

NCURA Pre-Award Research Administration III Conference

Conflict of Interest Issues in Sponsored Research

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(green and white)

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Conflict of Interest in Sponsored Research

☞ *Conflict of Interest*

- ✓ *A situation in which an individual in a position of trust has competing professional and/or personal that makes it difficult for the individual to fulfill his/her duties impartially*
- ✓ *May create an appearance of impropriety that can undermine confidence in the individual's judgment*
- ✓ *Conflict may be managed in various ways but the appearance/conflict still exist*

Conflict of Interest in Sponsored Research

- ☞ Perspectives (regulatory ... priority but not sufficient)
 - ✓ More diverse perspectives in comparison with other regulatory settings
- ☞ Origin of Conflicts
 - ✓ All based on individual interests, but the role of the individual affects the context
 - ◆ Technical vs. Business/Administrative
 - ◆ Project vs. Institutional Leaders
- ☞ Types of Conflicts
 - ✓ **Financial**
 - ✓ Other ("non-financial")
 - ◆ e.g., Tenure and Promotion, Reputation - there are established procedures for dealing with these potential conflicts
 - ◆ See NEJM, Sep. 5, '02, v347 (10): 759-761.
 - ✓ Commitment
 - ✓ Organizational
 - ✓ Institutional

Focus of Presentation

- ☞ Primary
 - ✓ Individual financial Conflict of Interest (fCOI)
- ☞ Secondary
 - ✓ Institutional financial Conflict of Interest
 - ✓ Conflict of Commitment

Terminology Approaches

☞ Disclosing fCOI

- ✓ Disadvantages –
 - ◆ Negative Assumptions by Faculty/Key Personnel
 - ◆ Faculty/Key Personnel make individual assessments and only disclose those that they determine there is a potential conflict
- ✓ An Engaged University and individuals should have Potential fCOIs
- ✓ Certain fCOI are Beneficial
 - ◆ Support for a Research Project (including Salary support)

☞ Disclosing Multiple Relationships

- ✓ Advantages –
 - ◆ Maintaining multiple relationships often is beneficial and positive
 - ◆ Easier for Faculty/Key Personnel to understand why they need to disclose
 - ◆ Disclosures that are not related do not need to be disclosed unless they are covered by University policy

Policies and Procedures

☞ Focus

- ✓ Full disclosure to meet regulatory compliance requirements, state requirements and institutional policy
- ✓ Development and Implementation of appropriate management plans

☞ Goal

- ✓ To disclose and manage Financial Conflict of Interest (fCOI) so that they do not interfere with OBJECTIVITY in the conduct of research

Conflict of Commitment

- ☞ Up until the 2000's, Conflict of Commitment (COC) reporting requirements were often combined with COI but as the field became more and more focused they are now often handled by separate policies and/or procedures.
- ☞ Reason – COC is much more discipline specific
 - ✓ Humanities
 - ✓ Law
 - ✓ Business
 - ✓ Architect
 - ✓ Land Grant Colleges/departments

Conflict of Commitment

- ☞ The term "conflict of commitment" refers to situations in which outside relationships or activities (such as professional consulting for a fee) adversely affect, or have the appearance of adversely affecting, an employee's commitment to his/her University duties or responsibilities
 - **University of Colorado**
- ☞ A Conflict of Commitment involves a situation in which an employee engages, interferes, or appears to interfere, with fulfillment of the employee's obligations to the University, even if the outside activity is valuable to the University or contributes to the employee's professional development and competence.
 - **University of Iowa**
- ☞ Faculty Policy on Conflict of Commitment and Interest (RPH 4.1)
 - **Stanford University**

Maintaining Objectivity – Avoiding Conscious or Unconscious Bias

- ☞ Focus is on maintaining the trust by others that academic decisions are made responsibly
 - ✓ *"You don't have to do anything improper to have a conflict of interest; it is strictly situational"*
 - ◆ Paul J. Friedman. 1992. *The Troublesome Semantics of Conflict of Interest*. *Ethics & Behavior* 2(4):245-251.
- ☞ The presence of a conflict of interest does not mean that there has been or will be a misdeed
- ☞ Failure to disclose a conflict of interest is a misdeed

Why fCOI is the most recent Research Compliance Concern

- ☞ Expansion of the mission of the University
 - ✓ Education – Traditional Role
 - ✓ Service – Late 1800's – Land Grant Institutions
 - ✓ Research – 1940's – V. Bush vision of combining the educational role and the research role
 - ✓ Economic Development – 1980's Bayle-Dole Act

