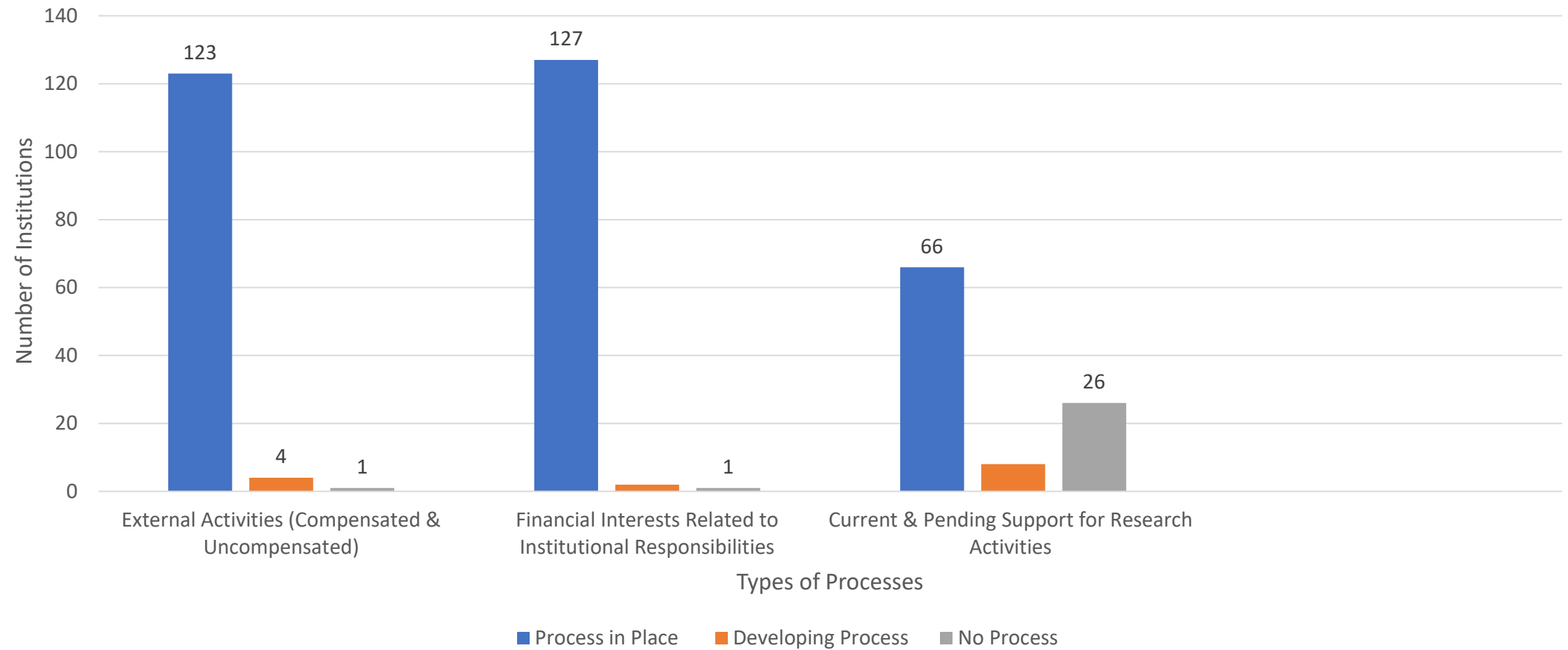
- Administered via Survey Gizmo to all 190 COGR member institutions
 - 57 total questions
 - Branching logic
- Dates of Administration: July 29 to August 5, 2020
- Response Rate: 68% (N= 131)
 - 93 public institutions
 - 38 private institutions
 - 120 colleges and universities
 - 7 independent research institutions
 - 4 stand-alone healthcare facilities
 - 65 responders reported having an associated academic medical center

Major Themes

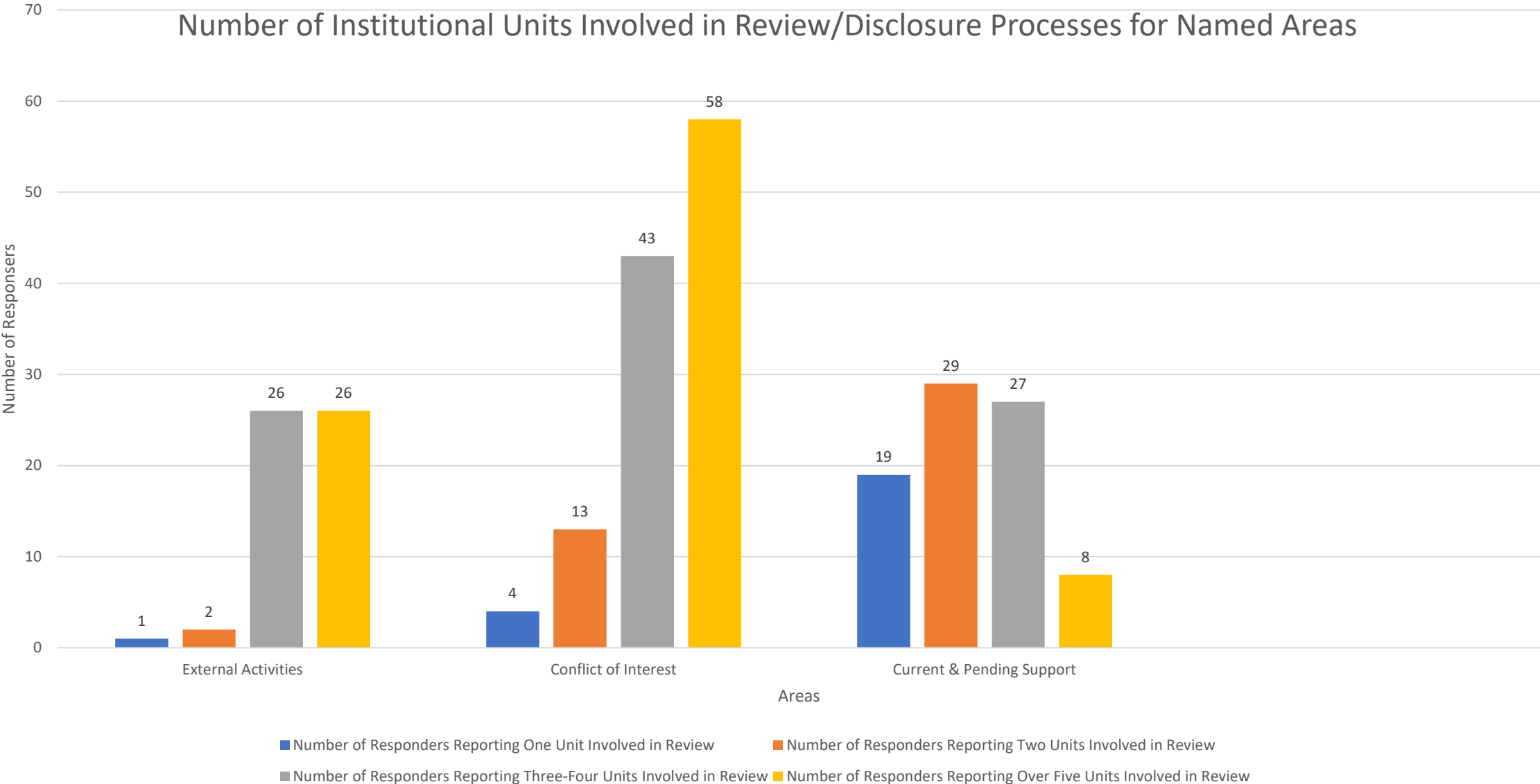
Theme 1: Multiple Paths for Disclosure and Multiple Units Involved in Processes

