

# NCURA CONFERENCE

**Analyzing Relatedness under PHS Financial Conflict of Interest Regulations**

May 3, 2016

# Agenda

- Background
- Overview of the PHS Regulations
  - General
  - Investigator Requirements
  - Institutional Requirements
  - Subcontractor Requirements
- Relatedness/FCOI
  - What does the regulations tell us?
  - Common Practices
- Other Funding Agencies
- Questions

# What Is This About?

## Conflict of Interest

“A set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest”

Institute of Medicine, *Committee on Conflict of Interest in Medical Research, Education, and Practice*, edited by Bernard Lo and Marilyn J. Field. Washington, DC: National Academies Press, 2009).

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*“Try this—I just bought a hundred shares.”*

# Understanding COI

**Primary interest:** Determined by professional duties of physician, researcher, teacher

- Normally good agreement about what these duties are and that they should be the primary consideration in any professional decision about the health of patients, the integrity of research

**Secondary interest:** Examples include financial gain, desire for professional advancement, wish to do favors for family or friends

- Usually not wrong by itself. May even be a necessary and desirable part of professional practice. **Only its relative weight in professional decisions is problematic.**

**Goal:** Not to eliminate or reduce financial or other gains. Rather, to prevent these secondary factors from dominating – or appearing to dominate – the relevant primary interest when making professional decisions.

# Conflict of Interest:

## A few common misconceptions

- A conflict of interest does not imply wrong-doing
- A conflict exists whether or not a particular individual is actually influenced by secondary interest.
- It exists if the circumstances are reasonably ***believed*** to create a risk that decisions may be unduly influenced by secondary interests
- Conflicts can be mitigated (or managed) but they still exist.

# Checks and Balances

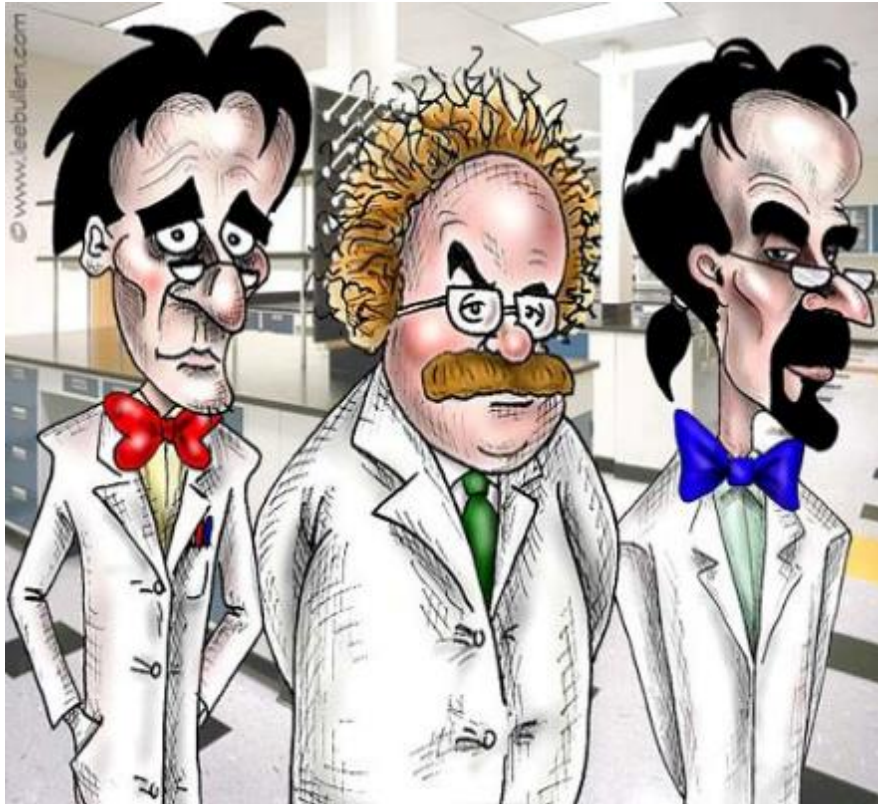
## ➤ **Federal COI Regulations: 42 C.F.R. 50 Subpart F**

- applies to all *Investigators* on research funded by the Public Health Service (PHS)
- some foundations have adopted and follow the regulations

## ➤ **Institutional Policies**

- typically applies to all researchers and/or faculty
- may be broader and/or stricter than federal regulations

# Who is an “Investigator”?



*Investigator* means the project director or principal Investigator and any other person, regardless of title or position, who is *responsible for the design, conduct, or reporting* of the research..., which may include, for example, collaborators or consultants.

