Training & Education in Financial Conflict of Interest

PHS/NIH Financial Conflict of Interest Regulations, Requirements & UMass Amherst Policy

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Financial Conflict of Interest Regulations For Public Health Service Agencies – What is it all about?

• New UMass policy effective April 6, 2012
• Applicable to any funding from the Public Health Service (PHS) – NIH, CDC, HRSA, SAMSHA, FDA, AHRQ
• Includes mandatory training
• Requires disclosure and reporting to awarding agency & mandates public disclosure upon request
• New management process for evaluating SFI/COI
• University policy revised to comply with the new Federal regulation - 42 CFR Chapter 50 Subpart F
What is the purpose of these regulations?

- The FCOI regulation (42 CFR Part 50 Subpart F) promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct or reporting of research funded under PHS awards will be free from bias resulting from Investigator FCOIs.

- Institutions are required to implement policies and procedures consistent with the regulations; such policies and procedures can reflect institutional priorities and culture so long as they are in full compliance with the requirements of the regulation.

- Actual or apparent conflicts of interest are to be expected as a result of research & entrepreneurial activities, but appropriate disclosure, institutional review and management in accordance with UMass policy ensures compliance with the PHS regulation and protects investigators.
What are the key changes to previous (1995) regulations?

- Definition of Significant Financial Interest (SFI)
- Extent of Investigator’s disclosure of information to their Institution regarding his/her SFI
- Institution’s management of identified Financial Conflicts of Interest (FCOIs)
- Information reported to the PHS funding component (e.g., NIH)
- Information more accessible to the public; and
- Investigator training required
Applicability - Who & What is Covered?

- **Institutions** – any domestic or foreign, public or private entity or organization (excluding a Federal agency) that applies for or receives research funding by means of a grant or cooperative agreement.

- **Investigators** – through his/her Institution’s implementation of the regulation, it applies to each investigator who is planning to participate in, or is participating in, PHS-funded research.

- **Research** - basic & applied research (publication-oriented) or product development (diagnostic test or drug) awards from a PHS agency, including research grants, career development awards, center grants, individual fellowships, infrastructure awards, institutional training grants, program project and research resources awards.

- SBIR/STTR Phase I are not covered by the regulation.
Key Definitions

- **“Investigator”** – Principal Investigator or Project Director and any other person (regardless of title or position) who is responsible for the design, conduct or reporting of research funded by PHS agencies, including those who are subgrantees/contractors, consortium participants, collaborators or consultants.

- Broad definition by design so as to ensure maximum opportunity for disclosure & appropriate management of FCOIs.
Key Definitions

“**Institutional Responsibilities**” means an investigator’s responsibilities on behalf of the Institution, as defined by the Institution, including but not limited to:

- Research
- Research consultation
- Teaching
- Professional practice
- Institutional committee membership
- Service on panels Institutional Review Boards or Data and Safety Monitoring Boards
Key Definitions

- **Financial interest** – anything of monetary value, whether or not the value is readily ascertainable

- **Financial Conflict of Interest (FCOI)** – a Significant Financial Interest (SFI) that could directly & significantly effect the design, conduct or reporting of the research

- **Manage** – taking action to address an FCOI, which can include eliminating or reducing the FCOI, to ensure to the extent possible that the design, conduct and reporting will be free from bias

- **Senior/Key Personnel** – PI/PD and anyone identified as such in grant proposal, technical reports or other report submitted to PHS/NIH
Key Definitions

- Significant Financial Interest (SFI)
  - *Publicly Traded-Entities* - With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
  - *Privately Held Entities* - With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or domestic partner and dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
Key Definitions

- **SFI (cont’d)**
  - *Intellectual Property* - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests
  - *Travel Reimbursements* - Investigators also must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities in the twelve months preceding the disclosure; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
Key Definitions

- SFI does not include:

  - salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights

  - income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles
Key Definitions

- SFI does not include:
  
  - income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education
  
  - income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education
Overview of Responsibilities

- **Investigator** – disclosure & compliance with institutional policy

- **Institution** – institutional policy, implementation, evaluation of SFIs, identification of FCOIs, management, compliance with regulations and reporting to funding agency

- **PHS funding agency** – oversight, education and outreach
Responsibilities under the Policy & Regulations