- Institutions have multiple paths for disclosure in response to federal regulations in the areas of conflict of commitment, conflict of interest and current and pending support.
- Multiple units within each institution are involved in the disclosure and review processes.

Institutions with/without Disclosure Processes in Place or Under Development for Named Items



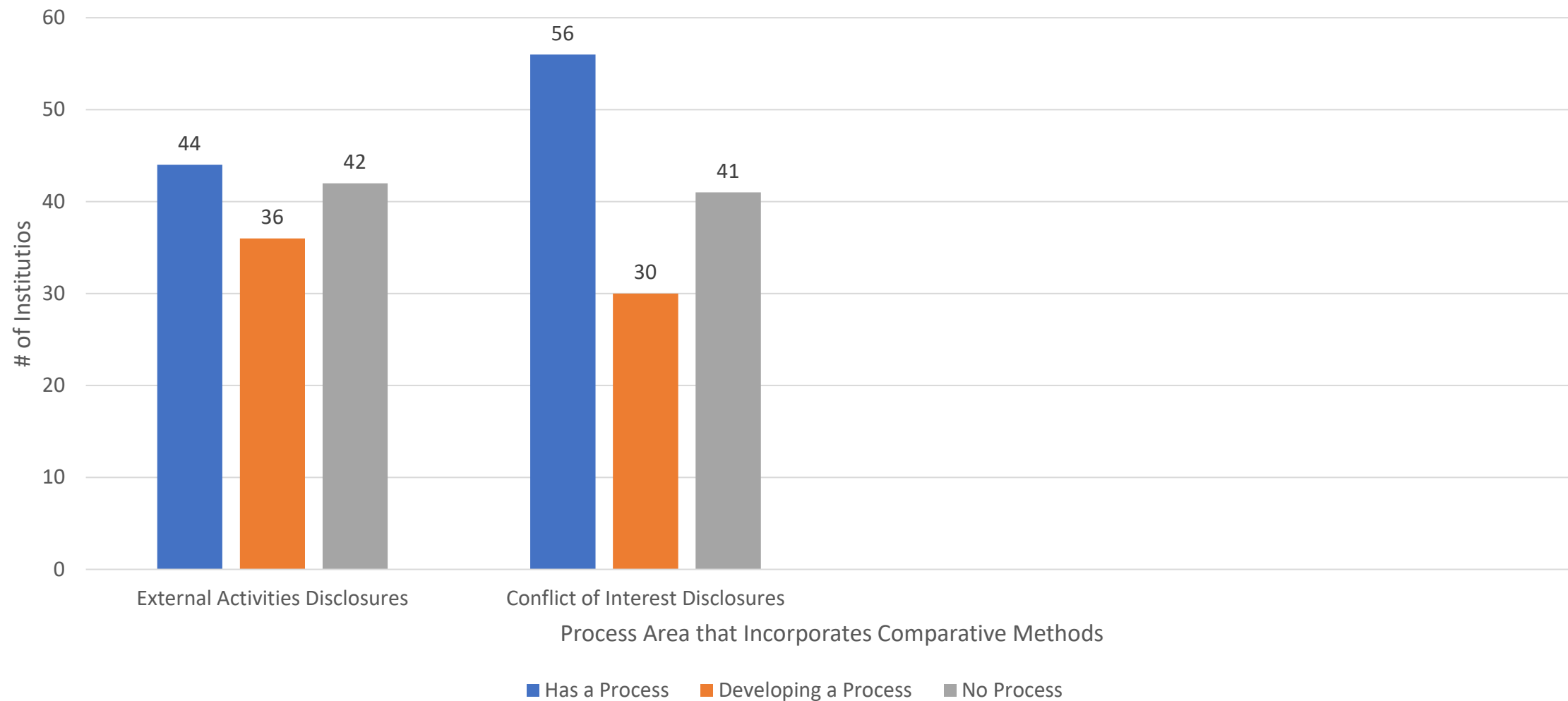
Number of Institutional Units Involved in Review/Disclosure Processes for Named Areas



