COI Management and the Responsible Conduct of Research

Conflicts of Interest Office

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Today’s Agenda

• General Overview
• Definitions
• COI Filing Process
• Managing COIs with Research
• COI Management Plans
• Example Scenarios
General Overview
What’s a COI?

• A **potential** Conflict of Interest (COI) may exist if an individual’s outside interests, especially financial, may affect or be perceived to affect his or her research, teaching, or administrative activities at the University.
Why should you care about COIs?

- Protection of human subjects and integrity of research may be compromised
- Public may lose trust in the University and its research findings
- Loss of investigator/faculty member respect in the academic community
- University may lose research funding
Why should you care about COIs?

• Research results may be excessively delayed or not published
• Negative impact on students, trainees, and junior faculty
• University resources may be misused
• Scandals, negative media attention, increased government oversight...
Top Cancer Researcher Fails to Disclose Corporate Financial Ties in Major Research Journals

Dr. José Baselga, the chief medical officer at Memorial Sloan Kettering Cancer Center, in 2015. Cindy Ord/Getty Images
From the Headlines

Memorial Sloan Kettering Leaders Violated Conflict-of-Interest Rules, Report Finds

A policy review follows months of turmoil at the cancer center, which pledged an overhaul, including new rules on public disclosure and limits on outside profits.

by Charles Ornstein, ProPublica, and Katie Thomas, The New York Times, April 4, 3:41 p.m. EDT

Update, April 4, 2019: This story was updated to include additional details of the law firm Debevoise & Plimpton’s review as well as comments about the new conflict-of-interest
Definitions
Significant Financial Interest (SFI)

• An external financial interest that reasonably appears to be related to an individual’s institutional responsibilities

• Examples
  • Consulting remuneration of $10,500 from Pfizer
    • Related
  • Equity in McDonalds
    • Most likely not related
Institutional Responsibilities

• Professional responsibilities performed on behalf of the University of Pittsburgh
  • Research
  • Teaching
  • Institutional committee memberships
  • Service on institutional review boards or data and safety monitoring boards
  • Miscellaneous administrative activities
Investigator

- Any individual, regardless of title or position, who is (or may be perceived to be) independently responsible for or significantly influences the **design, conduct, or reporting of research**.

- More guidance available on the COI Office website under “Regulations and Policies”
Public Health Service (PHS)

• Agency for Healthcare Research and Quality (AHRQ)
• Agency for Toxic Substances and Disease Registry (ATSDR)
• Centers for Disease Control and Prevention (CDC)
• Food and Drug Administration (FDA)
• Health Resources and Services Administration (HRSA)
• Indian Health Service (IHS)
• National Institutes of Health (NIH)
• Substance Abuse and Mental Health Services Administration (SAMHSA)
A Brief Quiz

• Melissa is an undergraduate work study employee in the Department of Cell Biology responsible for moving lab supplies between rooms and other buildings at the University. She has no other duties related to the conduct of the research.

• Is Melissa an investigator?
A Brief Quiz

• Dr. Smith is listed as an “observer” on an IACUC protocol. She does not have any contact with the animals being studied. However, Dr. Smith interprets data collected from the animals at her office in another building.

• Is Dr. Smith an investigator?
COI Filing Process
Who Must Disclose

• University Members
  • All tenure and tenure-stream faculty
  • Any person meeting the definition of an “Investigator”

• Designated Administrator/Staff
  • Administrator IV or above, or equivalent
  • Any employee making, directing, or materially influencing University business decisions
  • Any employee with input of outside vendor or service provider selection
  • Any employee directed to do so by their supervisor
When to Disclose

• Upon appointment
• Annually between January 1 and April 15
• Within 30 days of discovering or acquiring and becoming aware of a new SFI related to institutional responsibilities
How to Disclose

• Online at pi.tt/coifiling

• Two disclosure systems
  • All University Employees with UPMC or UPP Dual Appointments
    • UPMC/Pitt Joint COI Form
    • My HUB
  • All University-Only Employees
    • COI Superform System
    • HSConnect
Special Disclosure Circumstances

• PHS Funded Investigators
  • University-Only Employees (HSConnect)
    • Must select the “PHS Funded” version of the Faculty/Researcher COI Form
    • **DO NOT** complete both the “PHS Funded” and “regular” forms
    • Choose one or the other
  • University Employees with UPMC or UPP Dual Appointments
    • Must answer “yes” to the PHS funding question at the start of the form

• Foreign Influence
  • Report engagements outside of the U.S. where required
COI Database Administrative Access

• Allows search functionality and “read only” access within COI disclosure database

• Request access at pi.tt/coifilingaccess

• Two access levels
  • Basic – limited view
  • Operational – full access
    • Requires department chairperson approval

• UPMC CCEHS office manages access to CITI COI training records
A Brief Quiz

• Dr. Smith is full-time faculty in the Department of Medicine with a UPP appointment. He plans to apply for NIH funding in the next four to five months but does not currently conduct PHS-funded research. Dr. Smith is also responsible for procurement of lab supplies for his department.

