Research Conflict of Interest

William F. Stenson, MD
What is a Financial Conflict of Interest?

Situations in which financial or other personal considerations may compromise, or may have the appearance of compromising, an investigator’s professional judgment in conducting or reporting research.

Financial Interests that would reasonably appear to be affected by the research and in entities whose financial interest would reasonably appear to be affected by the research.
Conflicts of Interest

Threaten the integrity of our research, teaching, and patient care missions.

Physicians, scientists, and academic institutions with privileged position in society—high expectations.
Conflicts of Interest

**Clinical COI** - A physician takes money (as a consultant, or serving on an advisory board, or for giving lectures) from a company whose products he uses on or prescribes to his patients.

**CME COI** – A faculty member who receives income from a company (as a consultant) or receives research support from a company and gives CME talks that discuss the products of that company.

**Vendor COI** - A University employee receives income from a company and controls University purchasing from that company

**Conflict of Commitment**

**Research COI**
Examples of Financial Interests

- Consulting
- Serving on a Scientific Advisory Board or Board of Directors
- Position/Employment with a Company
- Speaking Fees/Honoraria for lectures (non-CME sponsored lectures)
- Product Evaluation Payments
- Personal Gifts
- Royalties for books
- Equity interests: Stock, Stock Options, Partnership or Ownership interest in the company
- Royalties for inventions
- Any other
WU Annual Financial Disclosure Data - FY10

3,346 Individuals Reporting
4,098 Disclosures Submitted

Reported no financial interests 87% (3555)

Reported >$10,000 or equity/royalties 8% (335)

Reported <$10,000 and no equity/royalties 5% (208)
Jesse Gelsinger and University of Pennsylvania

In 1999, Jesse Gelsinger was an 18 year old who received experimental gene therapy and died.

Both the investigators and the University had undisclosed financial interests in the gene therapy.

The University came under scrutiny and the head of the Gene Therapy Institute stepped down.
External Forces That Care About COI

- Journals
- NIH and other government funding agencies
- Congress
- State governments
- The courts
- The press
Attorney General of New Jersey and Orthopedic Device Manufacturers

As part of a judgment against a series of orthopedic device manufacturers for payoffs to orthopedic surgeons the Attorney General of New Jersey required the companies to post on a web site payments to orthopedic surgeons.
Reporting Industry-physician Payments

States: Massachusetts, Vermont

Companies: Many large pharmaceutical companies (ex. Pfizer)

Institutions: Washington University, Cleveland Clinic, University of Pennsylvania, Stanford, Duke, University of Iowa, Northwestern, University of Miami, University of Virginia
The faculty member has a financial relationship with the company but not with the product being tested.

The faculty member has a financial relationship with the company and the product.
Faculty Member has a Financial Relationship with the Company but not the Product Being Tested

To have a COI you need both:

- A financial relationship with the company advisory board, honoraria for lectures, stock, stock option, licensing income, etc.
- A research project that involves a product of the company.
Resolution of Research Conflicts of Interest Where the Financial Relationship is with the Company Sponsoring the Clinical Research

- Reduce financial interest to < $10,000 or
- Abandon the Research
Faculty Member has Financial Relationship with the Company and with the Product

To have a COI you need both:

- A financial relationship with the product (a patent, licensing income)
- A research project that evaluates the product.
Fundamental Problems

Under the Bayh-Dole Act the investigator has the right to patent intellectual property developed under NIH grants and the University is obligated to help promote the commercialization of the intellectual property.

The University is a not for profit organization and to maintain that status it cannot act like a for profit organization.
How Commercialization of Intellectual Property can Create Conflicts for the University

- Trainees working on commercial projects
- Using University resources to commercialize intellectual property conflicts with the University’s not for profit status.
- Using patients to test the University’s intellectual property may be in conflict with the University’s obligation to treat and protect the patient.
- The non-disclosure aspects of many commercial contracts impact academic freedom.
Non-conflicted Course to Commercialization

Dr. Smith, who studies osteoporosis under NIH funding, develops a new assay for Vitamin D. Dr. Smith and the University patent the assay and license it to a large commercial diagnostics company. Dr. Smith has no further interactions with the company and continues his NIH-funded research on osteoporosis at the University.
Conflicted Course to Commercialization

Dr. Smith forms a company to perfect the assay before licensing it to a large commercial company.

Dr. Smith uses his University lab to perfect the assay.

Dr. Smith is the president of the company and is an owner.