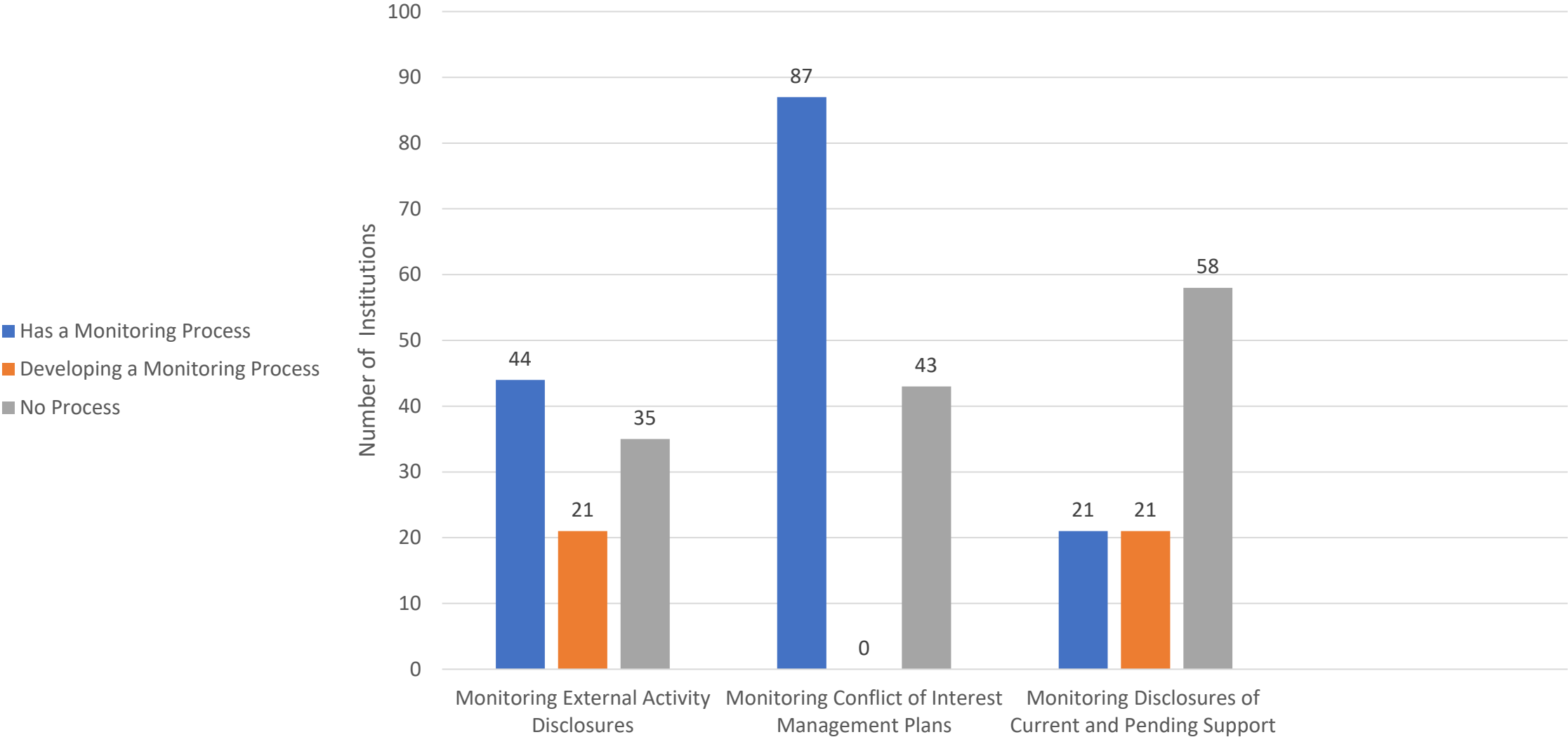
Theme 2: Trust but Verify

- Institutions are comparing disclosures made via different pathways.
- Institutions have or are developing monitoring and validation processes (e.g., publication review).

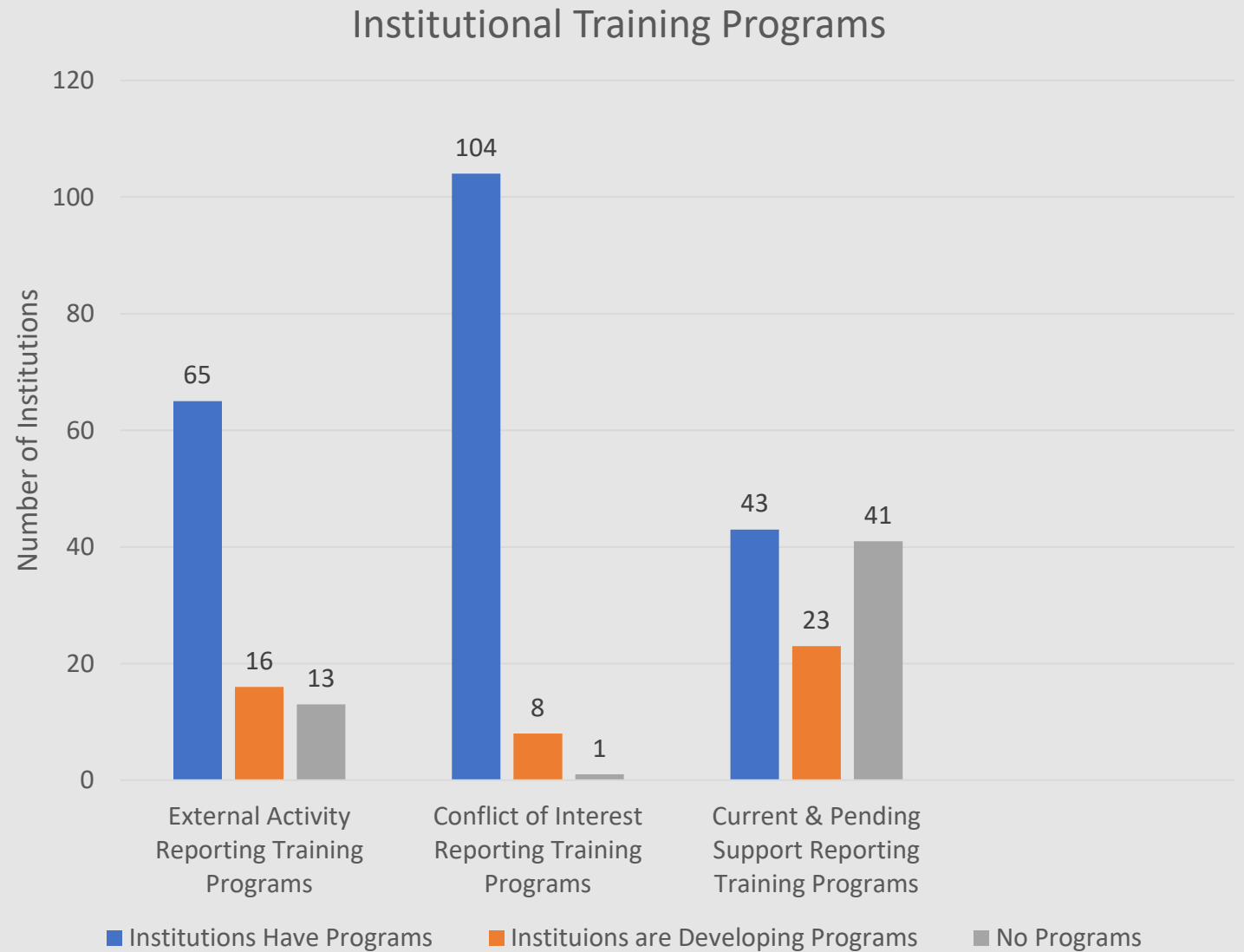
Number of Institutions Comparing Disclosures Made Via Different Pathways (e.g., disclosure of Current & Pending Support, COI disclosures, tech transfer disclosures) for Validation