- Investigator is responsible for
  
  - Following institutional policy and procedure, which may be more restrictive than the FCOI regulation
  
  - Completing FCOI training prior to engaging in PHS funded research and every four years and immediately when any of the following applies
    - Institution revises its policy or procedures in any manner that effects investigators
    - An investigator is new to an institution
    - An institution finds an investigator is not in compliance with the institution’s FCOI policy or management plan
Responsibilities under the Policy & Regulations

- Investigator is responsible for
  
  - Disclosing his/her known SFIs (or those of his/her spouse/domestic partner & dependent children)
    - That reasonably appear to be related to the investigator’s institutional responsibilities
    - Any reimbursed or sponsored travel related to the investigator’s institutional responsibilities
  
  - During the period of the award, updating financial disclosures annually or within 30 days of the acquisition or discovery of a new SFI
Responsibilities under the Policy & Regulations

- Investigator is responsible for
  
  - Disclosing SFIs no later than the time of application for PHS funding
  - Updating disclosures within 30 days of the acquisition or discovery of a new SFI
  - Providing an annual disclosure in accordance with institutional policy & its timeframes
Responsibilities under the Policy & Regulations

- **Institution is responsible for**
  - Creating & maintaining an up-to-date & enforced policy that complies with the regulation
  - Making institution’s FCOI policy publicly available
  - Informing investigators of the FCOI regulation, the institution’s policy and of the investigator’s disclosure responsibilities
  - Requiring investigators to participate in training on the institution’s policy and the investigator’s responsibilities, including disclosure & training
  - Designating institutional official(s) to solicit and review timely disclosures in compliance with the regulation
  - Taking necessary actions to manage FCOIs via a management plan
Responsibilities under the Policy & Regulations

- Institution is responsible for
  - Completing & documenting retrospective review if necessary and if bias is found, develop and submit a mitigation report to PHS funding agency
  - Providing initial and annual FCOI reports to PHS agency (for NIH, submitted via Commons FCOI Module)
  - Making available information concerning FCOIs held by Senior/Key Personnel to the public either via website or in response to a request within five business days of a request
  - Maintaining records for three years from date of submission of final expenditures report
  - Establishing enforcement mechanisms
  - Making information available to PHS funding agency, whether or not an FCOI is found
Responsibilities under the Policy & Regulations

- Institution is responsible for
  - Take reasonable steps to ensure subrecipient investigators’ compliance with the regulation, including:
    - Incorporate language in the subaward addressing whether the FCOI policy of the recipient or subrecipient will apply to the subrecipient’s investigators
      - If subrecipient policy applies, recipient institution must document certification of its policy’s compliance with the FCOI regulation
      - If subrecipient cannot so certify, subaward shall state that subrecipient’s investigators shall be subject to recipient institution’s policy for disclosing SFIs related to subrecipient’s work for recipient institution
Responsibilities under the Policy & Regulations

- Institution is responsible for
  - Making information about any SFI disclosed publicly available upon request within five business days; SFI must meet these criteria:
    - SFI was disclosed and is still held by the investigator
    - The institution determines that the SFI was related to the PHS-funded research
    - The institution determines that the SFI is an FCOI,
  - Information provided in response to request includes at a minimum the following information: investigator’s name; investigator’s title and role with respect to the project; nature of entity in which the SFI is held; nature of SFI (e.g., equity, consulting fees, travel, honoraria, etc.); and approximate dollar value
Responsibilities under the Policy & Regulations

- **Institution is responsible for**
  - Designating official(s) to solicit and review disclosures of SFIs; after reviewing, designated official(s) determine whether SFI is related to PHS funded research and if so, whether an FCOI exists
    - Designated official(s) take appropriate action to manage FCOI including financial conflicts of subrecipients if applicable
    - UMass policy allows designated official(s) to use a committee formed by the Vice Chancellor for Research & Engagement (VCRE) for assisting in SFI relatedness analysis – can be technical & participation of investigator in the designated official’s determination is allowable under the regulation
    - An FCOI exists when the designated official(s) reasonably determine that an SFI could directly and significantly effect the design, conduct or reporting of the research
Responsibilities under the Policy & Regulations

