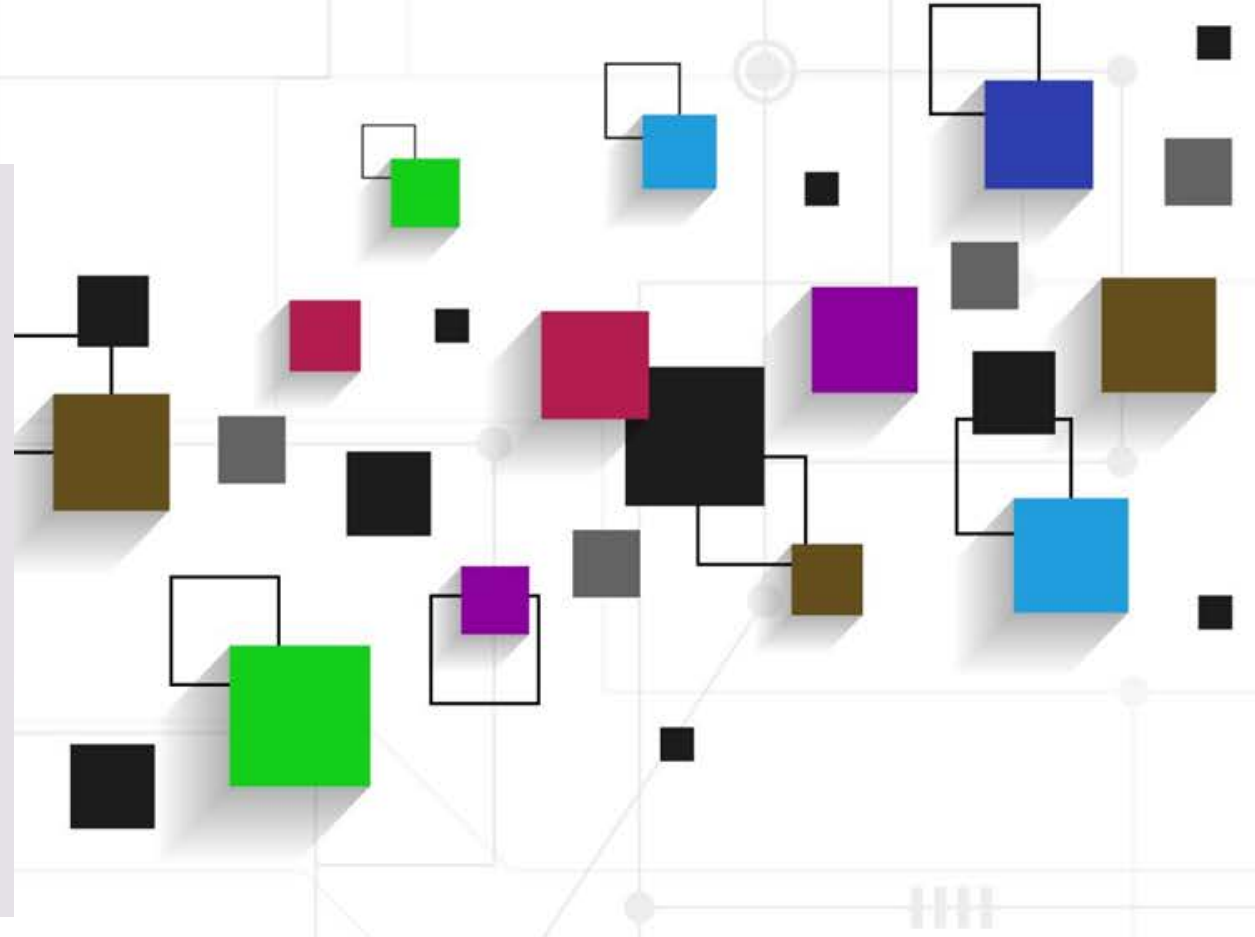


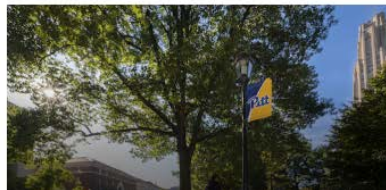
Conflict of Interest

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





Office of Research Protections



Conflict of Interest

- The **Conflict of Interest Committee** and **Conflict of Interest Division** implement best practices for managing potential conflicts from interactions with industry partners and engagement in entrepreneurial activities
- **Committee Chair:** Craig Wilcox, PhD → reports through Bill Yates, PhD, Vice Chancellor for Research Protections
- Conflict of Interest Division: Christina Gasdia, JD – Director

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

What is a conflict of interest?