Institutions' Monitoring Processes

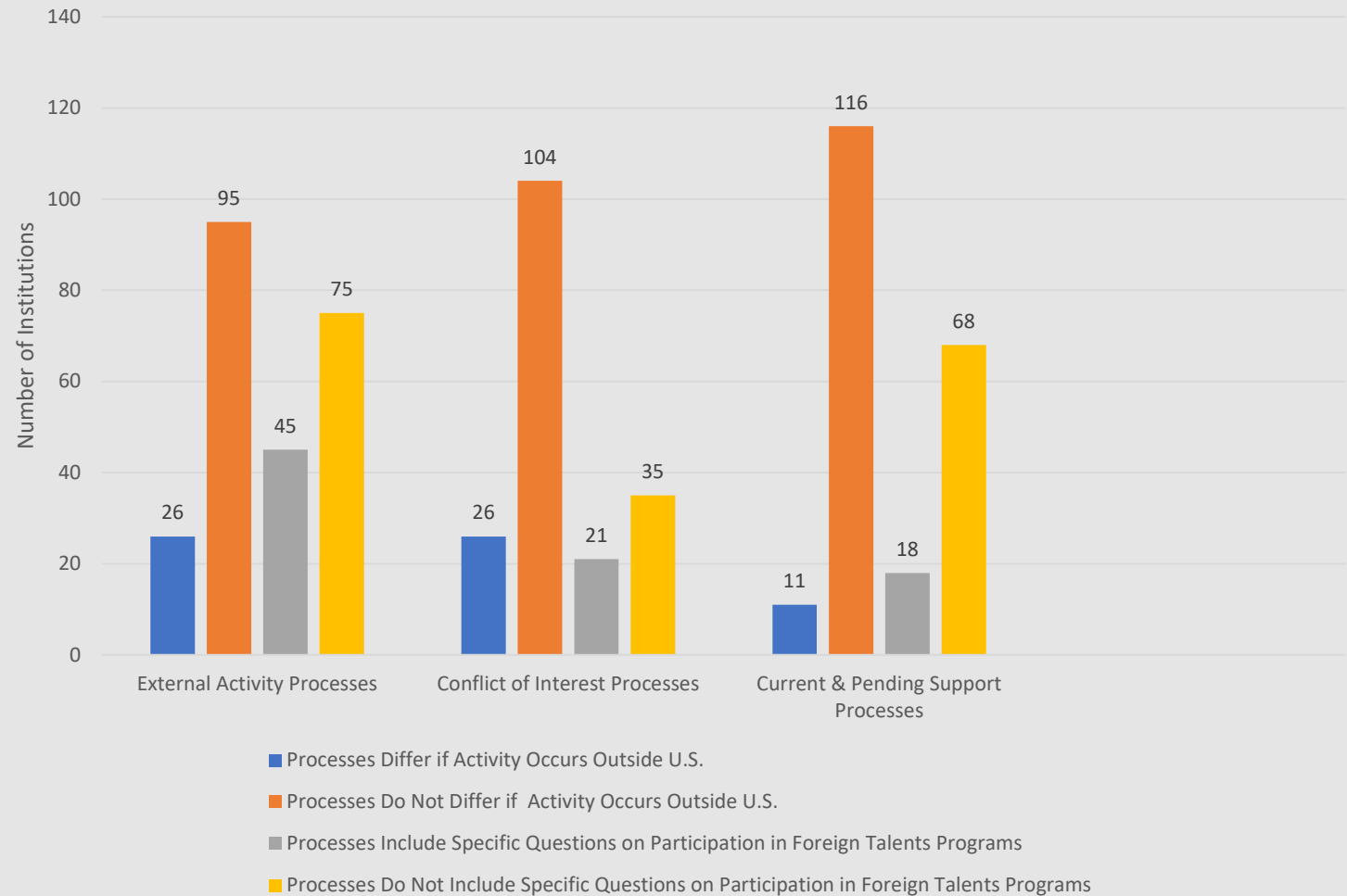


Theme 3: Established Training Programs with Improvements



Theme 4: Processes are Location Neutral, but Additional Scrutiny for Foreign Activities

Institutional Differences in Processes Based on Location of Activity Inside or Outside the U.S. & Questions on Foreign Talents Program Participation



External Activities

- 75% of survey Responders require disclosure of both compensated and uncompensated activities
- 67% of all survey Responders require institutional approval for some or all faculty external activities
- Over ½ of all survey Responders have or are developing a process to compare faculty disclosures made via different channels
- Over ⅓ of all survey Responders ask faculty members if they participate in foreign talent programs as part of external activity disclosures.

