Conflicts of Interest
Learning Objectives

• This module will help you to:
  – Understand the background of COI
  – Define various types of conflicts of interest
  – Describe general best practices
  – Provide specific case examples for learning
Conflicts for a scientist/engineer

• Conflict
  – Interest
  – Effort/commitment
  – Conscience
  – Interpersonal
Why conflict of interest

- COI may arise due to personalities as well as the environment the personalities are placed in
- Job pressures
  - Universities looking for revenue streams
  - Industry looking for lower costs
- Personal
  - Desire to be rich/ famous/ liked/…
  - Family/societal pressures
  - Extremes of
    - Eccentric scientist
    - Greedy entrepreneur
- Need for secrecy
- Organizational/personal expectations
- Personal beliefs/job function
Conflict of Interest: Definition

A conflict of interest is when one’s actual or imputed interest compromises or appears to compromise one’s ability to impartially perform one’s duty.*

“Gain considerations impair objective decision making”

The Real Issues

• Maintaining INTEGRITY in research, education, and service
  – Remove bias in performance of duties
• Fulfilling RESPONSIBILITIES to “authorities”, to oneself
  – Place obligations above personal profit
• Preventing loss of TRUST
  – Maintain the sanctity of the office, irrespective of who holds it
COI: Industrial Perspective

Each organization acts through its agents and employees. To fulfill the mission, it depends on individuals to adhere to the mission and existing policies. Moreover, each individual will have varying degrees of discretion. They have to judge which actions to adopt or reject. With more discretion, the need for more clarification of mission and goals and policies.

A conflict of interest arises when these outside interests begin to intrude (or appear to intrude) on the associate’s judgment about how to perform the job and how to conform to the mission of the institution.

A potential conflict exists whenever

(1) an employee or an employee’s close friends, relatives, or associates has a strong personal life interest,

(2) the employee is involved in decision making on behalf of the organization

(3) the employee’s interest may cause (or may be perceived as causing) the employee to exercise his or her organizational decision-making power to further personal interest rather than the organization’s mission

(4) to the detriment of the organization.

Are stakes in the company (employee shareholders) conflict of interest?
COI: Scientific/University Perspective

• Additional burdens and specific focus of COI
  – “For a scientist, integrity embodies above all the individual’s commitment to intellectual honesty and personal responsibility…” - Integrity in Scientific Research, National Academy of Sciences

• Major issue of public trust: The public expects University research to be objective and unbiased
  – May be funded by public
  – Implications for public
Types of COI

- Personal
- Financial
- Scientific
- Judicial
- Commitment
Personal conflict of interest

- A significant other conducting business with the organization.
- Usurping an organizational opportunity: where person obtains for individual benefit an opportunity that should belong to the organization.
- Competing with the organization, by having an independent business.
- Using the organization to advance a related activity or career of an individual
- *Discussion: Can you hire a relative?*
Financial Conflict of Interest

• Most frequently considered type of COI
• Most likely to be perceived by the public
  – Headline test
  – Objectively measurable
  – Regulation and Statute
    • Arbitrary boundaries
• Emphasis: Using position for personal financial gain
Financial Conflict of Interest

• Potential for bias in experimental results based on financial gains from:
  – Grants and contracts
  – Consulting
  – Advisory boards membership
  – Speaker’s bureaus
  – Patent/Royalty arrangements
  – Expensive gifts/trips
  – Ownership of company stock

• Discussion: what about potential future gains?
Suppose nobody gains or profits?

- Science depends on trust that data is unbiased
- Success of public policy decisions depends on unbiased data
- APPEARANCE of COI is as destructive of confidence as actual gain or profit
Financial COI: Gifts

- Generally an employee may not accept gifts that are given because of their positions or that come from certain prohibited sources (person/organization that conducts business with the agency, conducts activities regulated by the agency, or has interests that can be affected by the employee).

- Gifts with vendors
  - Typical policy: An employee can accept a gift valued at $20 or less from an entity does business with, provided the total value of gifts from the same person/organization is not more than $50 in a calendar year.

- Gifts from subordinates
  - Typical policy: Gifts can be provided to supervisors if they are valued at no more than $10.

- Hiring controversies in IL: relatives of gift-givers hired
Scientific Conflicts of Interest

• Scientific
  – Unfairly inhibiting competitors’ manuscripts or proposals
  – Unfairly implementing experimental techniques gained from competitors’ manuscripts or proposals
  – Unfairly promoting friends’ manuscripts or proposals

• Discussion: who should serve on review panels?
Judicial/Legislative Conflicts of Interest

- Potential for bias or appearance of bias when:
  - Testifying before legislative committees that appropriate funds for research
  - Testifying before legislative committees that will influence public policy
  - Engaging in paid expert testimony
  - Serving on advisory board of executive agencies

- Discussion: do “experts” have inherent COI?
COI in Publications

• Usually financial
• But may be other industry links
• Conflicts affect conclusions
• Rates of disclosure are low
• Many journals do not have a policy
• Effect on readers unclear
  – Do you read/are concerned?
  – Does disclosure automatically invalidate study?
• Better journals ask for disclaimers
  – Is voluntary disclaimer a good idea?
• Discussion: do reviewers have an inherent COI?
Authors and COI: Biomedical Sciences

- 3642 articles in the five leading general medical journals (Annals of Internal Medicine, BMJ, Lancet, JAMA, New England Journal of Medicine)
  - Only 52 (1.4%) declared authors' conflicts of interest
- Half of authors have received “research related gifts”
- A quarter of US researchers have received pharmaceutical funding
- Analysis of 789 articles from major medical journals**
  - 1 in 3 lead authors had financial interests in their research—patents, shares, or payments for being on advisory boards or as a director

Conflicts of Interest

• Ethical challenge: be cognizant of outside influences and personal biases and disclose, disclose, disclose
Really?

