Conflict of Interest management & the responsible conduct of research

Shawna J. Porter, MSW, Senior Compliance Coordinator
University of Pittsburgh Conflict of Interest Office
A Partner in Promoting Objectivity in Research, Teaching, & Administrative Activities
Today’s agenda

- A general overview of conflicts of interest (COI)
- Discuss why properly identifying and managing COIs is important
- Management of research-related COIs
- Requirements for PHS-funded research
- Implications of COI management
“Conflict of Interest”
What is a conflict of interest?

- A potential Conflict of Interest (COI) may exist if an individual’s outside interests (especially financial) may affect, or perceive to affect, his/her research, teaching, or administrative activities at the University.
Scenario 1

• Professor A. E. Moniz is a consultant for e-SCOPE. Under his contract, he may earn up to $35,000 this current year;

• e-SCOPE wants to sponsor human subject research at the University to evaluate new technologies for measuring the architecture of the brain.
Scenario 1 – Your thoughts
Should Dr. Moniz be the PI of the clinical trial sponsored by e-SCOPE?

A. Yes
B. No

50% 50%
Scenario 1—Your thoughts
Should Dr. Moniz be permitted to participate at all in the e-SCOPE sponsored trial?

A. Yes  
B. No
Scenario 1 – Other considerations

• If you were a potential research subject in the study, what kind of information, if any, would you want about Dr. Moniz’ financial relationship with the study sponsor?

• As a co-investigator working with Dr. Moniz on the study, what kind of information would you want?

• As a student what concerns, if any, would you have about working on this project?
Can an investigator have a financial conflict of interest with federally-funded research?

A. Yes
B. No

50% 50%
Scenario 2

• Dr. Ivette Semmelweiss developed a new method for treating OCD, which was patented by the University and licensed to Rehab, Inc., and she receives royalties exceeding $5,000/12-month period for the IP through Pitt;
• Dr. Semmelweiss is conducting research funded by an NIMH grant to further evaluate the technology.
Scenario 2—your thoughts
Do you think Dr. Semmelweis has a conflict of interest?

A. Yes
B. No

50% 50%
Why should you care about COI?

If conflicts of interest 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;
- University may lose public support and funding for research;
- the investigator/faculty member may lose the respect of the academic community;
Why should you care about COI?

• violation of scientific norms may result;
• research results may be excessively delayed or not published;
• there may be a negative impact on students, trainees, and/or junior faculty;
• University resources may be improperly used;
• increased government regulations may result;
• scandals or negative media attention may occur....
From the headlines

Johns Hopkins to continue with international alcohol study despite criticism about funding

By Andrea K. McDaniels • Contact Reporter
The Baltimore Sun

March 31, 2018, 8:00 AM

Johns Hopkins researchers are moving forward with an international study that will look at whether one drink of alcohol a day can decrease the risk of heart disease and diabetes despite criticism that it is funded by the liquor industry.

A New York Times investigation found that the 10-year government trial is funded mostly by Anheuser-Busch InBev, Heineken and other alcohol companies through donations to a private foundation that raises money for the National Institutes of Health.
From the headlines

Dollars for Doctors
How Industry Money Reaches Physicians

The Story So Far

Feature Stories

News App: Dollars for Docs

As Full Disclosure Near, Doctors’ Pay for Drug Talks Plummets

Dollars for Docs Mints a Millionaire

Med Schools Flunk at Keeping Faculty Off Pharma Speaking Circuit

Financial Ties Bind Medical Societies to Drug and Device Makers

Filter:

Show All (74)

Mailed Stories Only (5)

Unread Stories Only (74)

Author:

Show All (74)

Sort by:

Name (asc)

Why Pharma Payments to Doctors Were So Hard to Parse

By Charles Ornstein, Mike Nyrums and Ryan Crookswood Jones

ProPublica, Jan. 25, 2014

Flaws in information submitted to Open Payments, a government database of financial relationships in the medical field, complicated our analysis.

1 Comment

Subscribe to the ProPublica Podcast.

The ProPublica Podcast is a weekly program of interviews with reporters about our latest investigations.

