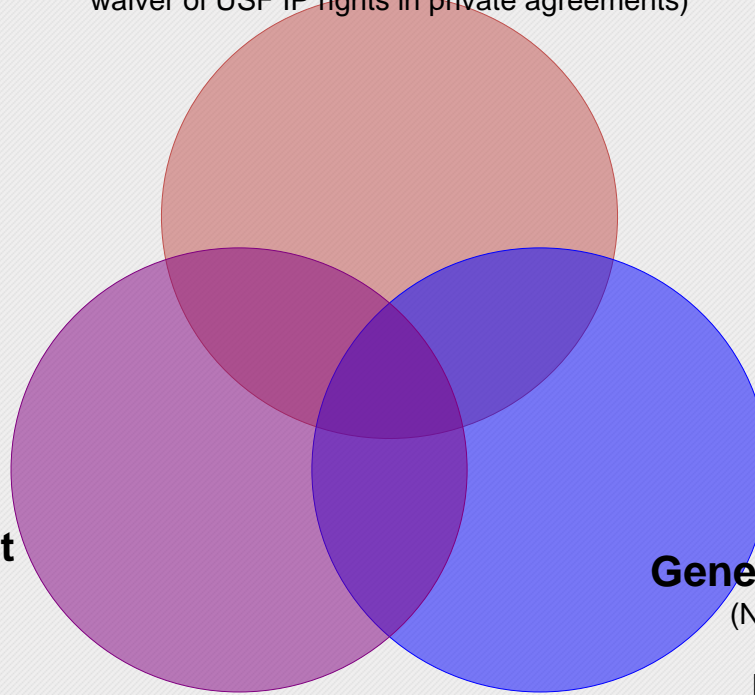


# Conflicts of Interest in Medicine and Research

Biomedical Ethics Class: February 12, 2008

# Conflicts of Interest and Commitment w/ University Employment

(Excessive time spent on external endeavors,  
use of USF resources/name/students  
in furtherance of private interests,  
waiver of USF IP rights in private agreements)



## Conflicts of Interest in Research

(Personal financial interests  
that may bias the design,  
conduct or reporting  
of USF Research)

## General COI: Everything Else

(Nepotism, Doing Business w/USF  
in Private Capacity,  
Board/Committee Membership,  
Purchasing Decisions, COI in Medical Practice)

# Learning Objectives

## Generally:

- Define a conflict of interest (COI)
- Recognize different types of “self-interest” that can create a conflict of interest
- Distinguish between a “COI in research” and other types of COI that can arise in a medical practice

# Learning Objectives (cont)

## Regulatory Context:

- Understand the difference between the state's interest in regulating COI and the federal government's interest in regulating COI
- Identify the three federal government agencies who have rules regulating COI in research

# Learning Objectives (cont)

## Practical Application:

- Identify the different types of conflicts of interest in a given scenario
- Perform a COI review and develop a management plan
- Discuss opinions on COI in medical practice

# “Working” Definitions

## **Conflict of Interest**

A conflict of interest exists when an individual’s professional or ethical obligations might be compromised by self-interest.

**Self-Interest** for COI purposes can manifest in the form of

- A financial interest
- Enhanced reputation
- Personal relationships
- Professional relationships
- Personal beliefs (political, religious, intellectual)

# “Working” Definitions

## **Conflict of Interest in Research**

A conflict of interest in research exists when an *investigator's financial interests* may compromise, or have the appearance of compromising, an investigator's professional judgment in the *design, conduct or reporting of research*.

## **Investigator**

Any person responsible for the design, conduct or reporting of research (or who is involved in the treatment or evaluation of human subjects).

# “Working” Definitions

**Financial Interests** include

- Ownership and equity
- Management positions in an external entity
- Paid consulting
- Honoraria
- Recruitment bonuses/incentives
- “Finders fees”

**General COI** =  
Individual +  
Self-Interest +  
An Ethical or  
Professional Duty

**COI in Research** =  
Investigator +  
Financial Interest +  
Objectivity in the  
Design/Conduct/Reporting of  
Research

HINT: The management goal is  
to protect the integrity of  
the research

# Hypothetical: COI in Research?

Dr. Needbucks of Public University invented a drug to prevent Alzheimer's disease.