Conflict of Interest

- Almost 100% of survey Responders have financial COI policies, with a majority reporting that policies cover all research no matter how funded.
- Approximately $\frac{3}{4}$ of Responders reported a monitoring process for COI management plans.
- 65% of all survey Responders reported a process for comparing disclosures, using both formal and informal processes.
- When international activities are identified in COI disclosure processes, additional review may be triggered.
- In addition to capturing faculty participation in foreign talents programs through normal COI processes, 16% of all Survey Responders include a specific question regarding foreign talent program participation in their COI disclosure processes.

Current & Pending Support

- 74% of all survey Responders have a policy for faculty members to disclose current and pending support for research activities
- Policy in this area is driven by sponsor requirements,
 - 83.7% of Responders require disclosure as prescribed by funding agencies
 - 98% of Responders relying on funders' definitions of Current and Pending Support.
- 45% require disclosure for faculty with federally sponsored research
 - 36% for faculty with any sponsored research & 19% for all faculty.
- 21% include specific question regarding foreign talents program participation.
- Area with least formalized training programs:
 - 26% have training programs
 - 23% developing programs

Areas for Further Consideration

- Monitoring – Further analysis of steps institutions are taking to validate information and compliance with processes
- Foreign Activities – Many institutions require additional scrutiny for foreign activities. Will this ultimately result in the development of different processes for foreign activities? Will specific questions about participation in foreign talents become the norm? Or will specific questions be less useful as types of foreign influence programs come and go?
- Current and Pending Support – How are institutions adapting to recent government guidance in this area? What training do faculty need to understand requirements?

Questions?
Contact:



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Changes to Institutional Research Disclosure Practices in the Era of Foreign Influence

THE UNIVERSITY OF TEXAS
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~~Cancer Center~~

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The road ahead: The risk, cautionary tales, one institution's approach, and questions

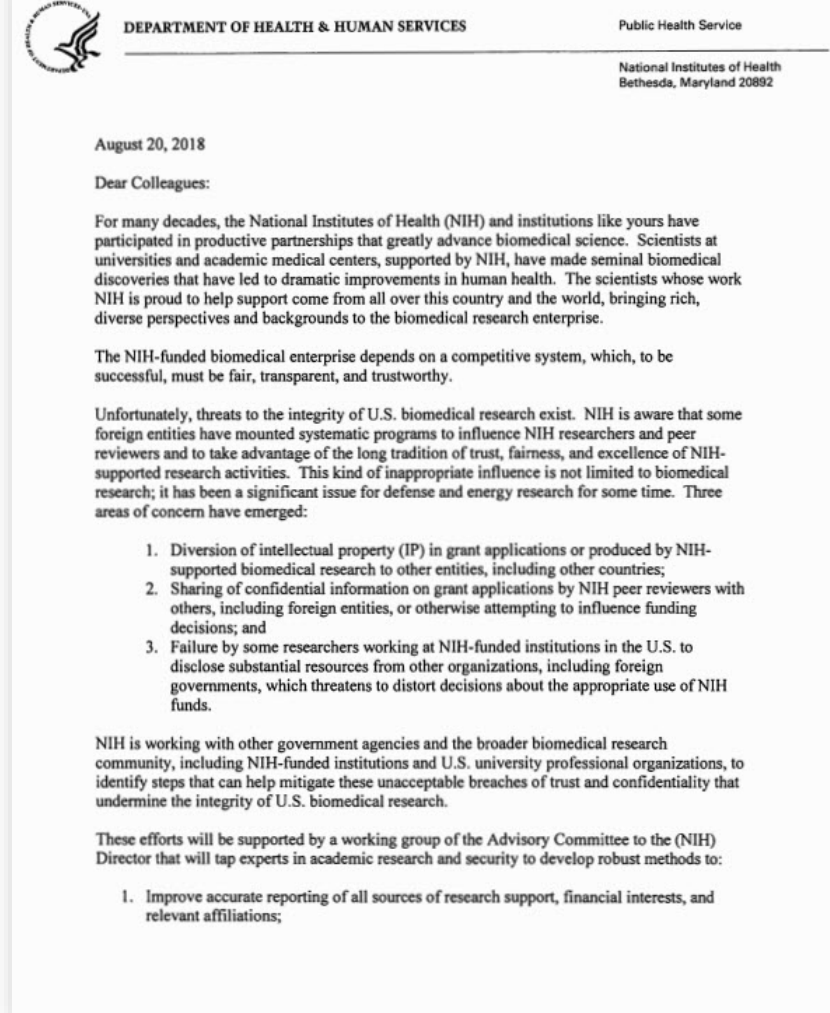
- The risk
 - Increased scrutiny by federal granting agencies and the DoJ
 - False Claims Act allegations, penalties
- Cautionary tales
 - “Lauer letters”, undue foreign influence
 - Van Andel Research Institute, failure to disclose
- One institution's approach
 - The University of Louisville journey and next steps
 - Goal: Make compliance second nature to researchers
- Important questions for academic medical centers



Cautionary tales: Dr. Collins's Dear Colleagues letter

Dr. Collins's Dear Colleagues letter – and subsequent communications from the NIH Deputy Director for Extramural Research – have led to investigations by Recipient Institutions of undue foreign influence:

- **Exclusive: Major U.S. cancer center ousts 'Asian' researchers after NIH flags their foreign ties**, Science Magazine, April 19, 2019
- **Emory ousts two Chinese American researchers after investigation into foreign ties**, Science Magazine, May 23, 2019
- **UCSD Eye Doctor Resigns After Investigation into Ties with China**, The Scientist, Aug. 23, 2019
- **Moffitt Cancer Center shakeup: CEO and others resign over China ties**, Tampa Bay Times, Dec. 20, 2019



Cautionary tales: Undisclosed foreign grants lead to FCA violations

December 2019: Van Andel Research Institute agrees to \$5.5 million settlement to resolve two FCA allegations

- Failure to disclose Other Support
- Hired a consultant who attempted to argue no scientific overlap; not well received!