Why fCOI is the most recent Research Compliance Concern

- ☞ The general public has a lot of trust in academic institutions
- ☞ As a result of that trust the public has been extremely supportive of the four mission of academic institutions
- ☞ When that trust is perceived as being vulnerable to abuse, the public generally becomes concerned
- ☞ With the addition of the economic development mission of the University, there is the potential for financial conflict between this mission and the research mission

Common Steps in the Development of Regulations

- ☞ Public Concern
 - ☞ Institutional Specific Solutions
 - ☞ White Papers from Professional Associations
 - ☞ General Consensus
 - ☞ Violations and/or concerns addressed by public¹
 - ☞ Agency specific clauses for Grants and/or Contracts
 - ✓ Hard for institutions to stay in compliance
 - ☞ Agency specific regulations
 - ✓ Definitions and/or process is inconsistent
 - ☞ Common Rule with Lead Agency
-
- ☞ ¹Law with subsequent regulations may or may not be passed

Protecting Important Public Trusts

- Informed Compliance
- Community of Scholars
- Impartial Stewardship - Intellectual Growth & Professional Advancement
- Fair and Honest Competition - Evaluation Based on Accepted Peer Review Standards
- Benefit from Research Results & New Knowledge in an Equitable and Timely Manner

Financial Conflict of Interest

- ➔ Often handled by a variety of policies and procedures
- ➔ Policies affecting Individual fCOI
 - ✓ Research Policies
 - ◆ Research Personnel

Institutional Policies: MSU

<http://www.msu.edu/~biomed/COI/>

- ☞ State Law
 - ✓ [Contracts of Public Servants with Public Entities Law](#) (09/01/68)
- ☞ Board of Trustees
 - ✓ [Bylaws - Outside Employment](#) (Approved 12/16/65, last revised 01/10/03)
- ☞ University Policies
 - ✓ [Conflict of Interest in Employment](#) (Approved 12/8/95)
 - ✓ [Conflict of Interest in Educational Responsibilities Resulting from Consensual Amorous or Sexual Relationships](#) (Approved 11/8/96)
 - ✓ [Standards of Official Conduct for Deans, Separately Reporting Directors, and Executive Managers](#) (Approved 6/18/04)
- ☞ Academic Human Resources Policies
 - ✓ [Supervision of Academic Work by Relatives](#) (Approved 03/22/94)
 - ✓ [Outside Work for Pay](#) (Approved 08/9/51 and last revised 5/5/06)
 - ✓ [Conflicts of Interest, Faculty](#) (Approved 4/13/06)
- ☞ Research & Creative Activity Guidelines
 - ✓ [Conflict Situations](#) (Adopted 03/20/70 -- AAUP / ACE joint statement, Dec. 1964)
 - ✓ [Guidelines for Potential Conflicts of Interest Pertaining to Applications for NSF and PHS Research Support](#) (10/2/95)
 - ✓ [IRB Member and Investigator Conflict of Interest](#) (4/21/05)
- ☞ MSU Extension
 - ✓ [Conflict of Interest](#) (5/26/99)
- ☞ Manual of Business Procedures
 - ✓ **Section 76 – [Independent Contractors; Professional, Personal Services Contract with Independent Investigator](#)**
 - ✓ **Section 270 – [Purchasing Department; Code of Ethics](#)**

Institutional Conflict of Interest

- ☞ Institutional Transactions and holdings
 - ✓ University Investments
 - ✓ Royalty Income, Licensing Agreements, Equity Positions, Board Positions
- ☞ Activities and holdings of institutional officials¹
 - ◆ Deans, Department Chairs, Division Chiefs, Centers Directors, etc
 - ◆ Individuals involved in the review and approval of research (IRB members, ESCRO members, potentially other compliance committees)
 - ◆ Grants and Contracts Officers
 - ◆ Purchasing Agents or individuals with transactional authority
 - ◆ Investment Personnel

¹Often disclosed as part of individual COI Procedures

Individual Financial Conflict of Interest - Definition

- ☞ Individual Financial Conflict of Interest in science refers to situations in which financial considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research - AAU

Types of Disclosure Systems

- ➡ Annual Disclosure System or
- ➡ Event Driven System

- ➡ Regardless of the basic type of disclosure systems implemented by an institution, the basic characteristics of the other system must be incorporated to allow for flexibility
 - ✓ Annual Disclosure System must have an event driven component for relating disclosure to events (grant, IRB application, patent, licensing agreements, etc)
 - ✓ Event Driven System must have an Annual Disclosure for updating purposes