DevicesRUs, wants to sponsor a study with Dr. N as the PI to develop and test a device that will deliver Dr. N's drug directly to the brain.

Dr. N's spouse is the president of Lab Solutions, Inc. that manufactures lab supplies and equipment.

Dr. N and her staff purchase all of their basic supplies and equipment from Lab Solutions.

# Ask:

## Investigator?

- ✓ Yes. The individual is an investigator on a research study.

## Financial Interest?

- ✓ Yes, management position of spouse in an external company that sells research products.

## What is the professional/ethical obligation that is potentially compromised?

- ✓ The duty of public stewardship--to refrain from using one's public position to enhance one's private interests.

**Conclusion:** This is a conflict of interest in a research setting, but not a "COI in Research" as we have defined it because the investigator's self-dealing, while perhaps a conflict with her public position, does not compromise the integrity of the research results.

# What if during the course of the study...

Dr. Needbucks purchases \$50,000 worth of stock in DevicesRUs?

# Repeat the analysis:

## Investigator?

- ✓ Yes. The individual is an investigator on a research study.

## Financial Interest?

- ✓ Yes, Dr. N's financial investment in the sponsor/manufacturer of the device being tested.

## What is the professional/ethical obligation that is compromised?

- ✓ The duty of objectivity in the design, conduct, or reporting of the research study.

**Conclusion:** This is a “COI in Research” as we have defined it. Note that there may be more than one type of conflict of interest at work in the research context—multiple avenues of self-interest and multiple professional or ethical duties.

## What type of self-interest is represented by these examples?

Dr. Guinn is the co-founder of a new method of behavioral therapy for which he has received worldwide recognition. He is approached about conducting a study for another form of therapy which, if effective, would render his form of therapy obsolete.

(Reputation )

Dr. Childress sits on the IACUC and reviews a study about cloning. Dr. Childress thinks cloning is immoral and unethical.

(Personal Belief)

# What type of self-interest is represented by these examples?

Dr. Matteo owns significant stock in a biotech company. The company approaches her about conducting research on the viability of a new genetics test.

(Financial Interest)

Dr. Pitman is an investigator for a study testing a new medical device. Dr. Pitman's brother is one of the owners of the company developing the device.

(Personal Relationship)

# What type of self-interest is represented by these examples?

Dr. Boyer sits on the board of directors of Company X. Company X is developing a new piece of equipment and they ask Dr. Boyer to conduct a study on the safety and efficacy of the equipment.

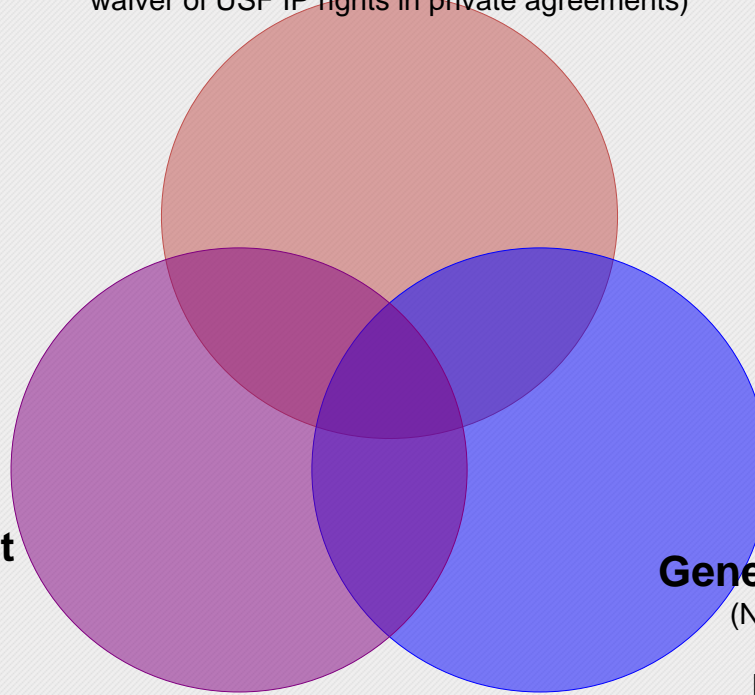
(Professional Relationship)