“The government claimed that VARI instead retained an outside consulting firm, and, relying on that firm’s advice, sent a Dec. 21, 2018 letter to NIH in which VARI stated that it was not required to disclose information about Professor 1’s foreign grants because “there was no undisclosed overlap of any budgetary resources, commitment, or scientific endeavor” between the Chinese grants and the NIH grants. NIH, however, requires disclosure of all financial resources available in support of an individual’s research endeavors. The government further alleged that VARI, in representing to the agency that “there was no undisclosed overlap” between the Chinese grants and the NIH grants, did not know whether that statement was true.”



Federal law enforcement focusing on wire, program fraud; Criminal False Claims Act liability

– Lieber charging documents

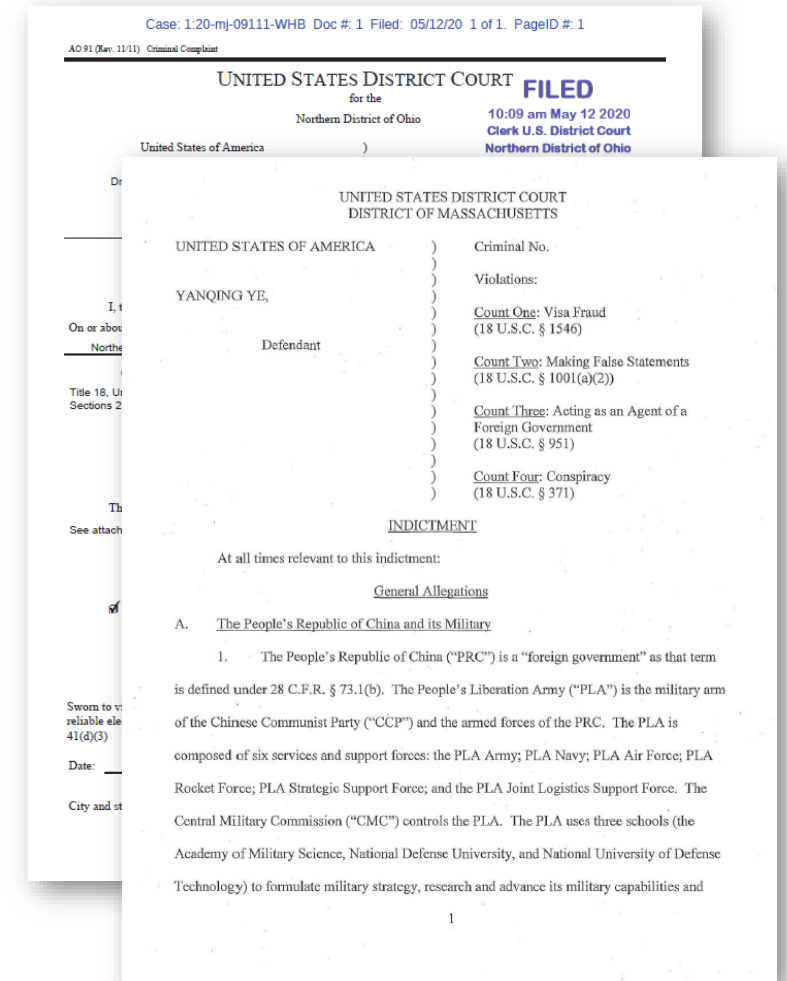
- Visa fraud: Misrepresented foreign military service (18 U.S.C. § 1546)
- Making false statements: Stated co-conspirator was an advisor and full professor; denied participating in co-conspirator's military projects (18 U.S.C. § 1001(a)(2))

– Wang charging documents

- False claims: Knowingly and willingly failed to disclose Chinese grants; position as Dean at HUST; scientific, budgetary and commitment overlap between NIH and CSNF grants (18 U.S.C. § 287)

– Additional, powerful theories being advanced by the DOJ

- **Failing to file a Report of Foreign Bank and Financial Accounts (FBAR)** under the Bank Secrecy Act, 31 USC 5311 *et seq.*
- **False statement to a government official** 18 U.S.C. § 1001 *et seq.*
- **Wire Fraud** under 18 U.S.C. § 1343



At play:

Three key legal concepts

Other Support

PIs completing NIH grant applications are required to disclose “**Other Support**,” which includes “all financial resources — whether Federal, non-Federal, commercial, or institutional — available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, or institutional awards.”

There is no designated format; however, the “Other Support” disclosed must include the source of support, among other things.

The definition is expansive and specifically includes all financial resources, whether commercial or institutional, but *explicitly excludes* training awards, prizes, or gifts.

Foreign Component

Defined as [t]he **performance of any significant scientific element or segment of a project outside of the United States**, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended.

Activities that would meet this definition include, but are not limited to:

1. the involvement of human subjects or animals,
2. extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or
3. any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.

Examples of other grant-related activities that may be significant are:

- collaborations with investigators at a foreign site anticipated to result in co-authorship;
- use of facilities or instrumentation at a foreign site; or
- receipt of financial support or resources from a foreign entity.

NIH Confidentiality and Security Policies

PIs participating in the NIH's Peer Review program are required to read the NIH's **Confidentiality and Non-disclosure Rules: Information for Reviewers of NIH Grant Applications and R&D Contract Proposals (the “Rules”)** and certify a Confidentiality Agreement before gaining access to information about the applications, proposals, or meetings.

Among other things, the Rules prohibit sharing applications, proposals, or meeting materials with anyone who has not been officially designated to participate in the peer review process.

To ensure data security for grant applications and other material, the NIH provides a secure platform, the **Internet Assisted Review (IAR)**, which permits Peer Reviewers to, among other things, read and submit other reviewers' critiques securely.