• What COI disclosure process should he follow?
A Brief Quiz

• Suzie is a staff member in the Department of Pathology with no UPMC affiliation responsible for purchasing lab supplies. She has no other direct relationship with research or other lab activities.

• What COI form(s) should she complete?
CMPs for Research: Standard vs. PI-Exclusion

• Refer to handout
• Download a copy at pi.tt/coiforms
Overview

- **COI Committee** responsible for managing potential conflicts related to human subject, animal research, and PHS-funded bench research.
- COI questions that appear on IRB and IACUC protocols apply to **all** investigators and research personnel:
  - Questions vary for PHS-funded studies.
  - PI is ultimately responsible for accuracy.
COI Declarations on Protocols

• COI declarations on all protocols must be kept current
• New outside interests must be reported on the protocol(s) through a modification
• Modification will notify the COI Office and regulatory committee (IRB, IACUC) for review and processing
Potential Conflicts to Disclose

• Financial relationship with an entity that...
  • Sponsors the research
  • Owns technology being evaluated or developed

• Inventor or author of intellectual property being evaluated or developed with receipt of royalties or other proceeds
Human Subject Research
PI-Exclusion Categories

• Equity in and/or cash remuneration from a public company (in aggregate) greater than $20,000 per 12-month period
• 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
Human Subject Research
PI-Exclusion Categories

• Inventor or developer of intellectual property when receipt of royalties and/or other proceeds exceeds $10,000 per 12-month period

• PHS-Funded Research Only
  • Reimbursed or sponsored travel from one entity exceeding $10,000 per 12-month period
Animal and Bench Research
PI-Exclusion Categories

• Management or officer position in any University Licensed Start-up Company
  • Exception requires approval from the Senior Vice Chancellor for Research, upon recommendation from the COI Committee

• No other limitations
COI Management Plans (CMPs)
Overview of CMPs

• Three general COI Management Plans (CMPs)
  • Human Subject, PI-Exclusion
  • Human Subject, Non-PI Exclusion
  • Animal and/or Bench

• Examples under “Regulations and Policies” section of COI website

• Certain cases use “special” plans that deviate from the examples, such as FDA-covered clinical studies
How a CMP is Implemented

Study team submits protocol and/or modification with COI declaration

COI Office receives ancillary review request notification

COI Office works with supervisor of person with conflict to finalize CMP terms

COI Office contacts person with conflict

IRB or IACUC staff proceed with remainder of overall review process

COI Office issues ancillary approval in ARO, PittPRO, or OSIRIS

Study team uploads management plan to protocol (PittPRO/OSIRIS only)

Person with conflict receives and agrees to CMP via email or DocuSign
**CMP: Human Subject, PI-Exclusion**

- Investigator with the SFI **cannot**:
  - be involved in recruitment
  - obtain informed consent
  - engage in recording of research data
  - be involved in clinical assessments of study eligibility criteria and intervention outcomes
  - directly participate in data and safety monitoring activities
  - be the only person responsible for interpretation of study results
CMP: Animal and Bench Research

• Similar management plans to human subject, but with some alterations
• Pain and distress classification of Category “E” and/or if no other faculty-rank investigators on study
  • Data steward oversight required if investigator has conflict
General Requirements in CMPs

- Investigator with the SFI must:
  - provide a list of individuals involved in the study to the COI Office so they are notified of the SFI
    - Replaces old paper notification forms
  - ensure students have department chairperson or dean approval to be engaged in research
  - disclose SFI in any related abstracts, presentations, press releases, or publications
  - notify the COI Office of federal grants supporting the protocol
  - disclose SFI in the informed consent form (human subject only)
Organizational Conflict of Interest (OCI)

• Risk of bias or unfair competition in bidding on or performance of federal government contracts
• Three “focus areas” for OCIs
  • Biased ground rules
  • Unequal access to information
  • Impaired objectivity
• All identified OCIs require mitigation plans
• Government agencies have final say regarding whether OCIs will prevent awarding of a contract
• See OCI language? Request help ASAP from COI Office
Example Scenarios
Dr. Adams is the Chief Medical Officer of Pittsburgh Therapeutics, Inc., a University Licensed Start-up Company. He would like to be PI of both animal and human subject research at the University that is of commercial interest to and sponsored by the same company through a Corporate Research Agreement (CRA).

From a COI management perspective, what is required?
Dr. Lincoln is evaluating a device owned by New Orthotics, Inc., a non-public company, under a human subject research protocol. It is not an FDA-covered clinical study. She consults for the company, which compensates her through equity plus cash remuneration of $19,500 per 12-month period.

Can Dr. Lincoln serve as PI of this study?
CMP Example 3

- Dr. Jefferson receives equity in and cash compensation from a publicly-traded pharmaceutical company for consulting services. The aggregate (total) compensation is $8,000. He is conducting PHS-funded animal research on a drug of commercial interest to the pharmaceutical company.

- Is a management plan required?
- Can Dr. Jefferson serve as PI of research that is of commercial interest to this company?
Thank You!

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