

Office of Research Protections, Conflict of Interest

Managing Financial Conflicts of Interest in Research: *Why “I Didn’t Know” Isn’t an Excuse*

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Agenda

What are conflicts?

Why do we focus on FCOIs?

How do we identify FCOIs?

How do we manage FCOIs?

What is the process?

Examples

What are conflicts?

COI, FCOI, and COC

Conflict of Interest (COI)

- Individual has an interest, activity or relationship that may compromise their judgment, bias their research, influence their decisions or behaviors or result in their personal gain to the detriment of the University

Financial Conflict of Interest (FCOI)

- Investigator has a **significant financial interest** that could directly and significantly affect the design, conduct or reporting of their research

Conflict of Commitment (COC)

- Individual has an activity or relationship that compete with the University's mission or with their ability or willingness to perform their University responsibilities

Significant Financial Interests

- Annual compensation for services (consulting, advising) exceeding \$10,000*
- Any equity in a private for-profit (includes start-up companies)
- Equity in a public for-profit that exceeds \$10,000* in value
- Officer, director or management role in a for-profit
- Inventor of intellectual property **and** annual royalty or other payments exceeding \$10,000
- Reimbursed or sponsored travel with amounts that are not proportional to the outside activity

* *The threshold is \$5,000 for federally-funded projects.*

Why do we focus on FCOIs?

Notable Cases

Jesse Gelsinger

- Gene therapy trial at Penn
- PI and Penn had financial interests in a start-up company

Charles Nemeroff

- Psychiatrist at Emory
- Payments from pharma - did not disclose to Emory
- FCOIs were not managed due to lack of disclosure

José Baselga

- CMO at MSKCC
- Financial interests in pharma and biotech - did not disclose in journals

Why do we focus on FCOIs?

- **Because we should!**

- Protect the objectivity and integrity of research
- Ensure safety of human participants
- Safeguard interests of other researchers
- Protect the reputation of the academic institution

- **Because we are required!**

- Federal agency regulations and policies

How do we identify FCOIs?

Teamwork!

- Mandatory Disclosers disclose in MyDisclosures
- PIs and investigators disclose in IRB and IACUC protocols
- Notifications from colleagues – OSP, IACUC, IRB, OIE, Purchasing, and P&AE
- Questions from department and school administrators
- Supervisor referrals in MyDisclosures



Mandatory Disclosers

- **Automatically identified in MyDisclosures**
 - Full-time faculty
 - Administrators based on job responsibilities
 - Some investigators, including postdocs

- **Add manually in MyDisclosures**
 - Part-time and adjunct faculty when required by supervisor
 - Investigators who do not meet automatic identification criteria
 - Individuals who can make, direct or materially influence University business decisions
 - Individuals with significant input over selecting outside vendors or service providers

Disclosure Requirements

- Financial, personal, and professional interests, activities, and relationships in an outside entity that could create a COI or COC
- With or without compensation
- For-profit or nonprofit
- U.S. entity or non-U.S. entity

Disclosure Requirements

Outside Activities

- Consulting or advising
- DSMC/DSMB
- Officer, director or manager roles
- Speaking engagement
- Medical-legal/expert witness

Ownership and IP

- Equity (includes founder shares)
- Stock or stock options when you control decisions to buy, sell or trade
- Inventor of optioned or licensed Pitt IP
- Inventor of IP not invented at Pitt when entitled to royalties or other payments

Other Relationships

- Appointments or affiliations with other universities
- Travel paid on your behalf or reimbursed directly to you

Research Support

- Research support that is not administered through Pitt

Reminder: Disclose to Your Federal Agency

- Federal agencies require disclosure of some interests and activities in your biosketch or other support
- **Your disclosure to your federal agency is *in addition to* your disclosure to Pitt in MyDisclosures!**
- <https://www.osp.pitt.edu/resources/faculty-resources/management-disclosures-funding-agencies>

How do we manage FCOIs?

Management Plan Conditions

- Disclose in abstracts, publications, presentations, and press releases
- Disclose to other researchers
- Include at least one non-conflicted faculty investigator in the evaluation of research results
- Obtain approval from the supervisor of any students who will be involved in the project
- Independent liaison to assist in addressing concerns
- Disclose to participants in consent forms (human research)
- Oversight by a data steward