# PHS Regulations: Requirements for the Investigator

- ✓ **report significant financial interests** (including sponsored travel) related to *institutional responsibilities* before grant submission to the institution;
- ✓ **submit updates within 30 days** of discovering or acquiring new interest;
- ✓ **submit annual update** of all interests.
- ✓ **complete training on the PHS regulations** and institution's COI policy before participating in research and every four years thereafter.
- ✓ **comply with all management** required by institution.



# PHS Regulations: Requirements for the Institution

- ✓ **Maintain policy on public website**
- ✓ **Review reported significant financial interests to determine:**
  - Whether interests are **related** to PHS proposed research
  - If related, determine whether financial interests pose a financial conflict of interest (FCOI)
- ✓ **Manage, Reduce or Eliminate any identified FCOIs**
- ✓ **Report identified FCOIs to NIH:** Detailed report includes value of the financial interest (in increments), nature of the FCOI, description of how FCOI relates to PHS funded research, and key elements of the Institution's management plan
- ✓ **Public Accessibility:** Institutions required to make available FCOIs held by senior/key personnel via (i) publicly accessible website or (ii) written response to any requestor within five business days

# PHS Regulations:

## Subcontractor Requirements

- **WHO IS COVERED:** An investigator is any individual, regardless of position or title, who is responsible for the design, conduct or reporting of research. An investigator may be a collaborator or consultant.
- **REQUIREMENTS FOR PRIME:**
  - ✓ Incorporating as part of the written agreement terms that establish whether Prime COI Policy or Sub COI Policy will apply to sub's investigators.
  - ✓ If Sub Policy applies, Sub shall certify that policy is compliant with PHS regs. If not, Prime Policy will apply.
  - ✓ If Sub Policy applies, agreement will reference time period for report of FCOIs to Prime which will allow Prime to report to PHS as required.
  - ✓ If Prime Policy applies, contract must include time period for the disclosure of all SFIs to prime to allow for timely review, management and reporting.

# Institutional Review: Determining Relatedness/FCOI

- Financial Interest → Significant?
  - A Significant Financial Interest (SFI) is one that meets a certain threshold
    - Cash Income >\$5,000 over a 12-month period
    - Equity Interest, private company – no threshold
    - Equity Interest, publicly traded - \$>5,000
    - Licensing Income not via the Institution  
(some exclusions: for example income from government agencies for services on review boards)

# Institutional Review: Determining Relatedness

- Significant → Related?
  - A SFI is related to research when the Institution determines that the SFI **could** be **affected** by the **research** or is in an entity whose financial interest **could** be **affected** by the research.

# Institutional Review: Determining FCOI

- Related → FCOI?
  - An FCOI exists when the institution **reasonably** determines that the SFI **could directly** and **significantly** affect the **design, conduct** or **reporting** of the research.

*Institution has to complete FCOI review prior to expenditure of federal funds!*

# Institutional Review: How do we do it?

- Involve Investigator in the review/ask questions.
- Review the research (summary, specific aims).
- Review the website of the SFI company.
- Involve peers/COI Committee/other expert faculty
- What can trip us up?
  - Is it directly related? If a tree falls in the forest....?
  - Lack of information about the company and what they do.
  - Investigator insisting that it is not related but the rationale for why not cuts too close (company is interested in human therapeutics, our research is in animals).

# Review Timeline

- One database for disclosure of financial interests– ask the investigator to update annually and before each grant submission.
- Before each grant submission, many institutions take the opportunity to ask questions intended to assist with the relatedness determination. Other institutions do this at JIT or at award.
- Relatedness analysis occurs between submission and award set-up (we also check for training and ensure complete during this interim).

# If FCOI, What Next?

## ➤ Management

- Divestment of financial interest
- Disclosure--
- Independent monitor/ outside oversight of science
- Modification of the research plan
- Change of personnel or personnel responsibilities (elimination of conflicting role)
- Reduction of financial interest
- Distinction of the science
- Clear delineation of roles, facilities and resources
- Increased internal reporting

## ➤ Report to awarding agency/funder

## ➤ Public Access— respond within 5 days or website



# Case Examples

- See handout.

# Other Funding Agencies

- NSF – similar requirements to PHS regulations but
  - institution must inform NSF only if there is an FCOI that cannot be managed
  - Investigator is not required to update within 30 days of acquiring a new SFI, if she updates annually.
- In response to uniform guidance, we are seeing all sorts of fun, new COI language.... Thanks to our colleagues at Northwestern for summarizing:  
<http://www.northwestern.edu/coi/contacts/Example%20of%20Federal%20Sponsor%20COI%20Terms.pdf>

# Questions?

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