How do Conflicts of Interest Affect You?

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What is a “Conflict of Interest”

A conflict of interest is present when an actual or potential personal or institutional financial benefit threatens the objectivity of the design, conduct, analysis, or reporting of research or program results. Expectation of unbiased results reporting.
Types of Conflict

♦ Intellectual Bias
  – Pet theories, personal preference

♦ Conflict of Financial Interest
  – You (or a spouse or relative) benefit financially from a relationship which may lead to bias in research

♦ Conflict of Commitment
  – Affects ability to perform primary duties (to employer/program)

♦ Institutional Conflict
What is Significant Financial Interest?

- Any monetary value including, but not limited to, the following:
  - Salary or other payments for service (e.g. consulting fees or honoraria) (NIH threshold $\geq 10K in aggregate per annum)
  - Equity interests (e.g. stocks, options) (NIH $\geq 10K in aggregate or 5% equity)
  - Intellectual Property Rights (e.g. patents, copyrights and royalties from such)
  - From PHS 42CFR Part 50
Why do We Care?

- Individual Conflicts lead to credibility concerns
- Institutional Conflicts can lead to degradation of institutional reputation, loss of public trust
- Can lead to physical/monetary/psychological harm to research subjects, employees, students or trainees
- Can lead to additional regulatory oversight resulting in greater scrutiny, expanded programmatic requirements and greater institutional investment
Typical Scenarios for Conflict...

- Consulting for a research sponsor
- Owning equity in a research sponsor
- Getting royalties from a research sponsor (usually IP license)
- Speakers Bureau
Consulting with Research Sponsor

- Can create perception of bias
- Can involve/impact patient interaction
- Data analysis
- Publication of results
Equity in Research Sponsor

- Greater than perception – can be actual
- Can involve patient care
- Data analysis
- Publications
- Similar opportunities for bias with royalties
Conduct Research on Mentor’s IP

Can Create:

- Pressure from Mentor
- Perception that results could be biased
- Negative reports on your performance
The purpose of conflict management

To protect
- The integrity of research
- The individual/students/post docs
- The research participant
- The Institution

Goal
When possible, remove conflicted person from the decision making process which would allow him to act on his bias
Management of Conflicts

3 Most Important Actions for Management of COI:
Disclosure, Disclosure, Disclosure!
(Stanford/Cleveland Clinic – new disclosure policies)

Disclose to:
- Study Participants/IRB
- Co-investigators and Collaborators, including trainees/students
- Research Sponsors
- Research Office/Tech Transfer Office/Institution
- Journal Editors → readers and other users of research results
Who Needs to Disclose?

- Investigator = principal investigator/program director and any other person who is responsible for the design, conduct, analysis or reporting of research.
- Not just PI, it can be anyone (key personnel, Lab tech) who is involved in the design, conduct, or reporting of sponsored research.
- Term also includes investigator’s spouse and dependent children.
What is Disclosed?

- Any payments – received or planned (consulting)
- Any equity interests
- Any executive position (fiduciary responsibility)
- Any proprietary interest in the study agent (FDA)
- Investigator’s personal financial interests include those of spouse or domestic partner, children, parents, siblings, etc. (including “step”, “half” and “in-law” etc).
Management of Conflicts

- Public disclosure of financial interests
- Monitoring by independent reviewers (Dean/Chair/Oversight Committee)
- Consenting done by someone with no conflict
- Removing cause of conflict:
  - Sell ownership interest/place holdings in escrow
  - Resign office or board position
  - Reduce or eliminate compensation/fees
  - Modification of research plan
Benefit of a Management Plan

- Increases subject safety by providing information at time of consenting so subject can give true informed consent
- Increases study integrity
- Addresses current and future questions related to potential and/or actual COI
- Assists researcher in meeting federal reporting requirements
- Protects reputation of researcher and institution
Federal COI reporting Requirement

- At time of application: investigator submit significant financial interest to institution
- Prior to expenditure of funds: institution reports any financial COI to NIH & assures management, reduction or elimination of conflict
- Financial COIs identified after initial report must be reported within 60 days of identification & be managed, reduced or eliminated
Take Home Messages…

◊ Not every reportable financial interest represents a conflict of interest

◊ Conflicts come in small, medium, and large sizes, as do management strategies

◊ Conflicts are not just about personal ethics

◊ When in doubt ask for advice before making commitments.