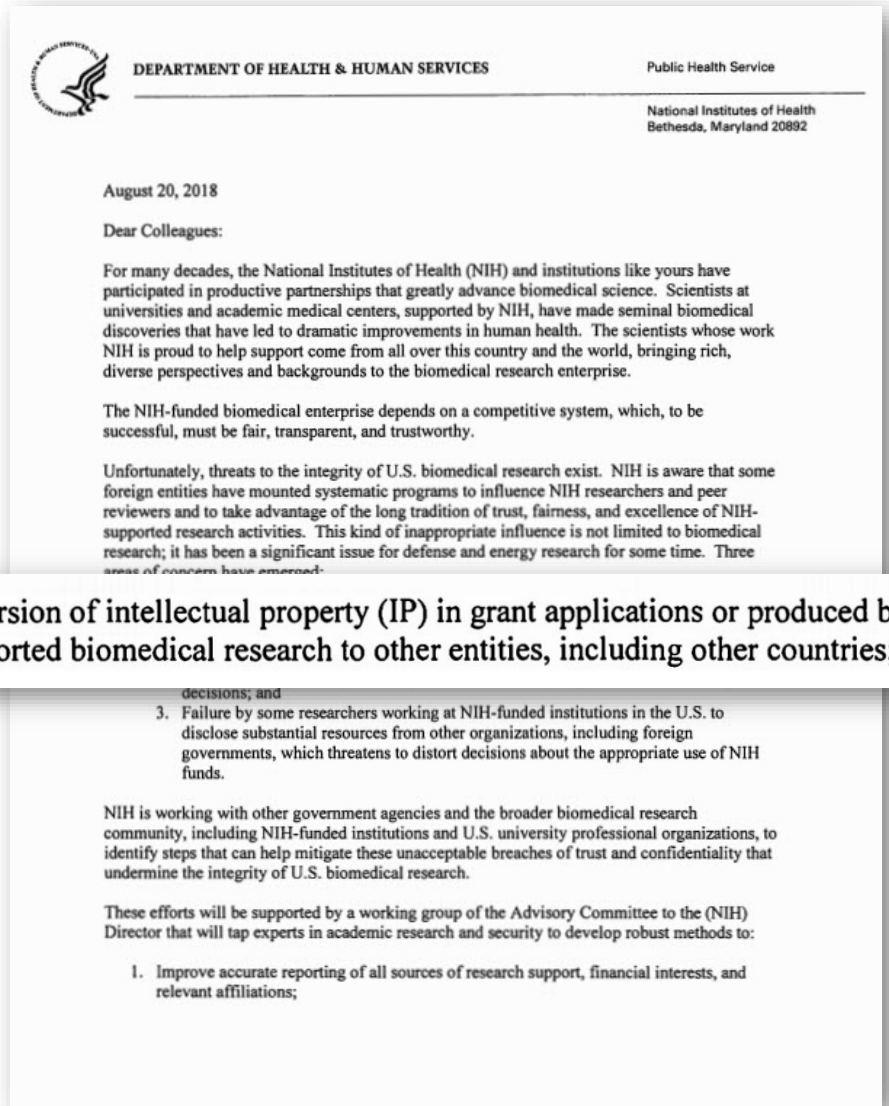
NIH Peer Reviewers are specifically admonished from sending application related information via unsecured email.

What about an effort allocation?

To date, the NIH has not pressed this.

My surmise:

1. The NIH's theory of injury, as evidenced by the Francis Collins's "Dear Colleagues" letter, is the diversion of Intellectual Property and know-how.
2. The IP was generated from labor, the cost of which was charged appropriately against NIH awards.
3. The labor still was pitted toward the aims of the grant; however, the fruits of the labor were inappropriately shared.
4. Therefore, my surmise is that the NIH does not really see this as an allowable costs issue. It's really about IP diversion, fraud, misrepresentation.



1. Diversion of intellectual property (IP) in grant applications or produced by NIH-supported biomedical research to other entities, including other countries;

Then there's working within the peer review process

- All peer review business is supposed to be conducted on the Internet Assisted Review (IAR).
- Download/export of grant review material to fellows for administrative support technically violates the NIH's Confidentiality and Security Rules.
- **Best practice:** request permission from the SRO to export the documents or add the fellow/support to the IAR.

10/14/2020 NOT-OD-18-115: Maintaining Integrity in NIH Peer Review: Responsibilities and Consequences

Maintaining Integrity in NIH Peer Review: Responsibilities and Consequences

Notice Number: NOT-OD-18-115

Key Dates
Release Date: December 22, 2017

Office of Extramural Research
July 2015

**NIH Confidentiality and Nondisclosure Rules:
Information for Reviewers of NIH Grant Applications and R&D Contract Proposals**

Rules related to the confidentiality of information disclosed to advisory committee members in the course of NIH peer review **prohibit** a peer reviewer serving on an NIH peer review committee from, among other actions:

and security - in the peer review process is essential for without fear of reprisal; protecting trade secrets or other tion; and providing reliable input to the agency about research

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Home » Help & Tutorials » Internet Assisted Review (IAR) » Overview of Internet Assisted Review (IAR)

Overview of Internet Assisted Review (IAR)

What is the purpose?

The Internet Assisted Review (IAR) module is a system to expedite the scientific review of grant applications. It provides a standard process for reviewers to submit critiques, preliminary scores and final scores and to view grant applications and related meeting materials via the eRA Commons. The IAR module is used during the pre-award phase of the grant application process. IAR allows one-click email capability between the scientific review officer and reviewer.

NOTE: You must be logged into IAR via [eRA Commons](#) with the appropriate role(s) to complete the activities described here.

Main Screenshots

Click on thumbnail image to expand to full view.




Figure 1: Navigation tab in eRA Commons for users with the IAR role.




Figure 2: List of Applications screen in the IAR module.