Conflict of Interest (COI) exists whenever personal, professional, commercial, or financial interests or activities outside of the University are, or have a reasonable potential of,

1. Compromising a University Member's judgment;
2. Biasing the nature or direction of scholarly research; or
3. Influencing a faculty or staff member's decision or behavior with respect to teaching and student affairs, appointments and promotions, uses of University resources, interactions with human subjects, or other matters of interest to the University; or
4. Resulting in personal or immediate family member's gain or advancement to the detriment of the University or in ways prohibited by University policy

Example: Potential COI exists if you are consulting for a company that also sponsors research in your laboratory.

What is a conflict of commitment?

Conflict of Commitment exists when outside interests, relationships or activities have a reasonable potential to compete or interfere with

- i. The University's educational, research or service missions, or
- ii. The ability or willingness to perform the full range of institutional responsibilities at the University

Example: Potential Conflict of Commitment exists if you are a full-time employee at Pitt and a full-time employee at another university



Who must disclose:

- Pitt faculty or researcher
- Pitt administrative role:
 - Classified as Admin IV or above
 - Individuals who make, direct or materially influence University business decisions
 - Any employee with significant input over selection of vendors or service providers
- UPMC Employees or those who conduct clinical research on UPMC premises or under UPMC oversight and are in a position to materially influence such research

Must report at least annually through
MyDisclosures:

- Satisfies University and UPMC requirements
- Does **not** satisfy reporting requirements for grants, contracts or other funding
- Changes in potential conflicts should be reported through *MyDisclosures* ASAP

Significant Financial Interest

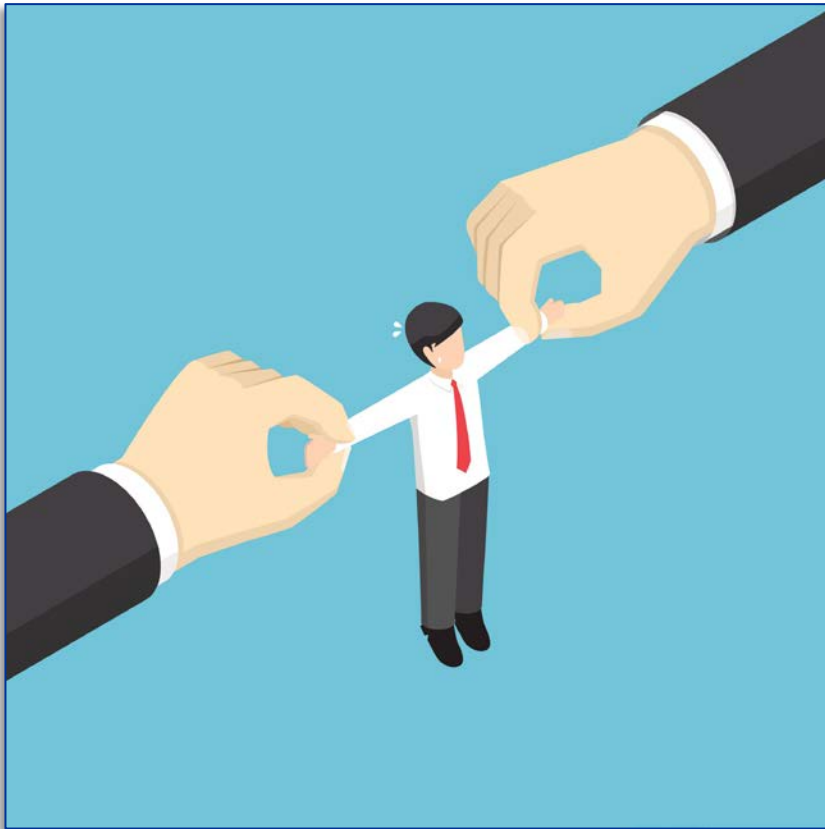
(NIH Definition)