LISTEN NOW
Open Payments Database

Open Payments

Creating Public Transparency of Industry-Physician Financial Relationships

The Official Website for Open Payments (the Sunshine Act)

Open Payments creates greater transparency around the financial relationships of manufacturers, physicians, and teaching hospitals. The program requires that the following information is reported annually to CMS:

- Applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report payments or other transfers of value they make to physicians and teaching hospitals to CMS.
- Applicable manufacturers and applicable group purchasing organizations (GPOs) to report to CMS certain ownership or investment interests held by physicians or their immediate family members.
- Applicable GPOs to report to CMS payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year.

Important Information

Physician and Teaching Hospital Registration in the Open Payments System

Physicians and teaching hospital representatives can register in the Open Payments system. Visit the Physician page or Teaching Hospital page for more information.

View the instructional videos on Physician and Teaching Hospital Registration and Physician and Teaching Hospital Review and Dispute tutorials to learn how to register in the Open Payments system and nominate individuals to perform system actions on your behalf, as well as how to review, affirm, initiate, and withdraw disputes in the system. You can also download instructional PDFs from the Downloads section, below.

Industry, Physicians and Teaching Hospitals:

The Open Payments review and dispute process ends by September 10, 2014. The review, dispute and correction process allows physicians and teaching hospitals to review and initiate any disputes regarding the data reported about them by applicable manufacturers and applicable GPOs before CMS makes the information public on September 30, 2014. Visit the Dispute and Resolution page for more information.

Updated Resource for ALL Open Payments System Users:

The Open Payments User Guide has been extensively updated to provide industry, physicians, and teaching hospitals with a comprehensive understanding of the Open Payments system and requirements. New chapters include physician and teaching hospital registration in the Open Payments system, and review and dispute processes.
Ban or manage?
02-06-01: Outside Employment: This policy establishes the conditions under which faculty members may perform professional services outside the University.

“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 02-06-01)
Manage! – University Policies (02-06-01)

• Permission from the department chair, dean or 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 for outside work are commensurate with services provided and the faculty member's professional standing
Manage! – University Policies

11-01-03 Conflict of Interest Policy for Faculty, Scholars, Researchers, Research Staff/Coordinators

• The opportunity for University personnel to receive financial...rewards from [relationships with industry] ...is not intrinsically unacceptable, as long as they do not adversely affect the objectivity, integrity, or professional commitment of investigators and scholars.
Manage! – University Policies (11-01-03)

• Purpose – to assure that:
  – the advantages of interactions w/industry are realized without the loss of the fundamental values of objectivity and freedom of inquiry in research and scholarship;
  – University’s research programs and reputation are not compromised; and
  – no one unfairly benefits from the University’s public trust or reputation
Manage! – University Policies (11-01-03)

• Requires disclosure of financial relationships to the University using the Superform system
  – **Annual disclosure** between Jan 1st – April 15th
  – Disclosures must be kept up-to-date throughout the year
  – University’s Superform system [https://coi.hs.pitt.edu/](https://coi.hs.pitt.edu/)

• Those with appointments at UPMC/UPP should use Joint Pitt/UPMC form to fulfill obligations to both institutions
  – My HUB > Human Resources tab > COI
Manage! – University Policies (11-01-03)

- Outlines COI management of regulated research
- Outlines restrictions on faculty interaction with Licensed Start-up Companies
  - Not publicly-traded
  - Option or license to University intellectual property
  - University or one or more of its employees have ownership interest
Manage! – Industry Relationship Policy*

- Ended participation in Speaker’s Bureaus
- Limits site access for Industry and banned the provision of gifts and meals by Industry
- Outlines criteria for faculty participation in Industry-sponsored events and engaging in consulting activities
- Explicitly bans sales, marketing, and promotional activities, and otherwise proscribes faculty interactions with Industry

* AKA: Policy on Conflicts of Interest and Interactions between representatives of Certain Industries and Faculty, Staff and Students of the Schools of the Health Sciences and Personnel Employed by UPMC at all Domestic Locations
Who must submit a COI disclosure?
Staff engaged in research should complete a University Faculty/Researcher COI disclosure form.

