

Building a Conflict of Interest Program

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Program Overview

- What is a conflict of interest?
- Why have conflict of interest policies: basis in law ?
- How do we manage conflicts of interests?
- Conflict in human research/clinical trials/hospital Settings

Acknowledgments & Additional Resources

- Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the implementation of COI Policies in Human Subjects Research, AAMC-AAU (February 2008)
- The Scientific Basis of Influence and Reciprocity: A Symposium, AAMC (June 12, 2007)
- Approaches to Developing and Institutional Conflict of Interest Policy, Council on Governmental Relations (COGR) http://www.cogr.edu/files/publications_Conflicts.cfm
- Recognizing and Managing Personal Financial Conflicts of Interest, Council on Governmental Relations (COGR), http://www.cogr.edu/files/publications_Conflicts.cfm
- Ehringhouse, et. al., Response of Medical Schools to Institutional Conflict of Interest, JAMA, (February 13, 2008, p. 665)
- Working Paper On Conflict Of Interest, American Council On Education (January 2008)
- Daniel L. Kurtz and Sarah E. Paul, Managing Conflicts of Interest: A Primer for Nonprofit Boards (Board Source 2d ed. 2006).
- Alexander E. Dreier and Martin Michaelson, A Guide to Updating the Board's Conflict of Interest Policy (Association of Governing Boards of Colleges and Universities 2006)
- Sample Conflict of Interest Policy. Internal Revenue Service, <http://www.irs.gov/instructions/i1023/ar03.html>
- College Code of Conduct. New York State Attorney General, <http://www.oag.state.ny.us/press/2007/apr/College%20Code%20of%20Conduct.pdf>

What is an individual conflict of interest?

A potential conflict of interest occurs when there is the possibility, from the perspective of an independent observer, that an individual's private interests, or his or her family's interests, may influence the individual's professional actions, decisions, or their judgment.

In what areas may individual conflicts of interest occur?

- Contracts and procurement;
- Gifts;
- Research;
- Hiring and employment;
- Using knowledge or information obtained through position for personal gain;
- Commitment of time and effort;
- Other competing material interests (financial and personal).

What is an institutional conflict of interest?

A potential institutional conflict of interest may be deemed to exist where the relationship between the University and an external entity compromises (or appears to compromise) the integrity of institutional decision making.

In what areas may institutional conflicts of interest occur?

- Equity Interests/Technology Licenses:
 - University has an equity interest in a company that sponsors research or clinical trial (e.g. Univ. of Penn Med Center death in clinical trial; Wall Street Journal Articles on Cleveland Clinic and Johns Hopkins)
 - University has technology licensing agreement with company sponsoring research or clinical trial.

In what areas may institutional conflicts of interest occur?

- Gifts: Where there is also an academic, research, business or financial relationship
 - Example 1: corporate sponsor of research or clinical trial also gives a gift
 - Example 2: company doing business with University also gives a gift (e.g. student loans).
 - Example 3: person who gives gift affects academic decision making (e.g. Hunter College course on counterfeiting products)

In what areas may institutional conflicts of interest occur?

- Procurement: Where University has a business relationship with company providing goods or services to the University or University Community
 - (e.g. study abroad; affinity cards)

Why have conflict of interest policies?

- Help assure the integrity and objectivity of the institution's decision making process.
- Protect institutional funds:
 - Proper stewardship
 - Limit imposition of damages & fines.
- Protect the institution's reputation:
 - Increased media attention
 - Increased regulatory and governmental scrutiny.

Challenge in managing conflicts of interest.

- No one uniform or comprehensive source of legal guidance.
- Where law and ethics meet (conflict of interest may be legal but perceived as unethical).
- Embraces a wide range of activities at an institution (e.g. research, purchasing, grants and development, human resources).
- Issues tend to arise in personal and complex factual contexts.

Legal and regulatory background

- Federal Tax regulations for not-for profits (*See* new form 990).
- State Law requirements for public institutions and not-for-profits (*See* NY Charities Laws and filing requirements).
- Common law fiduciary duty requirements.
- Deceptive practice statutes (*See, e.g.,* Attorney General enforcement actions re: student lending and study abroad programs).
- FDA and HHS regulations.

Managing Conflicts of Interest

- Most conflicts of interest are not *per se* illegal. Rather conflicts of interest generally require:
 - Disclosure, and
 - Management.

Managing Conflicts of Interest – Policies

- Because of the legal and factual complexity of conflicts of interest in higher education, you frequently find that several different policies are needed:
 - Governing board policies;
 - Officer and employee policies;
 - Faculty and Research policies, and
 - Institutional policies

Elements of a Standard Conflict of Interest Policy

- *Definitions and/or examples* of conflicts of interest to help the community recognize potential conflicts of interest.
- Regular, *periodic disclosure* of financial interests by trustees, officers, key employees, and researchers.
- *Ad hoc disclosure* when potential conflicts of interest arise.
- *Cognizant individual*, office or committee designated to receive and review disclosures and to answer questions about the policies and their application.
- *Procedures* to address and manage disclosed potential conflicts of interest.
- *Note:* There is no one “best” policy format. College and University Policies are readily available on the Web. You should tailor your institution's policies to your particular needs.
- *Sample Handouts:*

Conflict of Interest Programs & Research Oversight

Types of research-related conflicts of interest

- Individual
 - Financial and/or time conflicts of PI, study personnel, IRB/IACUC members
- Inventor
 - Technology transfer, revenue sharing
- Institutional
 - Interests held by the institution or officials of the institution

Data integrity

- Issues of conflicting potential interests impact on data and data analysis
- Publication requirements

Ethical principles in research

- Respect for persons
 - Autonomous agents
 - Protection for those with diminished capabilities
- Beneficence
 - Do no harm
 - Maximize benefits & minimize harm
- Justice
 - Distribution of research burdens & benefits

Respect for persons

- Autonomous agent
 - Capable of deliberation & acting on that deliberation
- Requires that individuals enter into research voluntarily & with adequate information
 - Adequate information should include information about conflicts of interest

Regulatory requirements & guidance

- Federal law
- State law
- Boards of regents policies
- Other guidance

Federal regulations & guidance

- 42 CFR part 50 / Public Health Service
- 21 CFR part 54 / Food & Drug Administration
- OIG findings & recommendations to NIH
 - NIH response

State regulations

- KSA 46-247 through 252 (Kansas)
- OCGA 45-10-20 (Georgia)
- MCL 15 Act 317 (Michigan)
- Political Reform Act of 1974 (California)

Boards of regents policies

- Kansas Board of Regents
- South Dakota Board of Regents
- Colorado Board of Regents

Other Guidance

- American Council on Education
- Association of American Universities
- Association of Academic Medical Centers
- Association for the Accreditation of Human Research Protection Programs
- Department of Health & Human Services

COI requirements

- Institutional official
- Written policies & procedures
 - Conflicts of interest
 - Conflicts of time
- Annual & ad hoc reporting
- Mitigation / management

Management of conflicts

- Disclosure
- Removal: divestiture of financial interest
- Third-party evaluation: independent monitoring
- Recusal: disqualification from participation in some or all of the research activities
- Modification of research plan

COI committees

- Composition
 - Areas of representation / expertise
- Reviews
 - Full committee / chair reviews
 - Process considerations
- Relationships with other committees
 - IRB, IACUC, DSMB, ESCRO

Cases

- Jesse Gelsinger
- Jarvik-7