

# Managing Conflict of Interest: Protecting the Integrity of Research

Conflict of Interest Office

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# Today's Agenda

- General Overview
- Policy Discussion
- COI Filing Process
- COI Management for Research
- 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

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## *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' with 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 titled '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 title 'CANNA' and a play button icon.



# Ban or Manage?

- **Manage!**
- Federal regulation and University policy directs the COI management process



# Policy Discussion



# Policy CS09 (Formerly 02-06-01) Outside Employment

“The University recognizes the obligation to make the special knowledge and intellectual competence of its faculty members available to government, business, labor, and civic organizations; as well as the potential value to the faculty member and the University.”

# Policy CS09 (Formerly 02-06-01) Outside Employment

- Permission from department chair, dean or regional campus president
- No use of University name, property, or facilities
- Time given to outside activities is not to exceed one day per week on average
- Fees must be commensurate with services provided and the faculty member's professional standing

# Policy RI01 (Formerly 11-01-03): COI for Research

“...University Members are encouraged to engage in outside activities ... and are permitted to have management or officer positions in outside entities and receive financial benefit from their outside professional activities, so long as these interests do not interfere with their University duties or distort the judgements expected of them.”

# Policy RI01 (Formerly 11-01-03): COI for Research

- Conflict of Commitment
- Conflict of Interest
- Conflict of Interest Committee (COIC)
- Conflict Management Plans
- Licensed Start-up Companies
- Management Interest
- Significant Financial Interest
- University Member

# Policy RI01 (Formerly 11-01-03): COI for Research

- Advantages of industry interactions are realized without loss of fundamental values of objectivity and freedom of inquiry in research
- University's reputation and research programs are not compromised
- No one unfairly benefits from the University's public trust and reputation



# Policy RI01 (Formerly 11-01-03): COI for Research

- Licensed Start-up Companies
  - Legally recognized, non-public companies
  - Option or license to University intellectual property
  - University or one or more of its employees have an ownership interest

# UPMC/University of Pittsburgh Industry Relationship Policy

- Applies to interactions between certain industries and members of the Schools of Health Sciences and UPMC
- Addresses gifts, meals, consulting relationships, samples, site access, off-campus meeting support and other matters
- Prohibits engagements with speakers' bureaus and ghostwriting
- Contains disciplinary enforcement measures
- More information on the COI website under "Regulations and Policies"

# Consulting Contract Approval Process

- Varies based on affiliation
  - UPMC/UPP dual appointees have different review process than University-only personnel
- Generally starts with department-level approval
- More information on COI Website under “Outside Activities” tab

# Public Health Service (PHS) Agencies

- 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)

# Public Health Service (PHS) COI Regulations


- 42 CFR Part 50, Subpart F
  - “Promoting Objectivity in Research” (Grants)
- 45 CFR Part 94
  - “Responsible Prospective Contractors” (Contracts)
- 21 CFR Part 54
  - “Financial Disclosure by Clinical Investigators” (FDA Only)
- More on COI website under “Regulations and Policies”

# PHS COI Regulation Specifics

- Institution is responsible for determining if financial interests constitute Financial Conflicts of Interest with PHS-funded research
  - Lower reporting thresholds
  - Requires reporting of sponsored & reimbursed travel related to institutional responsibilities
  - Additional training requirements
- Managed FCOIs subject to public disclosure
  - Published on Pitt COI website for public inspection

# CITI COI Training

- Accessible at **pi.tt/coitraining**
- Required for all externally funded investigators
  - PHS-funded investigators must complete the PHS version
- Must be renewed every four years

 University of Pittsburgh  
**PROJECT INVESTIGATOR LIST AND CITI COI TRAINING TABLE**

Institution Number	##
Funding Proposal Number	FP
Funding Agency	
Grant/Contract Number	
Full Project Title	

Principal Investigator	
Email (used in HSConnect)	
CITI COI Course Completion Date	MMDDYYYY

The Principal Investigator (PI) is responsible for determining who is an Investigator<sup>1</sup> on this project and ensuring that all Investigators have completed COI training. This table is to be submitted to the Office of Research at the time of initial award and updates (personnel changes or new training completion dates) should be provided as they occur during the project.