A. True  
B. False
Annual COI filing – Faculty/Researcher forms

• All regular full-time faculty

• Anyone, regardless of title or position, who engages in research at the University of Pittsburgh

• Anyone who is or expects to be an investigator on a PHS-funded project must complete the PHS Faculty/Researcher form, instead of the regular form
  – Only complete the Faculty/Researcher form that applies to you, not both
Public Health Service (PHS) COI regulations

• Policy 11-01-03 revised August 24, 2012 to reflect PHS COI regulations for “promoting objectivity in research”—42 CFR Part 50, subpart F (grants) & 45 CFR Part 94 (contracts)

• See PHS section of COI website for more information http://www.coi.pitt.edu/PHS/index.htm
Agencies of the 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)
PHS COI regulations

- Lower reporting thresholds
- Institution is responsible for determining if financial interests constitute Financial Conflicts of Interest with PHS-funded research
- Requires reporting of sponsored & reimbursed travel related to institutional responsibilities
- Additional training requirements
- Managed FCOIs with PHS-funded research to be disclosed on publicly-accessible website
Who must submit a COI disclosure?
Only the PIs of grants from PHS agencies need to complete the PHS Faculty/Researcher COI disclosure form.

A. True 
B. False
PHS COI review – grants & contracts

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

- **Awards**: the Office of Research refers to the COI Office awards on which Investigators have reported outside financial interests on PHS Faculty/Researcher forms.
COI CITI Training

- All Investigators who are externally funded must complete the CITI COI training course with re-certification required every 4 years.

- Guidance to address who meets the definition of an Investigator is available on the COI website.
Managing COIs with research

• The COI Committee is responsible for managing potential conflicts related to human subject research (HRPO) and animal research (IACUC)
• COI questions that appear on protocol applications apply to all investigators and research personnel
  ‒ There are different questions for PHS-funded studies
  ‒ Questions reflect SFI categories & thresholds
  ‒ PI is responsible for ensuring that all investigators and study personnel review these questions
Managing COIs with research

- '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.
Managing COIs with research

• Reporting must be kept current
  – Whenever new outside interests are accrued, investigators should notify the COI Office and the appropriate regulatory committee (e.g., HRPO, IACUC), and update their COI disclosure forms
Human subject research (HRPO)

• NB: Protocols that are “Exempt” or receive a “Not Human Subjects Research” designation are not subject to regulated research section of COI policy.
Human Subject Research (HRPO)

- Standard COI Management Plan (SMP)
  - A financial interest (aggregated value of equity and remuneration) in a publicly-traded entity that exceeds $10,000
  - Remuneration from a non-publicly traded entity that exceeds $10,000
  - Any equity in a non-publicly traded entity
  - Management or officer position in a company
  - A financial interest as an author or inventor of IP that has been optioned or licensed to an external entity when royalties, milestone fees, or other proceeds exceed $10,000/12-month period.
Human Subject Research (IRB)

- FCOIs that do not require “PI-exclusion rule”
  - SFIs with value > $5,000, but < $10,000 (PHS-funded studies only)
  - Reimbursed or sponsored travel (PHS-funded studies only)
  - Having a Proprietary Interest in the Tested Product (FDA covered studies only), provided licensing related income has not exceeded $10,000/12-months

- COI Office will work with department chair to develop a COI Management Plan (CMP)
Animal research (IACUC)

- Same SFIs trigger “PI-exclusion rule.”
- Management plan similar to SMP, less the items specific to human subject research, e.g., those related to administering the informed consent and determining subject eligibility.
Managing COIs with research

• All research CMPs will contain at least the following elements:
  – The investigator will **disclose** the existence of his/her SFI in any abstracts, presentations, press releases, and in related applications or proposals for research funding only if disclosure is required by the funding source.
  – Other individuals (students, staff, or other faculty members) engaged in the PHS-funded research project with the investigator should be **notified** of the existence of his/her SFI through the use of the standard notification form.
  – **Students** will be engaged in the project only with the approval of their department chair or dean.
Managing COIs with research