Examples of Financial COI in Research

- ☞ salary, stock or stock options/warranties, equity, dividends, royalties, profit sharing, capital gain, forbearance or forgiveness of a loan, interest in real or personal property, or a legal partnership
- ☞ Consulting fees, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other emoluments, or “in kind” compensation from a financially interest company (or entitlement to the same), whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable cost of conducting the research (as specified in the research agreement) - AAMC Report
- ☞ corporate or for-profit leadership position, such as executive officer, board member, fundraising officer, agent, or member of a scientific advisory board, member of a scientific review committee, or member of a data safety monitoring committee related to the company sponsor, regardless of compensation.

Definition of Financial COI in Research¹

- ☞ Consulting fees, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other emoluments, or “in kind” compensation from a financially interest company (or entitlement to the same), whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable cost of conducting the research (as specified in the research agreement)

☞ ¹AAMC Report

Definition of Financial COI in Research

Part 2

- ☞ Equity interests, including stock options, in a non-publicly-traded financially interested company
- ☞ Equity interests (or entitlement to the same) in a publicly-traded financially interested company (see exceptions below)
- ☞ Royalty income or the right to receive future royalties under a patent license or copyright, whether the research is directly related to the licensed technology or work;

Definition of Financial COI in Research

Part 3

- ☞ Any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution). This includes any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested company or from the institution.

Definition of Financial COI in Research

Part 4

- ☞ Service as an officer, director, or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service.

Definition of Financial COI in Research

Part 5

☞ Exceptions

- ✓ Interest of any amount in publicly traded, diversified mutual funds
- ✓ Payments to the institution, or via the institution to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the institution.
- ✓ Salary and other payments for service from the institution.

Significant Financial Interest: MSU

- ☞ "A faculty member's financial interests or other opportunities for tangible benefit must be judged not only by his/her personal holdings, but also on an aggregate basis with members of his/her immediate family (spouse, domestic partner, dependent children, and other dependents that reside with the faculty member) and any legal entity that one or more of them owns or controls."
- ✓ Salary, consulting fees, royalties or other payments of any kind from a single entity which exceeded \$10,000 over the last 12 months or which are expected to exceed \$10,000 over the next 12 months, or
 - ✓ Ownership interests in a single entity which have a fair market value of more than \$10,000 or are more than one percent (1%) of its equity, or
 - ✓ Intellectual property rights which have a fair market value of over \$10,000 or which generate, or are expected to generate, revenues of over \$10,000 per year, or
 - ✓ Unvalued stock options or other options for ownership in a privately held company, or
 - ✓ Paid or unpaid service on a governing or advisory board, or in a fiduciary or managerial role, for, or as a general partner of, an entity, or
 - ✓ Serving as a trustee for a trust or estate, or having a beneficial interest in a trust or estate, whose value exceeds \$10,000
 - ✓ Indebtedness to or from a single entity exceeding \$10,000, or
 - ✓ Receipt of gifts of goods, property, or services, like airline tickets, resort or hotel accommodations, or other recreational or personal amenities whose value exceeds \$250 from a single entity.

Significant Financial Interest Does not Include (MSU)

- ☞ salary or other remuneration from the University or paid at the University's behest (including remuneration from a University approved practice plan),
- ☞ income from seminars, lectures, service on committees or review panels, or other educational activities sponsored by public or not for-profit entities,
- ☞ any financial interest arising solely by means of investment in a mutual, pension, or other institutional investment fund over whose management and investments neither the faculty member nor any immediate family member of the faculty member exercises control (*e.g.*, TIAA-CREF), and
- ☞ indebtedness from a bank, credit union, or other commercial lender

Federal Regulations & Policy Guidance

(persons "responsible for the design, conduct, or reporting")

☞ Food and Drug Administration

- ✓ [21 CFR Part 54](#)

☞ Health & Human Services

- ✓ [45 CFR, part 94](#) (contracts)

- ✓ [Final Guidance](#)

- ◆ Financial Relationships and Interests in Research Involving Human Subjects Guidance for Human Subject Protection

☞ Public Health Service

- ✓ [42 CFR, part 50, subpart F](#) (grants)

- ◆ [NOT-OD-08-063](#), Updated FAQs on Financial COI Requirements for NIH-Supported Institutions
- ◆ <http://grants.nih.gov/grants/policy/coifaq.htm>

☞ National Science Foundation

- ✓ [Grant Policy Manual 510](#), as amended by 60 FR 35820

☞ Other Agencies

- ✓ Primarily as a condition of the award

Covered Individuals

☞ PHS and NSF Policy

- ✓ Principal investigator, co-principal investigator and any other person who is responsible for the design, conduct, or reporting of funded research
- ✓ Investigator's spouse¹
- ✓ Investigator's dependent children

¹Significant Other (?)

