University of Pittsburgh

Conflict of Interest Office

A Partner in Promoting Objectivity in Research, Teaching, & Administrative Activities

Conflict of Interest Management

FACULTY/STAFF
DEVELOPMENT PROGRAM

COI Office
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What is a Conflict of Interest?

- A Conflict of Interest may exist if an individual's outside interests (especially financial) affect, or perceive to affect, his/her research, teaching, or administrative activities at the University.
  - Not always "unethical" or "impermissible"



Examples of outside financial or fiduciary interests

- An ownership interest in a company (stock or stock options)
- Consulting remuneration from a company
- Serving in a management or officer position
- Inventor of intellectual property for which one is receiving royalties, milestone payments, or other licensing income.





Examples of potential Conflicts of Interest (COIs)

- Engaging in research sponsored by a company in which you have an outside interest

- Engaging in research that is evaluating or developing a technology or a drug owned by a company in which you have a outside interest (regardless of whether or not the research is sponsored by the company)

Examples of potential COIs

- Purchasing products or services from, or establishing a research subcontract with, a company in which you have a financial interest

- Overseeing a mentee or student engaged in research that is of commercial interest to a company in which you have a financial interest



If COIs are not managed…

- Protection of human subjects may be compromised;
- Integrity of research may be at risk;
- The public may lose trust in the University and its research findings;
- The investigator/faculty member may lose the respect of the academic community;
- Scandals or negative media attention may occur;
- University may lose public support and funding for research.





Today's topics

- Department's responsibilities:
  - Annual COI filing process
  - COI oversight & management
- University-level COI Management:
  - Research protocols
  - Entrepreneurial endeavors
  - Purchasing
  - PHS COI reviews



Who has access to the COI database? (i.e., the "COI Superform system")

- COI Office and COI Committee Chair
- Research administrators/coordinators
- Division chiefs; department chairs; deans; regional campus presidents
- Office of Research
- HRPO/IACUC
- Center directors
- Purchasing
- Internal Audit
- University Counsel



Request access to the COI database

- To request access, email one of the Compliance Coordinators
  - Malini Srinivasan mas225@pitt.edu; Brendan Linton brendan.linton@pitt.edu
- Provide the name, HSConnect username, departmental affiliation, and level of access to be granted ("Basic" or "Operational")
  - "Basic" access allows user to determine whether investigators have a current COI form on file (but not the confidential details of the form);
  - "Operational" access allows user to see details of forms for those in his/her department;
    - Department chair must first send an approval email for this level of access to COI Office.

Reporting outside interests: when?

- University policies 11-01-03 and 07-05-02 require the reporting of the outside interests of faculty, administrators, and researchers:
  - Upon appointment
  - By April 15 of each year
  - Within 30 days of accruing a new outside interest



COI Superform system: **https://coi.hs.pitt.edu**

- University employees with appointments at UPMC/UPP should instead use the joint Pitt/UPMC COI questionnaire in My HUB (instructions available at http://www.coi.pitt.edu/directive.htm)

Reporting outside interests: what?

- Questions asked in the University COI forms capture Significant Financial Interests (SFIs) as defined by Policy 11-01-03
  - PHS form uses PHS thresholds and includes travel expenses
- Disclose *only* those relationships described
  - Note explanatory text that describes exceptions and gives examples
- Disclose only relationships that are related to your Institutional Responsibilities

New in 2018

- **Technology Transfer** question now only asks about intellectual property (IP) for which the inventor/developer received or expects to receive royalties, milestone fees, or other proceeds that exceed $5,000 (PHS)/$10,000 ("regular") during any twelve-month window within the past 12 months through the coming 12 months?

New in 2018

- **Organizational Conflicts of Interest (OCIs) -** Do you have access to nonpublic information or have you performed or do you expect to perform work for the federal government that may provide you or another member of the University of Pittsburgh with an unfair competitive advantage in applying for federal funding or that could appear to bias its judgment?
  - Assists the University in identifying potential OCIs described in Subpart 9.5 of the Federal Acquisition Regulation and in Policy 11-01-08

Definition: Institutional Responsibilities

- An Investigator's University responsibilities, including: research, teaching, professional practice, institutional committee memberships, service on IRB and DSMB panels, and other administrative activities.
- Are the company's commercial interests in your field of academic specialization/clinical practice?



COI oversight by supervisors

Faculty/Researcher COI forms ("regular" and PHS-funded)

Department level review

- Ensure that all required individuals have signed and submitted a Signature Page by April 15

- Department Chairs & Directors review submitted Faculty/ Researcher Signature Pages;
  - Prepare Management Reporting Form (MRF) for each individual who disclosed outside interests, identifying COIs and explaining how they were managed.

