Individual Financial Conflict of Interest Policy

College of Engineering Orientation

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“Conflict of interest” is really

“Confluence of Interest”
Why COI?

“Ample research shows that people who have a vested self-interest, even the most honest among us, have difficulty being objective. Worse yet, they fail to recognize their lack of objectivity.”

http://www.nytimes.com/2011/04/21/opinion/21bazerman.html?_r=2&nl=todaysheadlines&emc=tha212

Stumbling Into Bad Behavior
By MAX H. BAZERMAN and ANN E. TENBRUNSEL
Published: April 20, 2011
Purpose of the FCOI Policy

- Reduce the potential for research bias
  - Including unintentional bias
- Protect the public, especially human subjects
- Protect the researcher
- Protect students and subordinates
- Protect the University of Utah
- Enable commercialization of research
Conflicts of Interest Under the Spotlight

- Bayh-Dole Act (1980)
  - Challenge: Find the right balance between academic/scientific integrity and entrepreneurship

- Recent High Profile Cases
  - Congressional attention and scrutiny
  - Negative publicity
  - Potential to undermine public confidence in the research enterprise
University of Utah Conflict of Interest Policy:

- Approved Spring 2012: U Pol 1-006, Revision 11
- Covers all research regardless of funding source
- Defines activities that require disclosure
- Defines activities that are not allowed
- Establishes a process to identify, evaluate and manage individual conflicts of interest

Available at: http://regulations.utah.edu/general/1-006.php
What Constitutes a Financial Conflict of Interest:

• If the discloser has *significant financial or other interest* in a *business entity* that is:
  1. sponsoring the research *or*
  2. whose business is substantially related to the subject of the project:

  - What is the business entity?
  - What is the nature of the financial interest?
  - How does the discloser propose to manage the conflict?
Definition of Significant Financial Interest

“Significant financial or other interest”:
- Equity interest >$5,000 or 5% ownership in a public company
- Any equity interest in a private company
- $5,000 or more income per year from the sponsor or competitor
- DOES NOT INCLUDE
  - salary, royalties or other remuneration from Univ. Utah
  - income from seminars, lectures, teaching engagements, or service on review panels/advisory committees sponsored by public or nonprofit entities
  - income from mutual or pension funds
Activities that require disclosure update (“triggering event”):

- Submission of a new grant or contract to the Office of Sponsored Projects (OSP)
- Submission of a new protocol to IRB
- Request for signature authority on a University account
- Submission of an invention disclosure to TVC
Other COI Information

- Required COI training every 4 years
- Disclosure of related financial interests, stored in the “Business Relationships Reporting” (BRR) database
- Disclosures updated within 3 months of a triggering event
- Possible COI identified by COI Committee rather than investigator
- For all PHS/NIH funded and human subjects research, COIs identified on website.
- Issues limited to PHS/NIH funded research
  - Disclosure of travel
  - Retrospective reviews and mitigation reports for non-compliance
Rebuttable Presumption

- “Rebuttable presumption” against participation of conflicted investigators in human subjects research
  - May be allowed if the Committee finds a “compelling circumstance”
What Does This Mean to Me?

- Must report any and all significant financial interests related to your professional responsibilities at the University of Utah
  - [https://faculty.utah.edu/brr/s/](https://faculty.utah.edu/brr/s/)

- Must update every time you submit a proposal, IRB application, or invention disclosure, unless most recent update was less than 90 days earlier

- If you have any significant financial interests, the COI committee will review your interests and your research projects to determine if there are any conflicts

- If conflicts are found, a management plan will be put in place
Typical COI Concerns

- Protection of human subjects
- Research integrity
- Protection of students and subordinates
- Purchasing authority
- Intellectual property disclosure
Examples of Management Options:

- Disclosure of the conflict in presentations and publications
- Disclosure of conflict to potential human subjects
- Conflicted individual prohibited from enrolling human subjects
- Decision-making by a non-conflicted investigator
- Blinding of data
- Monitoring of the research by a non-conflicted peer, not a member of the research team.
- Individual divests financial interests [rare]
- Prohibit involvement of conflicted individual [rare]
- Conduct research elsewhere [rare*]
Process

OSP, IRB, or TVC

Investigator

Funds

Application

Col Disclosure

Col? (Y/N)
Category I or II?

Col Committee

Approval

Management Plan

http://www.research.utah.edu/integrity/conflict/procedures.html
Conflict of Interest
Committee Members
(contact information at www.research.utah.edu/integrity/conflict/)

- **Sandy Meek** (Mechanical Engineering)
- **Bruce Gale**, Chair (18)
  Mechanical Engineering
- Plus 19 more from other colleges...

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