# State Regulations (Code of Conduct of Public Officers and Employees)

- The state regulations only address general COI of public officers and employees and are designed to prohibit and/or manage conflicts between a public employee's duties to the state employer and the employee's personal interests
- Example: A public employee acting in a private capacity, may not sell goods to his or her own agency.
- Example: A public employee may not have an ongoing or regularly recurring conflict with his or her public employment (catch-all provision).
- What interests are the state COI regulations designed to protect?

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# Federal Regulations (NSF/PHS and FDA)

- The federal regulations only address COI in research
- Require institutions receiving federal funds for research to have policies to manage bias in the design, conduct or reporting of research funded with federal dollars (PHS/NSF).
- Require a sponsor of a new drug/device to certify that COI of investigators in studies supporting the FDA approval of the drug/device either does not exist or is adequately managed (FDA).
- What interests are the federal regulations designed to protect?

# Federal Regulations

The federal regulations only address one type of “self-interest”:

FINANCIAL INTERESTS

(Why?)

# General Principles in Dealing with COI in Research

- COI is virtually unavoidable.
- COI does not preclude participation of an investigator in a project.
- Must have a culture of honest and full disclosure so that steps can be taken to manage conflicts effectively
- Not all COI can be managed.

# COI Committee Review

## **MOTIVATION**

How much incentive does the INV have to bias the design, conduct or reporting of the research?

## **OPPORTUNITY**

Is the INV in a position to bias the design, conduct or reporting of the research?

# COI Committee: Hypothetical

Investigator Clifford is approached to conduct a study for Company X and files a financial disclosure stating that she anticipates receiving \$9,999 in income from Company X over the next 12 months.

Clifford also served on the advisory board of Company X to assist with the study design and analysis on the study that she has been asked to conduct for Company X.

Clifford might receive more \$\$\$ from Company X if she is asked to give lectures on the study during the year.

# COI Committee: Hypothetical

## Additional facts:

The study in question is a multi-center trial that will obtain data from 10 different sites aggregate. Clifford is the PI for one of the sites.

Data analysis is externally conducted—i.e., Clifford is not involved in the analysis of study data

The COI is disclosed in manuscripts submitted for publication per journal requirements.

# COI Committee: Hypothetical

The research subjects' informed consent will outline Clifford's interests related to Company X.

There are other investigators on the study who do not have an interest in Company X.

# Some Issues to Consider

What information do you need from INV Clifford?

- The purpose of the study and the study procedures (get the protocol).
- The role of INV in the study—e.g., will she recruit subjects, conduct experimental portions of the study, etc.
- What is INV doing for the company? (e.g., training other investigators to use a company manufactured device, promoting a company drug at conferences, is it the same drug being studied or a different drug manufactured by the company?)
- Are the non-interested investigators supervised by Clifford?
- What is the number of subjects anticipated to be enrolled at the PI's study site? What percentage of the entire study population does this number represent?

# Some Issues to Consider

How would the Committee handle the “uncertain” amount of income that may be received annually?

- Could review it *as if* the amount were “significant”;  
or
- Re-evaluate later once additional amounts are disclosed to Committee as required
  - Assumes that INV is compliant and will disclose changes in financial interests as required-consider that PIs are usually busy and subsequent disclosure will not be high on the list of priorities (“unintentional noncompliance”).
  - Solution for institution: “Ask the Question” annually.

