

COI Management and the Responsible Conduct of Research

Conflict of Interest Office

Brendan A. Linton

Compliance Coordinator

Jane L. Volk, JD

Associate Director

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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...

From the Headlines

☰ 🔍 HEALTH The New York Times SUBSCRIBE NOW LOG IN

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

The image shows a screenshot of a news article from The New York Times. At the top, there is a navigation bar with a menu icon, a search icon, the word "HEALTH", the newspaper's name "The New York Times", and two buttons: "SUBSCRIBE NOW" and "LOG IN". The main headline is in italics: "Top Cancer Researcher Fails to Disclose Corporate Financial Ties in Major Research Journals". Below the headline is a photograph of Dr. José Baselga, a man with glasses wearing a dark suit and a red tie, speaking at a podium with microphones. The background of the photo is dark with some lights. Below the photo is a caption: "Dr. José Baselga, the chief medical officer at Memorial Sloan Kettering Cancer Center, in 2015. Cindy Ord/Getty Images".

From the Headlines

The screenshot shows the ProPublica website interface. At the top, there are navigation links for 'ProPublica', 'Electionland', 'ProPublica Illinois', 'Local Reporting Network', and 'Data Store'. On the right, there are social media icons for Facebook and Twitter, and a red 'Donate' button. The main header features the ProPublica logo and a navigation menu with 'TOPICS', 'SERIES', 'NEWS APPS', 'GET INVOLVED', 'IMPACT', and 'ABOUT'. A 'SIGN UP' button is located on the right side of the header.

The article title is 'SLOAN KETTERING CANCER CENTER'S CRISIS' with a Facebook icon. Below it, the main headline reads 'Memorial Sloan Kettering Leaders Violated Conflict-of-Interest Rules, Report Finds', accompanied by icons for Twitter, email, and a speech bubble. A sub-headline states: '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.' Below this, there are icons for Creative Commons (CC) and a dollar sign with a slash (\$/).

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

At the bottom left, there is a section for 'SLOAN KETTERING CANCER CENTER'S CRISIS' with the subtext 'Prominent Cancer'. To its right, an update notice says: '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'. On the right side of the article, there is a video player with the 'CANNA' logo and a play button icon.



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?



Managing COIs with Research



CMPs for Research: Standard vs. PI-Exclusion

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



COI Management Plans for Research: Standard vs. PI-Exclusion

Type of Research	HUMAN SUBJECT RESEARCH		ANIMAL & BENCH RESEARCH	
Public Health Service* Funding†	Yes	No	Yes	No
Equity in and/or cash remuneration from a public company in aggregate greater than \$5,000 but not greater than \$10,000	Standard	N/A	Standard	N/A
Equity in and/or cash remuneration from a public company in aggregate greater than \$10,000 but not greater than \$20,000	Standard	Standard	Standard	Standard
Equity in and/or cash remuneration from a public company in aggregate greater than \$20,000 or 5%‡	PI-Exclusion§	PI-Exclusion	Standard¶	Standard
Remuneration from a non-public company greater than \$5,000 but not greater than \$10,000	Standard	N/A	Standard	N/A
Remuneration from a non-public company greater than \$10,000 but not greater than \$20,000	Standard	Standard	Standard	Standard
Remuneration from a non-public company greater than \$20,000	PI-Exclusion	PI-Exclusion	Standard	Standard
Equity in a non-public company	PI-Exclusion	PI-Exclusion	Standard	Standard
Management or officer position in any company	PI-Exclusion	PI-Exclusion	Standard†	Standard†
Investor or developer of intellectual property with receipt of royalties or other proceeds greater than \$5,000 but not greater than \$10,000	Standard†	N/A†	Standard	N/A
Inventor or developer of intellectual property with receipt of royalties or other proceeds greater than \$10,000	PI-Exclusion	PI-Exclusion	Standard	Standard
Reimbursed or sponsored travel from one entity greater than \$5,000 but not greater than \$10,000	Standard	N/A	Standard	N/A
Reimbursed or sponsored travel from one entity greater than \$10,000	PI-Exclusion	N/A	Standard	N/A
CMP Delivery Method	DocuSign	DocuSign	Email	Email

*The Public Health Service (PHS) includes the National Institutes of Health and several other federal agencies. [Visit the COI website](#) for a complete agency list and additional resources.

†Restrictions related to an ownership interest greater than 5% only applicable to projects not funded by the PHS.

‡Requires prior approval from the Senior Vice Chancellor for Research upon recommendation of the COI Committee for conflicted investigator to remain as PI of research sponsored by or of commercial interests to a [Licensed Start-Up Company](#) as defined in [University Policy 11.01-03](#). If approval is denied, the PI-Exclusion management plan applies.

§A CMP is required for research subject to the [COI/COI regulations](#) involving the evaluation or further development of intellectual property invented by the investigator, even if s/he has not received any royalties or proceeds.

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



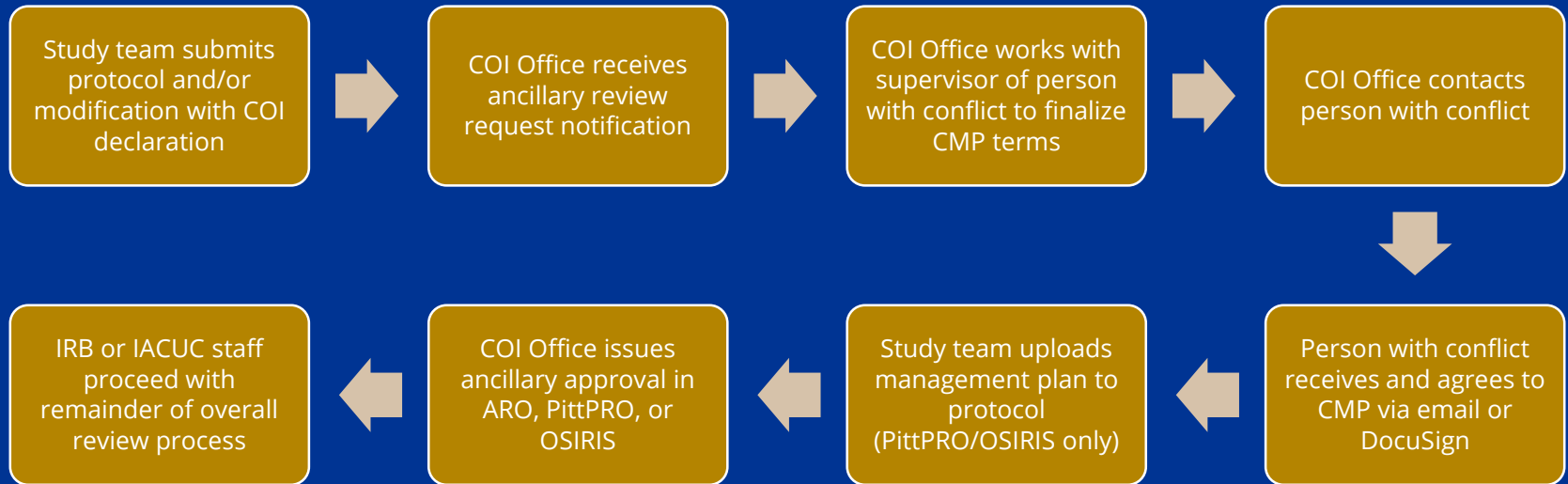
COI Management Plans (CMPs)



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



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

CMP Example 1

- 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?**

CMP Example 2

- 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?**



Questions?

Thank You!

COI Office General Inquiries

(412) 383-1021

coi@pitt.edu

www.coi.pitt.edu