Investigators	Email Address (Used in HSConnect)	CITI COI Course Completion Date

The undersigned confirms that the PI generated this list of Investigators and the dates of completion are accurate.

Completed by: \_\_\_\_\_ Date: \_\_\_\_\_

(Signature) \_\_\_\_\_ EMAIL: \_\_\_\_\_

(Print Name and title) \_\_\_\_\_

<sup>1</sup> Investigator includes 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 the research. Guidance to address who is an Investigator can be found [here](#).





# COI Filing Process



# 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

# 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

# How to Disclose

- Online at [pi.tt/coifiling](https://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

# 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





# COI Management for Research



# PHS COI Reviews: Grants and Contracts

- Submission
  - Office of Sponsored Programs checks for Faculty/Researcher (PHS Funded) COI form and CITI Training for PI and all investigators/key personnel
- Award Stage
  - Office of Sponsored Programs directs COI Office to awards on which investigators have disclosed an outside interest on their COI form



# Managing COIs with Research

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

# Managing COIs with Research

- 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

# CMPs for Research: Standard vs. PI-Exclusion

- Refer to handout
- Download a copy at [pi.tt/coiforms](http://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
<b>Equity in and/or cash remuneration from a public company</b> in aggregate greater than \$5,000 but not greater than \$10,000	Standard	N/A	Standard	N/A
<b>Equity in and/or cash remuneration from a public company</b> in aggregate greater than \$10,000 but not greater than \$20,000	Standard	Standard	Standard	Standard
<b>Equity in and/or cash remuneration from a public company</b> in aggregate greater than \$20,000 or 5%‡	PI-Exclusion§	PI-Exclusion	Standard¶	Standard
<b>Remuneration from a non-public company</b> greater than \$5,000 but not greater than \$10,000	Standard	N/A	Standard	N/A
<b>Remuneration from a non-public company</b> greater than \$10,000 but not greater than \$20,000	Standard	Standard	Standard	Standard
<b>Remuneration from a non-public company</b> greater than \$20,000	PI-Exclusion	PI-Exclusion	Standard	Standard
<b>Equity in a non-public company</b>	PI-Exclusion	PI-Exclusion	Standard	Standard
<b>Management or officer position in any company</b>	PI-Exclusion	PI-Exclusion	Standard¶	Standard¶
<b>Investor or developer of intellectual property</b> with receipt of royalties or other proceeds greater than \$5,000 but not greater than \$10,000	Standard¶	N/A¶	Standard	N/A
<b>Inventor or developer of intellectual property</b> with receipt of royalties or other proceeds greater than \$10,000	PI-Exclusion	PI-Exclusion	Standard	Standard
<b>Reimbursed or sponsored travel</b> from one entity greater than \$5,000 but not greater than \$10,000	Standard	N/A	Standard	N/A
<b>Reimbursed or sponsored travel</b> from one entity greater than \$10,000	PI-Exclusion	N/A	Standard	N/A
<b>CMP Delivery Method</b>	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 she has not received any royalties or proceeds.

10/15/2019

# COI Management Plans (CMPs)

- Created centrally by the COI Office
- Department chairpersons and/or deans are consulted to refine CMP elements
  - May incorporate a data steward or other terms

# COI Management Plans (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

# COI Management Plans (CMPs)

- All will include the following at minimum:
  - Investigator must disclose SFI(s) in any abstracts, publications, press releases, etc. and in related applications or proposals for research funding
  - Other individuals engaged in the project must be notified of the SFI
    - COI Office facilitates this via email notifications
  - Students must obtain department chair or dean approval to be engaged in the project

# COI Management Plans (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)

# CMP: Animal or Bench Research

- No automatic PI-exclusion cases
  - PI with a management or officer position in any Licensed Start-up Company must secure prior approval of SVC-Research via COI Committee
- 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



# CMP: Human Subject Research, 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

A tall, illuminated Gothic-style building at night, likely a university tower. The building is lit up with warm yellow lights, and a bright blue laser beam extends from the top towards the sky. The scene is set against a dark blue night sky with some clouds. In the foreground, there are green trees and a lawn, also illuminated with lights. The text "Example Scenarios" is overlaid in white on the lower part of the image.

# 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

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