# Some Issues to Consider

Is \$9999 sufficient motivation to be concerned about bias in the design, conduct or reporting of the study?

**(HINT:** Don't answer too quickly just because it is under \$10,000—consider whether the interest will be *directly affected* by the outcome of the study)

- In the case of a consulting relationship, usually no direct effect of outcome on interest
- In the case of a proprietary interest (e.g., patent ownership, ownership in start-up company licensing the study drug or device) the interest will be directly affected by the outcome of the study

# Some Issues to Consider

A colleague reports that Clifford is diverting the best grad students to work on the Company X project to the detriment of other unfunded research projects in the Department. Should this issue be addressed in your review?

**QUALIFIED ANSWER:** Not if this Committee is *only* reviewing the impact of the investigator's financial interests on the design, conduct or reporting of the research ("COI in Research"). However, this COI situation should be evaluated through some process or another at the institution.

# COI in Clinical Practice: Speaking for Industry

*From the headlines (1/27/08):*

- **Faculty member and clinical department head earns \$170,000 a year compensation from University**
- **Same faculty member earns \$40,000 a year, along with free dinners and travel expenses, as a speaker for several drug companies**

Should speaking engagements on behalf of drug companies be prohibited or restricted by the University employer?

# COI in Clinical Practice: Speaking for Industry

Arguments for University-imposed prohibition/restriction:

- "If you work for the drug companies, you're not working for the school." --David Rothman, a professor at Columbia U
- Promotion of the product by doc paid to speak is subconscious
- Docs' prescribing practices are influenced by drug promotions vs. evidence-based medicine--study shows that a 3-minute sales pitch from a drug rep resulted in a 52% percent increase in prescriptions for a new drug
- Establishes the wrong "culture" for residents and medical students. Trainees hear elaborate justifications of certain activities and are developing a sense of entitlement about industry benefits. Will these individuals be able to make evidence-based decisions or be industry influenced based on watching their supervisors?
- Physicians are victims of elaborate and well-funded marketing by a big industry; yet, there is a belief on the part of physicians that we are highly ethical and incorruptible.
- Allowing these relationships to exist creates a perception that the University and its physicians are influenced by industry objectives in the care and treatment of patients

# COI in Clinical Practice: Speaking for Industry

Arguments **against** University-imposed prohibition:

- Activity does not interfere with university duties nor compromise professional ethics—the ultimate goal in both instances is to promote better care
- Docs who speak for pharma are simply passionate about promoting treatment for certain disease states (but would not do it if they weren't getting paid)
- The pharma industry itself is drawing the line when it comes to extravagant compensation/gifts
- Docs can screen what companies they decide to promote and only promote drugs they think are reputable and effective
- University can't just set policy that says you can't do something. How would this be enforced? A better approach would be to recognize and disclose the conflicts through appropriate mechanisms and education.

# COI in Clinical Practice: Speaking for Industry

Arguments **against** University-imposed prohibition (con't):

- Academics have a role to play as educators who can attempt to bring balance to the presentation. It would be worse if private physicians were doing speaking engagements.
- Speaking engagements are useful and beneficial for purposes other than marketing, and the marketing aspects are fully disclosed upfront.
- You can teach trainees to recognize that they are being marketed to and to see truth and separate it from propaganda.
- Faculty consider that “their time is their own”. A decision to prohibit freelance work would have to be reached by faculty consensus, not administrative fiat.
- Additional income (if channeled through departments) can help departments fund research/patient care infrastructure.

# COI in Clinical Practice: Other Areas of Industry Interaction

- Gifts and Provision of Meals
- Consulting Relationships
- Drug or Device Samples
- Site Access
- Support of Continuing Education in the Health Sciences
- Industry Sponsored Meetings or Industry Support for Off-Campus Meetings

# COI in Clinical Practice: Other Areas of Industry Interaction

- Industry Support for Scholarships or Fellowships or Other Support of Students, Residents, or Trainees
- Ghostwriting