

# Conflicts of Interest in Research: Ethical, Regulatory, and Practical Considerations

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“What conflict of interest?!  
I work here in my spare time.”

## Interest vs. Conflict

- We all have personal and professional interests.
- Some are financial and some are not (e.g. glory, personal satisfaction, tenure review).
- An interest is not necessarily a conflict.
- A potential conflict is not necessarily an ethical violation.

“Conflicts may be potential or actual, perceived or real, harmful or insignificant.”

*DeAngelis, C.D.  
JAMA. 2000; 284: 2237-8*

## (At least) Three Types of Conflicts

### ■ Investigator, e.g.:

- PI invented the article under study
- PI financially invested in sponsor company or on payroll
- Sponsor rewards PI for meeting study goals

### ■ Institution, e.g.:

- Sponsor is spin-off from University
- University holds stock in sponsor
- University holds patent on article under study



### ■ IRB/IACUC Member, e.g.:

- Member is a co-investigator on proposed study
- Member's spouse is member of study team
- Member's chair is member of study team

## MANAGING CONFLICT OF INTEREST



## AAMC Reports

**2001-** “Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research”

**2002-** “Protecting Subjects, Preserving Trust, Promoting Progress II”

**2008-** “Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI policies in Human Subjects Research”

## AAMC 2008

A) **Covered Individual:** “the principal investigator and any other person who shares responsibility for the design, conduct, or reporting of funded research, and the spouse and dependent children of the investigator and any other person who shares such responsibility.”

B) **Compelling Circumstances:** distinction between high and low-risk research.

C) **Reporting:** eliminate *de minimus* thresholds. (PHS thresholds still ok for defining “significant” financial interest.)

D) **Pre-clinical Research:** consider requiring reporting for these, too.

E) **Disclosure of managed conflicts:** broaden the scope of disclosure both inside and outside the institution.

F) **IRB Members:** require reporting of all financial interests (no *de minimis* threshold) by IRB members as condition of service.

## Three Important Principles

### ■ Identify

- Note: define “covered individuals” and reporting thresholds/categories

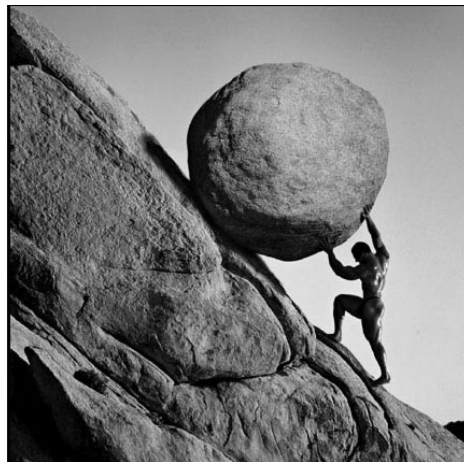
### ■ Understand

- Procedures and criteria for interpreting information about interests

### ■ Manage

- Decisions, plans, disclosure and monitoring

## One Step at a Time...



## Acknowledging I.O. Conflicts

### **Institutional Officials juggle numerous interests:**

- foster research productivity,
- balance numerous institutional interests,
- support IACUC-protect and reinforce its authority,
- enforce high standards for research integrity,
- produce indirects,
- spin off companies/patents/royalties/licenses,
- keep institution off front page of newspaper,
- and, in many cases, run a lab/do research.

## Managing Institutional Conflicts

- Easy to say, but hard to do.
- Some institutions are establishing separate COI committee outside of the institution to manage these.
- As a profession, our thinking on this issue is not very mature yet.

## Managing IRB/IACUC Member Conflicts

- Require a “Member Agreement” to appoint.
- Notify the Chair or the IRB/IACUC office of a COI in advance of a meeting.
- Declare the absence of a COI at the beginning of the meeting.
- Members with a COI must leave the meeting.
- Meeting minutes must record the name of the member with the COI and state they were recused.

## Managing PI/Investigator Conflicts

- Disclosure to subjects, funders, journals, audiences
- Oversight/monitoring
- Independent consent process
- Recusal from studies
- Divestiture of interests
- “Compelling exceptions”?

## Integrity = Do the Right Thing

“Conflict of interest represents the potential for biased judgment, but is not an indicator of the likelihood or certainty that such judgment or compromises will occur.”

*Cohen, J.J.  
Acad. Med 76.2 (2001): 209-14*