Conflicts of Interest

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Overview

- What is a COI?
- Why should we care about COI’s?
- The regulatory framework
- Evaluating and managing COI’s
- Best practices
Definition: COI in research

- A situation that occurs when an investigator’s private interests may compromise or have the appearance of compromising his or her professional judgment.
Types of COI

- Personal
- Professional
- Time
- Financial
How did we get here? Academic and industry collaborations

- Pre-1980
  - Federal gov’t retained rights to research
  - No tech transfer to industry
- Bayh Dole Act (1980)
  - Fund recipient has right to research
  - Recipient duty to transfer technology
- Dramatic increase in industry collaboration
Scope of industry collaboration

- 25% life science faculty members receive industry research funding
- 80% life science companies retain faculty as consultants
- Licenses of University research resulted in formation of 4,543 new companies since 1980

*FASEB Conflict of Interest Report (7/14/06)
Impact of collaboration

- **Benefits**
  - Translation of basic science findings
  - Improved flow of knowledge
  - Greater access to resources for research

- **Risks**
  - Concerns regarding objectivity
  - Erosion of public confidence
  - Perception public funds used for private purposes
Evidence of Risk

- **NSAIDs**
  - All 56 trials, manufacturer-associated
  - 100% = superior or comparable to comparison drug
  - 86% = safer than comparison drug
    - Re. toxicity, only 12 of 22 trials provided justification for finding manufacturer’s drug as less toxic → claims of superiority in side effects are often not supported by trial data

- **Second hand smoke**
  - Industry affiliated authors 94% pro-industry
  - Non-industry affiliated authors 13% pro-industry

- **Beverage studies (soft drinks, juice, milk)**
  - If funded by industry, 4-8X more likely to be favorable to industry
  - In industry-sponsored interventional studies, no negative findings reported
The Outcome

- Federal Regulations
- State Regulations
- Organizational Guidelines
- Institutional Policies
Federal Regulations

“Significant Financial Interest”

- Compensation exceeding $10,000 in one year period
- Equity interest exceeding $10,000 in value or 5% ownership interest
- Same interests held by spouse/dependent child
- Not salary from institution or payments from nonprofit/public entities
- Not mutual funds
Federal regs, cont’d

- Institutional Responsibilities
  - Maintain and disseminate COI policy
  - Review disclosures
  - Determine if conflict exists
  - Manage, reduce, or eliminate conflicts
  - Report conflicts to funding agency before expenditure of funds
State Regulations

- Vary by state

- May be more restrictive than federal regs
Journal Policies -- JAMA

- Results of study of relapse by pregnant women who discontinued antidepressant medication published in JAMA
- Authors failed to disclose ties to industry
- JAMA issued correction, revised COI policy
- Must disclose any financial ties regarding subject of article
2. Financial Disclosure and Funding Support. Please check the appropriate box(es) below (applies to the past 5 years and foreseeable future):

- I have no conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript.

or

- I certify that all my conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (e.g., employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are disclosed in the Acknowledgment section of the manuscript.
Common Financial Interests

- Consulting
- Honoraria
- Travel reimbursements
- Board positions
- Equity interests
- Patents & licensing arrangements
Start-Ups

- Increasing prevalence of researcher start-ups
- Issues to be considered
  - Conflict of interest
  - Conflict of commitment
  - Use of institutional facilities
  - Use of institutional personnel
  - Involvement of students
  - Financial support of research
  - Intellectual property ownership
COI Management Strategies

- Public disclosure
  - Departments
  - Sponsors
  - Students/research personnel
  - Publications
  - Conferences
  - Research subjects
"Under disclosure rules, I'm required to tell you I own stock in the company whose drug I'm prescribing."
Management Strategies, cont’d

- Independent monitoring
- Modification of research plan
- Disqualification from participation in research
- Divestiture of financial interest
- Severance of conflicting relationship
UCD COI Committee

- Appointed to evaluate investigator disclosures
- Determine if potential conflict exists
- Decide whether conflict should be managed, reduced or eliminated
- Recommend course of action to responsible official
Special COI issues in human subjects research

- AAMC guidelines
  - Rebuttable presumption against conducting human subject research while holding a significant financial interest
    - Amount tracks federal regulations
  - Compelling circumstances provide exception
  - Rigorous, effective, disinterested monitoring
COI/IRB Interaction

- IRB’s role is to evaluate risks of protocol and ensure the safety and welfare of subjects
- Notify IRB of all potential conflicts involving human subjects
  - Not just clinical research
Factors to consider

- Clinical trial?
- Phase of trial?
- Invasive vs. noninvasive?
- How many sites?
- How many subjects?
Factors to consider, cont’d

- Role of investigator
  - Design study?
  - Solicit consent?
  - Treat subjects?
  - Evaluate data?
  - Report adverse events?

- Independent data oversight
Human Subjects: Handling Conflicts of Interest

- Disallow
- Manage
  - Disclosure in consent
  - Limit role of investigator
    - No subject consent
    - No treatment
    - No data analysis
    - No reporting of adverse events
Human Subjects: Handling COI’s, cont’d

- Oversight
  - IRB
  - Data Monitoring Safety Board
- Reduction/divestment of financial interest
Best practices

- Thoroughly review your financial interests
- Consider the headlines
- Disclose, disclose, disclose
- Be proactive about management strategies
- Err on the side of disclosure with journals
Best practices, cont’d

- Scrutinize confidentiality/consulting agreements
- Limit management role in start-ups
- Exercise extreme caution when involved in research with human subjects
- Remember you owe your time and loyalty to your institution
- Talk about conflict of interest issues
Updates – Other Institutions

- Harvard Medical School (July 2010)
  - Faculty cannot accept gifts, travel or meals from industry
  - Maximum of $10,000 can be paid to faculty member by company whose product/invention is under study (previously $20k)
  - Corporate support for postgraduate classes only if it comes from at least 2 corporations
  - Faculty cannot give company speakers bureaus (company-produced slides to talk to other doctors about medications)

- Stanford
Updates – Proposed Changes

- NIH may require posting any significant financial interest on a publicly accessible website
- $5,000 minimum threshold (instead of $10,000)
Questions?

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