COI oversight by supervisors

Faculty/Researcher COI forms ("regular" and PHS-funded)
Department level review (cont'd)

- Instructions for completing MRF
  - Identify faculty member and supervisor
  - Enter only the category of financial interest (e.g., ownership interests, offices & positions, remunerative activities, outside employment of students/staff, technology transfer activities, etc.)
    - Do not re-enter detailed responses from Faculty/Researcher Form (this form accompanies the Signature Page which has this information)

COI oversight by supervisors

Faculty/Researcher COI forms ("regular" and PHS-funded)

Department level review (cont'd)

- Briefly describe all actions taken, or that will be taken, to manage any COIs between an individual's responsibilities at Pitt and his/her outside interests.

- If no management is needed, provide a justification
  - E.g., individual does not conduct research sponsored by, or of commercial interest to, the company; individual makes no purchasing decisions (etc.)

COI oversight by supervisors

Faculty/Researcher COI forms ("regular" and PHS-funded)

Department level review (cont'd)

Documenting the PHS COI review:

- If you become aware of any new outside interests, or of newly awarded PHS-funded grant(s), documenting the chair's PHS COI review can expedite future PHS COI reviews by the COI Office
- Email review to COI Office: coi@pitt.edu

COI oversight by supervisors

Faculty/Researcher COI forms ("regular" and PHS-funded)
Department level review (cont'd)

- Complete "Data Summary Report for Faculty/Researcher COI Forms"
- Submit to dean, director, or regional campus president for review only the following:
  - Signature Pages **disclosing outside interests**;
  - The related signed MRFs, and;
  - Department's Data Summary Report
- Keep Signature Pages with no reported outside interests on file in unit for seven years.

COI Oversight by Supervisors

Faculty/Researcher COI forms ("regular" and PHS-funded) — Dean/regional campus president level review

- Reviews forms received from chairs/directors
  - Approves or modifies MRFs, as necessary;
- Prepares the school's or regional campus's Data Summary Report for Faculty/Researcher COI Forms;
- Submits departmental Data Summary Reports, Signature Pages, MRFs received from all departments in unit, and the unit's Data Summary Report to the provost or senior vice chancellor for the health sciences.

Due May 15

COI Oversight by Supervisors

Designated Administrator/Staff COI Forms

Department level review

- Ensure all required employees have signed and submitted Signature Pages by April 15;
- Review Signature Pages received and develop COI Management Plans (CMPs), as needed
  - Document the plan and employee's agreement to it in the form of a *memorandum* (do not use the MRF); keep this on file in unit; **do not forward to next higher supervisor unless requested**;
- Prepare and submit Data Summary Report for Designated Administrator/Staff COI Forms to the next higher reporting authority within the responsibility center
  - List number of disclosures submitted and number that disclosed outside interests or activities.

Due May 15

COI Oversight by Supervisors

Designated Administrator/Staff COI Forms

Department level review (cont'd)

- Report **unresolved** conflicts to the provost, senior vice chancellor for the health sciences, or executive vice chancellor by May 15;
  - Hint: there should be no unresolved conflicts
- Signature Pages and management plans of **resolved** conflicts should **not** be forwarded, but should be filed in the department.

Lastly…

- Signature Pages, Management Reporting Forms, and Data Summary Reports are ultimately forwarded to the COI Office by the provost or senior vice chancellor for the health sciences

Everything you need can be found on the "COI Filing Process" section of the COI website.



Departmental COI Management

- Prospective approval from department chair or dean is required for
  - All outside professional activities (consultancies, speaking engagements, entrepreneurial endeavors, mgmt. or officer positions);
  - Involvement of students in outside entities or in research of interest to a company in which a faculty member has a financial interest;
  - Purchasing from, or subcontracting work to, a company in which an individual has a financial interest.
- Cannot use University facilities or resources
- Total time expenditures in all outside professional activities cannot exceed one day per week on the average.
  - Note: staff members must conduct all outside activities on their own time.

Departmental COI Management (cont'd)

- Department chairs are responsible for the development of COI management plans for
  - research not overseen by the IRB or IACUC
  - COIs with PHS-funded research arising from SFIs valued at > $5,000, but < $10,000
- Chairs may contact the COI Office for assistance;
- COI management plans should be forwarded to COI Office for our records.



Departmental COI Management (cont'd)

- All COI Management Plans (CMPs) must contain the following elements:
  - Disclosure of investigator's SFI in any abstracts, presentations, press releases, or publications and in any proposals or applications for research related to the SFI (as required by funding agency).
  - Notification of others engaged in the research project of investigator's
  - Students will be engaged in the project only with the approval of their department chair or dean.