Significant financial interest can include immediate family member with SFI:

- Income in excess of \$5,000 from a publicly-traded entity (a company whose stock is available for purchase by the general public) during the past 12 months.
- Stock valued in excess of \$5,000 at the time of disclosure in a publicly-traded entity.
- A combination of the above two items (stock and income) that exceeds \$5,000.
- Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity (such as a start-up company).
- Compensation that exceeds \$5,000 from a non-publicly traded entity in the past 12 months.



Conflict of Interest: Investigators



Conflicts of a financial nature, work commitments and intellectual and personal matters have to be managed to assure that the conflict doesn't interfere with the responsible conduct of research

- **Standard Conflict Management Plan:** conflicted investigator can remain as PI with approval of a department chairperson and/or the COI Committee
- **PI Exclusion Conflict Management Plan:** certain outside financial interests do not permit an investigator to serve as PI, but allow service as a co-investigator



COI Management Plan: Significant Financial Interest Not Requiring PI Exclusion

1. SFI disclosed in consent form
2. Notification of other investigators involved in the research, students may engage with appropriate departmental approval
3. Inform COI when new investigators are added to ensure proper notification
4. SFI disclosure in publications, press releases and other areas where relevant as well as certain future projects
5. Disclosure to other sites (as applicable)
6. Disclosure to FDA or other regulatory bodies (as applicable)
7. Notify COI of any changes in support for the project
8. Appointment of a data steward (as applicable)
9. When serving as PI, department will be asked if other management is necessary



COI Management Plan: Significant Financial Interest Requiring PI Exclusion

In addition to elements of standard COI management plan, the individual would be barred from the following:

1. Acting as principal investigator
2. Recruitment
3. Obtaining consent
4. Recording of research data
5. Clinical assessments for eligibility or stopping rules
6. Participation in DSMP or AE reporting
7. Sole interpretation of study results



PI Exclusion Rule Thresholds

- Equity in and/or cash remuneration from a public company (in aggregate) greater than \$20,000 per 12 month period or 5%*
- Remuneration from a non-public company greater than \$20,000 per 12 month period
- Equity in a non-public company
- Management or officer position in any company
- Inventor or developer of intellectual property when receipt of royalties and/or other proceeds exceeds \$10,000 per 12 month period
- Reimbursed or sponsored travel from one entity exceeding \$10,000 per 12 month period**

*5% restriction applies to non-PHS funded research only

**Only applicable to research funded in full or in part by a Public Health Service (PHS) agency

Exceptions may be considered by the authorized Institutional Official

Conflicts of Interest and IRB Members: Procedures

- IRB leadership, staff and affiliated IRB members are required to disclose SFIs related to any protocols they review
- Faculty and staff must report conflicts annually
- Unaffiliated members review policy at orientation and sign statement of understanding
- Policy is reviewed annually

If there is a conflict:

- Conflicted member steps out
- Cannot review, comment or participate in discussion of protocol
- May be allowed to address questions



Conflicts of Interest and IRB Members: Policy

What type of conflict:

- **Significant Financial Interest (SFI)** in the sponsor of the research or the technology being evaluated;
- **Listed investigator** (or having an immediate family member including the spouse, dependents, and all members of the employee's household including domestic partners listed as an investigator); or
- Any **other conflict** that might be perceived to inhibit a fair and unbiased review of the research



Unmanaged COI: Potential Risks

- Compromise of human subject protections
- Compromise of integrity of research
- Loss of public trust
- Damage to investigator reputation/standing
- Negative impact on students pursuing research
- Loss of publications



Training Requirements

All meeting the definition of investigator must complete the CITI Course for Conflict of Interest

<https://www.coi.pitt.edu/regulations-policies/coi-training-requirements>

Questions?

Please address questions either to askirb@pitt.edu or coi@pitt.edu