Dr. Smith uses his patients to test the assay.
Assessing Risk

Risk of a COI increases with the magnitude of the personal compensation received or expected (e.g. >$50K)

Risk of COI is inherently greater when an investigator holds equity rather than receiving personal cash compensation from a company. To the extent that the research outcome can influence equity value, and to the extent that the investigator can profit thereby, holding of equity may jeopardize research integrity.
Assessing Risk

- Involvement of trainees in research supported by a company creates risk that academic training will be compromised.
  - Primary goal of training must be to further academic development.

- Use of human subjects in work by an investigator who has a FI with a company creates for the human subjects additional risk for adverse consequences.

- Investigators in positions of leadership in the institution have a greater risk of COI. Adverse consequences are magnified when decisions are made by those with a high level of responsibility.
Federal COI Regulations

The University is responsible for developing and enforcing COI regulations.

Investigators must report any “significant financial interest” to the University.

The University must report to the federal funding agencies the identification of a COI and whether is has been managed, reduced, or eliminated.
New Federal COI Regulations

May include:

- Disclosure of financial interests related to all professional responsibilities (no longer limited to research)
- Expand who is required to disclose
- Mandatory education
- Increase reporting to PHS
- Post financial interest information on a public website
Research COI Policies

School of Medicine Disclosure Review Committee implements the policy

- Independent Faculty Committee
- Comprised of one senior faculty member from each department
Review Process

- 4000 annual disclosures submitted through the on-line system
  - 350 annual disclosures are administratively reviewed, with 200 of those disclosures sent to the DRC Chair/Committee
- 400 “transactional” reviews conducted annually
- Reviewed on a case-by-case basis
  - DRC identified 110 annual disclosures with a research conflict of interest

Based on Fiscal Year 2010 data
Disclosure

Individuals are required to disclose any financial relationship with a company or organization whose activities could possibly relate to the individual’s research, patent, or licensing activities, regardless of the value of the financial relationship.
Who

All faculty are required to complete a Financial Disclosure Statement.

Any individuals engaged in the design, conduct, or reporting of research at WU (we use the term key personnel at WU).
Significant Financial Interest ("review threshold")

Financial relationships greater than $10,000 in value, represents greater than 5% ownership interest in a publically traded company, or (regardless of value) any other ownership interest or licensing revenue/royalty income.
Positive Disclosures

If disclosure meets the “review threshold”, then it is prepared for the DRC Chair’s review.

Information is gathered regarding the financial interests and research projects in which the individual is involved.

The DRC may ask for:
- Research abstracts or proposals
- Protocol applications
- Licensing agreements
- Invention disclosures
- Consulting agreements
DRC Chair Review

Will review and evaluate each FDS to determine if there is a potential financial conflicts of interest

- Determine whether it needs further review by the Committee

Assesses the materiality of the potential conflict of interest and its potential impact on the objectivity of the research project, student academic programs, and the safety of human subjects.
Potential COI is Identified

Management strategies are determined and communicated to the individual, and Department Chair as necessary.

Notifications are sent to the appropriate research administration offices regarding the management of an individual conflict of interest, such as the Human Research Protection Office, the grants and contracts administrative offices, and the Office of Technology Management.

When applicable, the sponsor is also notified.
Management Plans (may include)

- disclosure of the financial interest
  - in publications and talks;
  - to students involved in the research and to the relevant thesis advisory committees;
  - to research participants;
- require non-tradable equity is not exercised without prior approval from the DRC;
- minimize an individual's role in the design, conduct, and reporting of the research;
- provide oversight of the research by a non-conflicted faculty member or committee;
- divestiture of the financial relationship;
- removal of the individual’s influence over the design, conduct, and reporting of the research
Clinical Research COI Policy

The DRC reviews and considers all requests for exceptions - "compelling circumstances"

If "compelling circumstances" are present, the DRC, Vice Chancellor for Research, and Executive Vice Chancellor for Medical Affairs and Dean must be in agreement to grant an exception
Compelling Circumstances

- Nature of the research
- Magnitude of the interest or the degree to which it is related to the research
- Extent to which the interest could appear to affect the integrity of the research
- Degree of risk to the human subjects involved that is inherent in the research
Contact Information

Jeneane Braden
Phone # 747.4152; E-Mail: bradenj@wustl.edu

Sharon Hahn
Phone # 747.2904; E-Mail: sharon.hahn@wustl.edu

Denean Marie
Phone# 362.1111; Email: mariede@wusm.wustl.edu

Policy, Forms, and Committee information can be found at: http://medcoi.wustl.edu