IAR Resources

- Overview of IAR
- Overview of Virtual Meeting
- Online Help
- User Guide
- Features & Updates
- FAQs
- Training

But wait, there's more: The challenge of visiting scholars and scientists

- MD Anderson trainees in the research laboratory setting generally are Ph.D. students and postdoctoral fellows. Occasionally, there also are some Masters and undergraduate students (especially in the summer) and a few medical students.
- Trainees that come from foreign institutions are here on J-1 and F-1 Visas.
- A few trainees are supported by their home institutions, e.g., visiting students who stay for several months to a year or two.
- Many times a trainee will not complete their work under an award before they return to their home institution, be it foreign- or U.S.- based. Therefore, the trainees contribute remotely at some level at their home institution.
- **Per the RPPR instructions**, Section 6.4 D Participants, D.,1, we are required to “Provide or update the information for:
 - program director(s)/principal investigator(s) (PDs/PIs); and
 - each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours or 8.3% of annualized effort).”
- **MD Anderson trainees may not meet the OSC definition. Nevertheless, they are often listed as OSCs** – at least when their work on the award so warrants it. They are not typically listed on Applications and RPPRs as Collaborators or Significant Key Personnel.

**It seems there are three major variables at play:
where the trainee's home institution is; the source of funding; and where the work is performed.**

The hard work that must be done: The MD Anderson experience, the University of Louisville approach

Year	NIH Award 5R01X	NIH Award 5R01X	NIH Award R37AI0X	SII Employment Contract	Changjiang Scholar Award	1,000 Talents Program	Professorship at Hebei University
2012							
2013							
2014	Application 8/1/14		Application 10/15/2014				
2015	JIT 12/5/14		JIT 4/27/15				
2016	JIT 4/27/15		RPPR 7/17/17 - 6/30/18				
2017	RPPR 2/1/18 - 1/31/19		RPPR 7/17/18 - 6/30/19				
2018	RPPR 3/1/19 - 2/29/20	Application 6/16/17					
2019	JIT 12/13/19	JIT 1/11/18					
	New application 2/27/20	RPPR 5/1/18 - 2/28/19					
	New application revision 5/12/20	RPPR 3/1/19 - 2/29/20					
2020							

A wide-angle photograph of the University of Louisville campus. In the background, the iconic Old College building with its large dome and classical columns stands prominently. The building is surrounded by lush green trees. In the foreground, a large, circular stone seal of the University of Louisville is embedded in the pavement. The seal features a profile of a person's head and the text "UNIVERSITY OF LOUISVILLE" and "1798". A low brick wall with the word "UNIVERSITY" in large letters is visible behind the seal. The sky is blue with some light clouds.

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Collection Foreign Involvement Disclosures:
One Institution's Approach



Journey of thousand miles begins with one step...

Timeline

- October 2018 – added GDPR information to annual disclosure form, including non-US teaching and consulting
- April 2020 – expanded upon GDPR section to include targeted disclosure questions on foreign engagements
 - Dept of Energy language
 - Affirmative responses triggered supplemental form
- Oct 2020 – annual disclosure form separated into US based and International activities



International Disclosures Approach

- Institution is supportive of research collaboration and wants to nurture and enhance these relationships. These connections must be supported in a way that makes compliance with the rules and regulations second nature for our researchers.



International Disclosure Components

- Appointments/Affiliations with international entities or governments
- Collaborations (including those anticipated to result in co-authorship)
- Equity Holdings and External Financial Interests
- External Professional/Research Activity
- Grants, Contracts, Cooperative agreements, Service Agreements or other funds
- Gifts
- In-kind or Donated Resources (Lab or Office Space, Equipment, Scientific Supplies)
- Scientific Materials not freely available to others
- Visiting faculty/scholars/scientists/postdocs/students (undergraduate and graduate)
- Additional International Activities



International Disclosure Objectives

- Provide guidance to researchers in how to accurately disclose to sponsors
- Assist with Section 117 reporting
- Support compliance checks for proposals, JIT, RPPR, etc.
- Identify opportunities to establish international agreements
- Ensure employment contracts are accurate



Next Steps

- Training triggers
- Task group recommendations
- Refine disclosure questions based upon reports, findings, etc.
- NDAA Section 889 compliance



Three important questions for academic medical centers

Will there be a change to the Fundamental Research Exemption?

- Formulated in 1985 by National Security Defense Directive (NSDD) 189
- Practically exempts “fundamental research” from restrictive export control framework
- Most basic science at academic medical centers may be classified as fundamental research
- Promulgates that where national security mandates controls, the primary control should be classification
- Therefore, altering the Fundamental Research Exemption would have a profound impact on the administration of basic science research at academic medical centers.
- Entities such as the AAU maintain that classification should remain the primary mechanism for restricting access to research results when necessary.
 - The Bush Administration created a security classification called Controlled Unclassified Information (CUI),
 - This includes a subcategory of Export Controlled Research



Three important questions for academic medical centers

Are Academic Medical Centers' COI and Research Integrity Programs accommodating the evolving government actions above and regulatory enforcement posture?

- When the institution is the grantee but the PD/PI holds the knowledge concerning “Other Support” and “Foreign Components,” how do Academic Medical Centers ensure complete disclosure to the NIH?
- Should failure to disclose fund sources be considered a species of research misconduct? See Jeffrey R. Botkin, MD, MPH, Should Failure to Disclose Significant Financial Conflicts of Interest be Considered Research Misconduct? JAMA (published online October 26, 2018), available at <https://jamanetwork.com/journals/jama/fullarticle/2712193>



Three important questions for academic medical centers

What is the line of demarcation between bona fide collaboration and undue foreign research?

- Premature sharing of IP from NIH-funded research, see NIH Grants Policy Statement 8.2.3 and Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources (64 FR 72090, December 23, 1999; http://grants.nih.gov/grants/intell-property_64FR72090.pdf)
- Violation of NIH Other Support and Foreign Component disclosure rules
- Participation in Talents Programs that:
 - Result in overlap of NIH and other support funding
 - Violate PHS, Recipient Institution conflict of interest policies
 - Don't forget conflict of commitment

A large, red-brick building with a prominent white portico supported by columns and a large dome on the roof. The building is surrounded by lush green trees under a clear blue sky.

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Discussion

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