• All managed FCOIs will be reported to the appropriate funding source

• In the case of PHS-funded research, this information will also be posted on the University’s COI website, as required by federal regulation
  – [http://www.coi.pitt.edu/PHS/FCOILList.htm](http://www.coi.pitt.edu/PHS/FCOILList.htm)
Examples & discussion

- Going back to the examples from the beginning, think about what issues might arise as a result of the investigator’s financial interest.
- Think about yourself as
  - the person with the financial relationship
  - someone working with that person
  - a participant in the research study
- Consider the elements in the SMP.
Scenario 1

- Professor A. E. Moniz is a consultant for e-SCOPE (his contract is for $35,000 in this current year);
- e-SCOPE wants to sponsor human subject research at the University to evaluate new technologies for measuring the architecture of the brain.
Scenario 2

• Dr. Ivette Semmelweiss developed a new method for treating OCD, which was patented by the University and licensed to Rehab, Inc.; she receives royalties for the IP through Pitt;

• Dr. Semmelweiss is conducting federally sponsored research to further evaluate the technology.
Discussion

• Why do you think certain elements of the COI management plan are required?
• What are the potential benefits of COI management?
Discussion

• What would you think if you received a form notifying you that one of the investigators on a study you are working on has a financial interest in the research?

• How do you think potential research participants would feel about reading the COI disclosure language in the informed consent document?
Questions?
Resources & assistance

COI website: www.coi.pitt.edu

– For information about filing a COI disclosure form, see “COI Filing Process”
– For information on engaging in consulting activities, see Industry Relationships Policy > Policy Compliance Tools, as well as the IRP FAQ page
– For information regarding PHS-funded research, see: http://www.coi.pitt.edu/PHS/index.htm

NIH FCOI website: http://grants.nih.gov/grants/policy/coi/

– Links to regulations
– Educational tutorial & FAQs
Resources & assistance

**COI Office Staff**

David T. Wehrle, CPA, CFE, CIA, Director
412-383-1774; dtw12@pitt.edu

Khrys X. Myrddin, MPPM
Associate Director
412-383-2828; kxm1@pitt.edu

Shawna J. Porter, MSW
Senior Compliance Coordinator
412-383-1735; sjp60@pitt.edu

Malini Srinivasan, MPH
Compliance Coordinator
412-624-6737; mas225@pitt.edu

Brendan Linton, BA
Compliance Coordinator
412-383-1968
Brendan.linton@pitt.edu

**COI Committee**

Craig Wilcox, PhD
412-624-8270; daylite@pitt.edu
RCR Training Evaluation Questions
Thank you for your participation

CTSI
Responsible Conduct of Research Center
By attending this program, I have learned enough that I would feel comfortable discussing this topic with a colleague.

A. Strongly Disagree
B. Disagree
C. Somewhat Disagree
D. Neither Agree nor Disagree
E. Somewhat Agree
F. Agree
G. Strongly Agree
What I learned today will change my research practices.

A. Strongly Disagree
B. Disagree
C. Somewhat Disagree
D. Neither Agree nor Disagree
E. Somewhat Agree
F. Agree
G. Strongly Agree
This program met my expectations.

A. Strongly Disagree
B. Disagree
C. Somewhat Disagree
D. Neither Agree nor Disagree
E. Somewhat Agree
F. Agree
G. Strongly Agree
My overall rating of this program is:

A. Very poor
B. Poor
C. Fair
D. Neutral
E. Good
F. Very good
G. Excellent
I was motivated to attend this program by the following (check all that apply):

A. Meet an NIH grant requirement
B. Meet an NSF grant requirement
C. Meet the requirements of another funding agency
D. Enhance my existing knowledge about this topic
E. Learn skills for a research area that is new to me
My research role is: (choose all that apply)

A. Department head, chair or senior faculty
B. Assistant or Associate Professor
C. Postdoctoral fellow/scholar
D. Medical resident
E. Medical student
F. Graduate student
G. Research coordinator/research staff
H. Administrative staff
I. Undergraduate student
J. other
I have been involved in research for ______ years.

A. <1-5
B. 6-10
C. 11-15
D. >15