◊ For students: If you feel the integrity of the project has been compromised, contact your advisor
General examples of allowable activity:

- University employee receiving royalties from the publication of books or the licensure of patented inventions (subject to univ. policy)
- University employee having equity in a corporation whose sole purpose is to accommodate the employee’s external consulting
- Nominal compensation (honoraria or expense reimbursement) for service to professional associations, review panels, presentations of scholarly work, or participation in accreditation
Small conflicts (usually disclosure is enough):

- Researcher conducts research sponsored by a large, publicly traded company in which he owns shares (other than product evaluation)
- Researcher conducts Federal or Foundation-sponsored BASIC research on a University invention that has been licensed to a company for which he consults and receives a share of University royalties
Small conflicts (usually disclosure is enough) continued....

- Researcher consults in the area of her professional expertise for a company that also makes an unrestricted gift to support research in her department.

- A staff member is responsible for the purchases from several potential suppliers, one of which employs his sister.
Activities generally requiring review and management:

- Researcher conducts Federal or sponsored research on a product developed by a company for which he is a consultant.

- Researcher conducts clinical research on a product developed by her and licensed to an external organization in which she owns equity or has other direct relationship (consulting).
Activities generally requiring review & management (continued):

- Researcher who is a member of a company’s Scientific Advisory Board conducts research sponsored by that company.
- An employee manages a design and construction project involving an architectural firm in which his spouse is a partner, when the university employee did not participate in the selection of the company.
- University employee requiring students to purchase textbook or other materials for which the employee or a family member would receive compensation.
Conflicts often not allowable:

• Researcher uses his laboratory, ESPECIALLY Students, to do product testing for a company which he has founded and maintains a substantial equity interest

• A clinician makes patient referrals to a diagnostic company in which he or his immediate family has a significant ownership interest
Conflicts often not allowable (cont):

- An employee directs the purchase of supplies for the university towards a business in which he or his immediate family has a significant ownership interest (absolute ban for NJ).
- Faculty member assigning students, post-docs to research projects sponsored by a company in which the faculty member or his immediate family has an ownership interest.
COI Resources

- Institutional policies –
  [http://www.umdnj.edu/oppmweb/Policies/HTML/AcademicAff/00-01-20-89_00.html](http://www.umdnj.edu/oppmweb/Policies/HTML/AcademicAff/00-01-20-89_00.html)

- 42 CFR Part 50, Subpart F –

- AAMC Website–
  [http://www.aamc.org/research/coi/start.htm](http://www.aamc.org/research/coi/start.htm)

- NJ Law – NJSA 52:13D-19.1
More Commercial Influence on Trials Today

- R&D Investments by Pharma companies increased from $1.3B in 1977 to $32B in 2002 (a 24 fold increase in 25 years)
- PhRMA companies alone spent more on pharmaceutical R&D than the total 2002 NIH operating budget of $24B
- The number of private practice physicians involved in drug studies increased by 60% over a 5 year span
- Conversely, the proportion of trials conducted in academic medical centers dropped from 80% to 40% over the same time period
- From Responsible Conduct of Research -- COI
Conflict Can Affect Public Health

• “A New Low in Drug Research: 21 Fabricated Studies” – WSJ, March 11, 2009

• “Doctor Accused of Faking Studies” – The Boston Globe, March 11, 2009
  – Dr. Scott Reuben, Baystate Medical Center in Springfield, Mass
  – Accused of falsifying 21 publications related to pain management
  – Pfizer funded 5 research grants b/n 2002-07
  – Member of Pfizer’s Speakers Bureau
  – Conflict lead to falsification?
Conflict Can Affect Public Health

• “Drug Maker is Accused of Fraud” – The NY Times, Feb 26, 2009

• “Another Drug Company Accused of Hiding Negative Study Results” – WSJ, Feb 26, 2009
  – Forest Labs accused of hiding negative data regarding efficacy and AE’s of antidepressants, Celexa, in children from physicians (off-label prescriptions to pediatrics)
  – Accusations that Forest paid kickbacks to physicians that prescribed the drugs (sporting event tickets, restaurants, paid vacations)
  – Accusations that some trials were really marketing efforts to promote drug’s use by doctors