☞ FDA Policy

- ✓ any listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator

☞ Agencies with fCOI requirements identified as a "condition of award"

☞ State Law

Covered Individuals

- ☞ In 2006 NIH urged institutions to “consider the **roles**, rather than the **titles**, of those involved in research and the degree of independence with which those individual work.”

OMB Circular A-110

☞ Codified at 2 CFR 215

✓ Subpart C – Post Award Requirements
PROCUREMENT STANDARDS

◆ § 215.42 Codes of Conduct

- The recipient shall maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts.
- No employee, officer, or agent shall participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved.

◆ § 215.43 Competition

◆ § 215.45 Cost and Price Analysis

☞ Also incorporated elsewhere in the CFR

✓ *e.g.*, 10 CFR § 600.142 -- Department of Energy

Federal Condition of Award

- ☞ P.L. 110-69 [*America Creating Opportunities to Meaningfully Promote Excellence in Education, Technology, and Science Act*](#) (August 9, 2007)
 - ✓ Sec. 8008(b). “Any person awarded a grant or contract funded by amounts authorized by this Act shall submit a statement to the Secretary of Commerce, the Secretary of Energy, the Secretary of Education, the Administrator, or the Director, as appropriate, certifying that no funds derived from the grant or contract will be made available through a subcontract or in any other manner to another person who has a financial interest or other conflict of interest in the person awarded the grant or contract, unless such conflict is previously disclosed and approved in the process of entering into a contract or awarding a grant. Not later than 60 days after receipt of the certification, the appropriate Secretary, Administrator, or Director shall make all documents received that relate to the certification available to the public.”
 - ◆ Effective 08/09/08 with two exceptions (math for pre-college)

Federal Acquisition Regulations

☞ Codified at 48 CFR

- ✓ Chapter 1, Part 9 -- Contractor Qualifications

 - ◆ Subpart 9.5 – Organizational and Consultants Conflict of Interest

☞ The two underlying principles:

- ✓ Preventing the existence of conflicting roles that might bias a contractor's judgment; and

- ✓ Preventing unfair competitive advantage. An unfair competitive advantage exists where a contractor competing for award (or subaward) possesses proprietary or source selection information.

Federal Awards to Small Businesses: Innovation Research (SBIR) Technology Transfer (STTR)

☞ National Science Foundation

- ✓ [Grant Policy Manual 510](#), as amended by 60 FR 35820
 - ◆ “Significant Financial Interest” does not include any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program.

☞ Public Health Service

- ✓ [42 CFR, part 50, subpart F](#) (grants)
 - ◆ This subpart does not apply to SBIR Program Phase I applications.
 - ◆ “Significant Financial Interest” does not include any ownership interests in the institution, if the institution is an applicant under the SBIR Program .

Financial Threshold

☞ PHS and NSF

- ✓ \$10,000 or 5% ownership interest in any single entity

☞ FDA

- ✓ Any equity interest in a privately held company or stock holdings in a publicly held company exceed \$50,000 in value
- ✓ Sponsor provided \$25,000 to the investigator and/or institution
 - ◆ Disclose "...any financial arrangement with a clinical investigator and any clinical investigator interest, whereby the compensation to the clinical investigator or interest could be affected by study outcome (e.g., payments in the form of stock options or royalties, possession of a patent, etc.).
- ✓ Time Period – Study time period plus one year following completion

☞ Human Participant Research

- ✓ OHRP Guidance (not regulations)
- ✓ "Determining the kind, amount, and level of detail of information to be provided to research subjects..."
- ✓ Often interpreted as 'income greater than \$0'

When to Disclose

☞ PHS and NSF

- ✓ At the time of application
- ✓ On an annual basis or as new reportable Significant Financial Interests are obtained

☞ Other

- ✓ Prior to the authorization for start of a project in the event that funding results from other than a written proposal
- ✓ Reported conflicts of interest must be revised and updated as the interest or situation which is the basis for the conflict changes