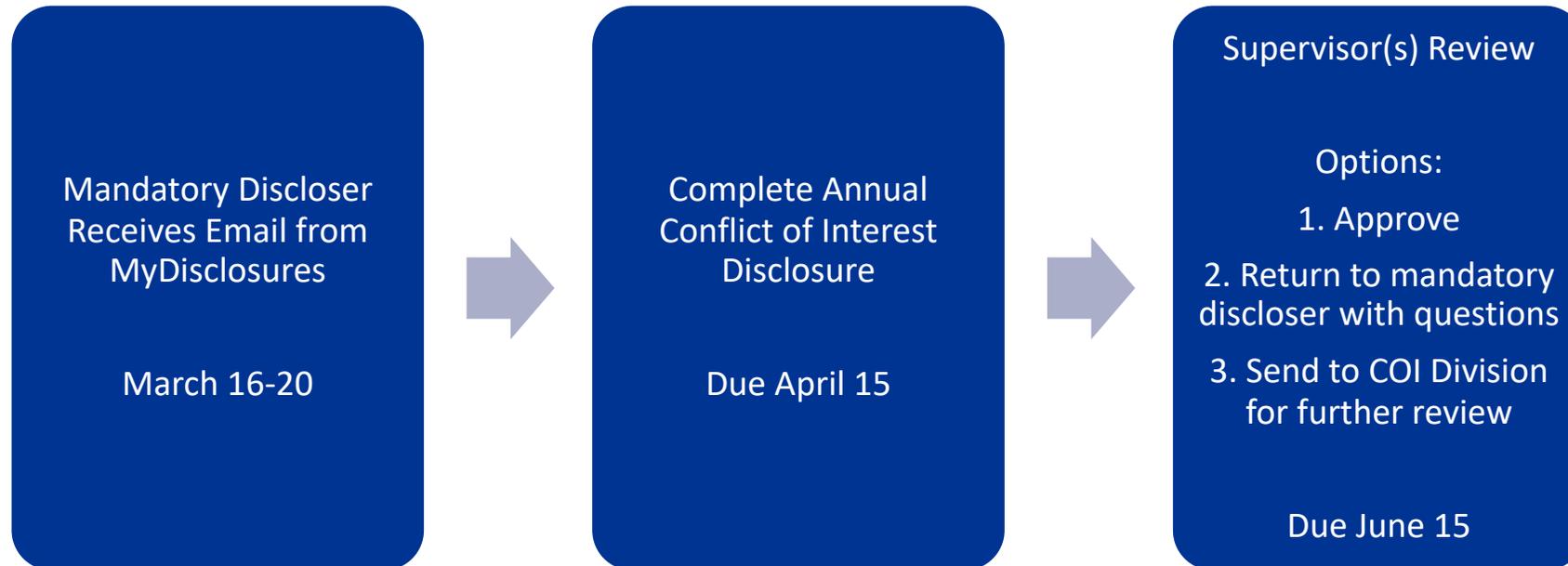
PI-Exclusion Rule

Applies when an investigator in human research has **significant financial interests** that include:

- Annual compensation exceeding \$20,000
 - Equity in a private for-profit
 - Officer, director or management role in a for-profit **or**
 - Intellectual property royalty or other payments that exceed \$10,000
- May not serve as PI
 - May not be involved in recruitment or consent of human participants
 - May not engage in the recording of research data from human participants
 - May not be involved in clinical assessments of study eligibility criteria or intervention outcomes
 - May not participate directly in data and safety monitoring activities (may participate only in the open portion of such meetings, provided FCOI is disclosed)

What is the process?

Annual Conflict of Interest Disclosure



Supervisor Reviews

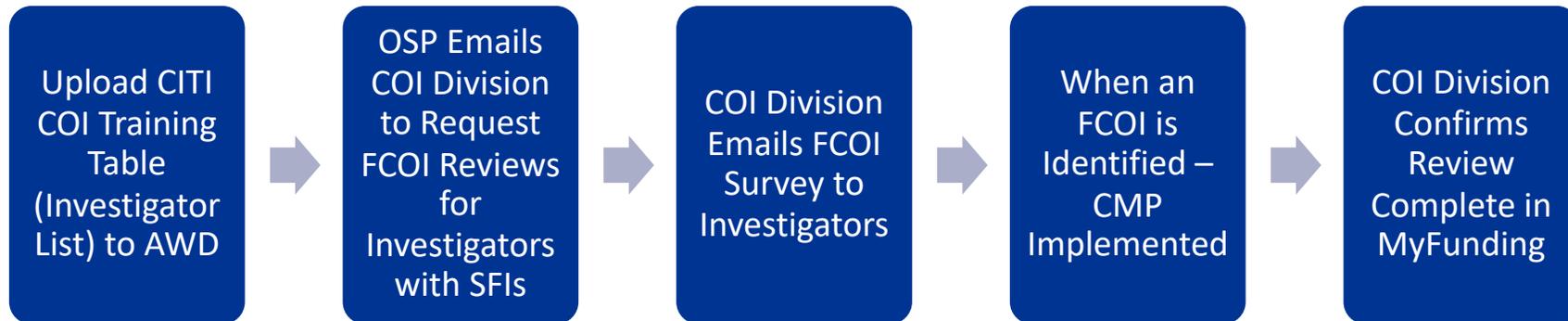
Questions:

- Are they using Pitt resources? Is the use only incidental?
- Is the time spent on outside activities appropriate?
- Are they adequately fulfilling their Pitt responsibilities?
- Does the outside activity interfere with their objectivity in teaching, research or other Pitt responsibilities?
- Do their financial interests create an FCOI in their research?

Outcome of review may include:

- Approval (*No concerns!*)
- Prohibit engagement in an outside activity that is detrimental to Pitt
- Limit time on outside activities to ensure standards of performance are met at Pitt
- Refer to COI Division for further review

Award (MyFunding)



Protocol Submission (PittPRO or ARO)



New Licensed Start-up Company (LSC)



Examples

Dr. Green and Pharma Inc.

- Full-time faculty appointment
- Consults for Pharma Inc.
 - 20 days per year with annual compensation of \$15,000

Dr. Ross and Pharma Inc.

- Full-time faculty appointment
- Consults for Pharma Inc.
 - 20 days per year and compensation of \$15,000
- Consults for multiple other companies
 - Additional 50 days per year

Dr. Green and Pharma Inc.

- Full-time faculty appointment
- Consults for Pharma Inc.
 - 20 days per year with annual compensation of \$15,000
- **Initiates Pharma Inc.-sponsored human study**

Dr. Corday and NewCo

- Full-time faculty appointment
- Inventor of IP developed at Pitt and disclosed to the Innovation Institute
- Founder and CMO of NewCo
- NewCo intends to license the IP
- NewCo received an SBIR to further develop the IP
 - Sub to Pitt to fund animal research

2026 Annual Disclosure Reporting Period

- **Starts on Monday, March 16!!**

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<https://www.coi.pitt.edu/>

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