• It should be noted that the appearance of a conflict of interest can be as damaging as the existence of an actual conflict.
One Statement of Ethical Standard

• Avoid “any circumstance which could cast doubt or even the appearance of doubt upon [a faculty or staff member’s] ability to act with total objectivity with regard to the University’s Interests” -- Columbia U.

• “Appearance” is crucial!
Steps to mitigate the ill-effects of COI

• Disclosure: individual
• Recusal
• Communication (organization) and independent opinion (individual)
• Regulatory policies: organization
Disclosure

• Disclosure of potential conflict of interest is almost always recommended as the first step in any organization’s effort to lessen conflict.

• Disclosure at the outset avoids the perception of dishonesty that arises if the conflict is discovered later in the relationship, and suspicions that it may have been hidden for a reason.

• To be effective, a disclosure policy needs to (1) clearly identify the types of relationship or interest that may constitute a conflict of interest; (2) require ongoing disclosure (annually); and (3) make the disclosure public to involved decision makers.
Recusal

• At times, conflict is not ongoing but rather arises in connection with a particular decision to be made by an organization.

• If an officer believes his decision may be influenced, he can excuse himself by withdrawing from participating in that particular decision.
  – This if often particularly appropriate for a board member.
Organizational Policies

• Clearly define what constitutes a conflict of interest.
• Establish a means of identifying conflict of interest.
• Develop a means of addressing conflict of interest so as to reduce potential harm.
• Institute a policy that a board member, officer, or employee must be recused or removed from the operating functions of the institution when a conflict exists that cannot be addressed by disclosure or mitigated by institutional features.
When are these policies applied?

- Financial COI: Thresholds offer easy solution
  - $10,000 most common
  - Federal standard
  - 5% equity
    - 3%, 10%
  - Zero Tolerance
    - $0, 0% in some cases
    - E.g., if human subjects involved
    - Administrative nightmare if too broad!

- KNOW your thresholds
What do I do if COI is reported?

• Identify what COI rules apply
  – Given situation might differ under different institutions’ policies
• Determine if absolute or relative prohibition
• Guide actors through policy/regulation steps
  – Investigators
  – Institutional Officials
Jesse Gelsinger Case

• 1999 University of Pennsylvania study, genetic therapy for liver disorders

• Jesse was a 16-year old with chronic OTC, a condition that normally kills its victims within a few weeks of birth.

• Jesse’s OTC was under control, but he “wanted to help the babies.”

• Jesse had a severe reaction, went into a coma, and died before his parents could reach him.
Gelsinger COI

- Adverse events not disclosed or reviewed in informed consent process
- Protocol not as approved
- PI had 10% stake in Genovo, the company sponsoring the trials
- University fined over $1M
- Researcher debarred for 10 years
- Settlement of civil suit estimated at $7-10M
Mitigation and Management
What you can do

• Public disclosure
• Monitoring by independent reviewers
• Modification of research plan
• Disqualification of individual all/part of research
• Divestiture of conflicting financial interest
• Severance of conflicting relationship
Institutional Responsibilities

*Federal regulations*

- Maintain written, enforced policy
- Designate reviewer of disclosure statements
- Establish mechanism for enforcement
- Provide for sanctions
- Provide guidelines to identify conflicting interests
Institutional Responsibilities II

- Take action to ensure conflicting interests are managed, reduced or eliminated
- **Maintain records** of disclosures and actions
- Certify compliance on each proposal
- Require updated disclosures
- Notify Sponsor, typically
  - Existence (but not nature) of COI
  - Assure COI is managed, reduced, eliminated
- Same processes for COI reported later
Reporting and Record Keeping

• If not responsible, notify/guide responsible person
• Help individuals meet reporting requirements
  – Set automatic reminders
  – Simplify forms
  – Can electronic response serve?
• Records may or may not best be kept with project
Closing Thoughts

• It’s not necessarily wrong to have a COI; it IS wrong not to disclose it and/or not to properly manage it.
• Doing the right things means resting assured that you are on safe ground.
• When in doubt, ask.
COI has degrees

• COI is situational
  – Nature of Conflict
  – Nature of Interest

• Cultures vary
  – Among Institutions
  – Among Disciplines, Schools
  – Management practices vary

• Committee will establish Institution’s cultural norm
Management Strategies

- Public disclosure of interests
- Monitor research by independent reviewers
- Modify research plan
- Limit participation in research
- Divest financial interests
- Sever relationships
- Other
“It is necessary for us to learn from others’ mistakes. You will not live long enough to make them all yourself.”

--Admiral Hyman G. Rickover
Case Studies

• Can a professor/T.A. the teacher accept gifts from students in their class?
• Can a person supervise the research of one with whom they are romantically linked? Other family?
• Can you hire your child as a summer intern?