☞ Entry Points

- ✓ Contract & Grant Administration
- ✓ Institutional Review Board
- ✓ MSU Technologies
- ✓ Others - Purchasing, Office of Land Management

When to Report to the Funding Agency

☞ PHS

- ✓ Report to the PHS Awarding Component the existence of a conflicting interest prior to expenditure of any funds
 - ◆ But, not the nature of the interest or other details
- ✓ Assure that the interest has been managed, reduced or eliminated
- ✓ Report any conflicting interest identified subsequent to the award as above within sixty days
- ✓ Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias

☞ NSF

- ✓ The institutional policy must include arrangements for keeping NSF's Office of the General Counsel appropriately informed if the institution finds that it is unable to satisfactorily manage a conflict of interest.

What to Report

- ☞ According to NSF / PHS requirements OR according to institutional definitions

Privacy and Confidentiality of Disclosed Information

- ☞ Considered as confidential and should be protected from unnecessary further disclosure
- ☞ It is possible that states may be compel the release of some or all of the information disclosed if that information is included in records which are sought pursuant to state's Freedom of Information Act (FOIA)
- ☞ An expected common means of managing many conflicts will be the public disclosure of at least some of the information the faculty member has provided
 - ✓ The faculty member may object to the release of the information as part of the plan for resolving the conflict and may decide not to undertake the proposed activity related to the interest that would have to be disclosed

AAU Operating Guidelines

- ☞ Develop robust campus management systems
- ☞ Many financial interest are not conflicts, and many conflicts can be managed
- ☞ Research involving human participants requires special scrutiny
- ☞ Treat research consistently, regardless of financial sources
- ☞ Disclose financial information to the institution, in publications, in oral presentations, sponsors, and to human participants

Management Plans - Disclosures

- ☞ Multiple Disclosures To the Institution
 - ✓ To fCOI Committee
 - ✓ To Grants and Contracts
 - ✓ To Institutional Review Board/Data Safety Monitoring Committees
 - ✓ To Participants
- ☞ Disclosures in Publications
- ☞ Disclosures in Presentations
- ☞ Disclosures on web sites
- ☞ Disclosures to Advisory Groups/Study Sections
- ☞ Disclosures to Companies/Foundations/Associations
- ☞ Disclosures to regulatory agencies (FDA)

Management Plans

- ☞ Establishment of Oversight Committee
 - ✓ Within the institution
 - ✓ With representation from outside the institution
 - ✓ External Oversight Committee
- ☞ Establish (in advance) when a particular relationship should not be allowed and apply it to a particular set of multiple relationships

Important Resources

- ☞ Association of American Medical Colleges (AAMC)
 - ✓ [2007 U.S. Medical School Policies on Individual Financial Conflicts of Interest: Results of an AAMC Survey](#)
 - ✓ [Endorsement of Bill Requiring Public Disclosure of Drug Industry Payments to Doctors](#)
 - ✓ [Financial Conflicts of Interest in Academic Medicine](#)
 - ✓ [Forum on Conflict of Interest in Academe \(FOCI-A\)](#)
 - ✓ [Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research](#) (AAMC - AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research)
 - ✓ [Task Force on Industry Funding of Medical Education](#)
- ☞ Association of American Universities (AAU)
 - ✓ [Report on Individual and Institutional Financial Conflict of Interest](#)
- ☞ Council on Governmental Relations (COGR)
 - ✓ [Recognizing and Managing Personal Financial Conflicts of Interest](#)
- ☞ Federation of American Societies for Experimental Biology (FASEB)
 - ✓ [Financial Conflicts of Interest in Research-- Shared Responsibility, Individual Integrity](#)
- ☞ National Institutes of Health (NIH)
 - ✓ [Conflicts of Interest in Extramural Research](#) (Report of the Office of the Inspector General - OEI-03-06-00460)
- ☞ Office of Research Integrity (ORI)
 - ✓ [Responsible Conduct of Research Resources](#)

MSU Guidance Documents

- ☞ [Summary](#) of the Faculty Conflicts of Interest Policy requirements
- ☞ Model College Procedure ([MS Word](#) and [Adobe Acrobat](#) in fillable formats) for reporting conflicts of interest under the Policy
- ☞ [Checklist](#) of Important Considerations when reviewing and assessing reported conflicts of interest
- ☞ [Guidelines](#) for preparing plans to manage reported conflicts of Interest