Departmental COI Management (cont'd)

- If the supervisor believes the financial interest gives rise to an unmanageable COI:
  - require the individual to reduce the value of the financial interest
  - not approve outside activity (e.g., consulting, entrepreneurial endeavor)
- Supervisor may add other elements to CMP

Departmental COI Management (cont'd)

- Additional Management Options
  - Dilution of investigator's role in study, e.g.
    - cannot be PI, but may be co-investigator
    - cannot record research data
    - cannot be the only person involved in the interpretation of study results
  - Addition of a data steward to a particular research project
  - Establishment of an oversight committee

Proper use of students/staff by faculty members with outside interests

- Prospective review and approval of activities by students' department chairs or deans
- Formal notification of faculty members' interest in an outside company
  - Faculty members should distribute Student/Staff Notification Form (provided by COI office) for signature by students/staff;
  - Students/staff should discuss any concerns with faculty members' non-conflicted supervisor and/or COI Office



Proper use of students/staff by faculty members with outside interests (cont'd)

- Work under approved Corporate Research Agreement (CRA) should correspond to effort provided for in the CRA
  - Cannot be compelled to perform work that will benefit the company;
  - Compatibility with academic interests of students;
  - Timely ability to publish research results for academic credit without hindrance by the company's commercial interests



Proper use of students/staff by faculty members with outside interests (cont'd)

- Assurance that students' intellectual property is protected
- Employment of students at faculty member's company
  - Salary must be commensurate with tasks performed.

University-level COI Management: Research Protocols

- The Conflict of Interest Committee (COIC) is responsible for managing potential conflicts involving research overseen by the HRPO and IACUC
- COI questions appear in all research protocol applications and apply to all Investigators listed in the protocol
- Referred to COI Office for review & management

University-level COI Management—Licensed Start-up Companies (LSCs)

- Licensed Start-up Companies
  - Are not publicly-traded
  - Have an option or license to University intellectual property (IP)
  - University and/or University employees or students, or members of their immediate families hold equity (including stock options)
- The COI Committee is responsible for managing potential conflicts involving LSCs
- Special restrictions on relationships with these companies

University-level COI Management — Purchasing

- Purchasing Services refers issues to the COI Office for review
  - E.g., if the individual completing a Directed/Sole Source form has a financial relationship with the company from which a purchase is being requested.
- Purchasing Services reports quarterly to the COI Committee on purchases made from companies in which University employees have a financial interest.



University-level COI Management — Office of Research

- University must attest that the PI of a grant has a current COI disclosure on file
  - Dept. grants administrators can query COI database to verify compliance in advance of submission to OR
- Contract officers also query the database to determine whether PI or other investigators have disclosed a relationship with an Industry sponsor
  - If yes, matter is referred to COI Office for review & management

Public Health Service COI Regulations

- The University is required to review an investigator's disclosed Significant Financial Interests and determine if any are related to and give rise to a Financial Conflict of Interest (FCOI) with any PHS-funded research in which the investigator participates in the design, conduct, or reporting of the research.

Public Health Service COI Regulations

- Lower reporting thresholds
- Reimbursed or sponsored travel expenses exceeding $5,000 in a 12 month period from a single entity must be reported
- Publicly accessible website disclosing managed FCOIs
- COI training at least every 4 years.

Public Health Service COI Regulations

- "Relatedness" assessment
  - Is the PHS-funded research evaluating or developing any intellectual property, product, or technology owned by an entity in which the investigator has an SFI?
  - Is any entity in which the investigator has an SFI providing support (including the provision of drugs or devices) to the PHS-funded project?
  - Is the PHS-funded research evaluating or developing any IP developed by the investigator for which s/he has received more than $5,000 in royalties or licensing income?

Public Health Service COI Regulations

- FCOI: An SFI that could *directly* and *significantly* affect the design, conduct, or reporting of the PHS-funded project.

Public Health Service COI Regulations

- Management of FCOIs
  - For SFIs in the $5,001-$10,000 range, department chairs determine level of COI management
  - For SFIs valued over $10,000 and equity in non-publicly traded entities, centralized management proceeds as normal.

PHS COI Reviews—Office of Research

- **Submission stage**: Office of Research checks that PI/PD and all Senior/Key personnel have PHS Faculty/Researcher forms on file & have completed the CITI PHS COI Training module.

PHS COI Reviews—Office of Research

- **Award stage:** Office of Research check COI PHS Faculty/Researcher forms of key personnel for SFIs
  - Positive responses referred to COI Office for review
    - COI Office contacts Investigator to obtain supervisor's review
      - Depending on nature of SFI, supervisor review may be final, or COI Committee will review
    - If supervisor and/or COIC determines that there is no FCOI, COI Office informs the Office of Research that funds can be released.
- If there is an FCOI, Investigator must agree to a management plan before funds can be released
  - COI Office reports managed FCOI to funding agency

PHS COI Regulations—Public Accessibility

- Managed FCOIs are posted on a public website: http://www.coi.pitt.edu/PHS/FCOIList.htm
- Information disclosed includes
  - Date disclosed
  - Investigator with FCOI
  - Title
  - PHS Funding (number and title of grant)
  - Role on research project
  - Name of entity in which SFI is held
  - Nature of the SFI
  - Approximate dollar value of the SFI

Resources

- COI website www.coi.pitt.edu
  - Filing Process section includes:
    - Provost/EVC memo
    - Instructions for using Superform and Joint UPMC/Pitt form
    - All forms
  - PHS-Funded Investigators
  - Links to COI-related University policies
  - SOHS Industry Relationship Policy



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Questions?