- When must UMass provide information to PHS funding agencies?
  - Authorized official must certify at the time of submission that:
    - It has an up-to-date, written & enforced administrative process to identify & manage FCOIs
    - It promotes and enforces investigator compliance with regulatory requirements including those pertaining to disclosure of SFIs
    - It shall manage any FCOI and provide initial, annual and ongoing reports to PHS funding agency, consistent with regulation
    - It shall make information available, promptly upon request, to PHS funding agency
    - It shall fully comply with requirements of the regulation
Responsibilities under the Policy & Regulations

- When must UMass provide information to PHS funding agencies?
  - Prior to spending any funds under an award, the institution must submit an FCOI report for any identified FCOI; if the FCOI is eliminated prior to the submission of the first report, no FCOI report is required; institution must submit FCOI reports for subrecipients
  - Within 60 days (during an ongoing award) for any SFI that is determined to be an FCOI subsequent to submission of the initial report
  - Complete a retrospective review within 60 days for those SFIs that were not disclosed in a timely manner by the investigator
  - Promptly notify PHS funding agency if bias is found - mitigation report required
  - Annually for any FCOI previously reported under an ongoing award
Responsibilities under the Policy & Regulations

- Report to PHS agency must include:
  - Project number
  - PI/PD name (or contact PI/PD for multiple investigator)
  - Name of investigator with FCOI
  - Name of entity with which the investigator has an FCOI
  - Nature of financial interest
  - Value of financial interest
  - Description of how financial interest relates to PHS funded research & the basis for determination that the financial interest conflicts with such research
  - Key elements of management plan (role of conflicted investigator in research, conditions of management plan, how plan will safeguard objectivity; confirmation of investigator’s agreement with plan; monitoring of plan; and other information as needed to fully describe management of the FCOI.)
Noncompliance & Enforcement

- Regulation addresses noncompliance & enforcement actions required:
  - when an FCOI is not identified or managed in a timely manner
  - when Investigator fails to disclose
  - when the University fails to review or manage FCOI
  - when Investigator doesn’t comply with a management plan

- Failure to comply triggers mandatory retrospective review & potentially a mitigation report (if bias is found) to sponsoring agency

- Failure to disclose may generate disciplinary action, including misconduct remedies per University policies and under State Ethics Law (MGL Ch. 268A)
Summary of UMass Conflict of Interest Policies

1. Faculty Consulting and Outside Activities

2. Conflict of Interest Relating to Human Subjects Research

3. Massachusetts General Law Chapter 268A

4. Conflict of Interest Relating to Intellectual Property & Commercial Ventures

5. Conflict of Interest for Faculty Funded by NSF (& Other Federal Agencies)

6. Conflict of Interest for Faculty Funded by Public Health Service (PHS, NIH, etc)
Outside Activities

- Established, existing policy (University Trustee Policy T96-047)
- Recognizes Outside Activities (OA) can be valuable to faculty & the University, but they require disclosure
- Policy was required for status as “special state employees” & it relieves University faculty from portions of the state ethics law (MGL 268A)
- Applies only to faculty members
- OAs are non-academic activities in area of expertise (eg, employee, consultant, executive, trustee or director)
- Applies to for-profit or non-profit entities
- Cannot interfere with University responsibilities (ie, conflict of commitment)
- Must be Disclosed and Approved by Head/Chair
- Faculty identify & separately disclose any conflict of interest to VCRE
- OAs reported by dean to the VCRE and CVIP Director semi-annually
Financial Conflict of Interest for Research Involving Human Subjects

• Established, existing policy

• UMass Medical School policy statement governs & is the default for the other campuses absent a separate, distinct policy

• Requirements devised to address human subjects welfare & protections – most rigorous COI policy for that reason

• FCOIs prohibited except in very unusual circumstances
Conflict of Interest Relating to Intellectual Property and Commercial Ventures

• Policy allows exception to Mass General Law Chapter 268A for faculty (i.e., faculty come under this for matters relating to IP and technology transfer; other matters still governed by 268A)

• Recognizes the beneficial aspects of interactions among faculty & commercial entities, but establishes parameters

• Defines Significant and Substantial Financial Interest

• Establishes System-Wide Conflicts Committee to oversee COIs and management plans
Massachusetts General Law
Chapter 268A - Conduct of Public Officials and Employees

• Applies to all faculty & staff as employees of the Commonwealth

• Seeks to prevent conflicts between private interests and public duties

• Restricts gifts & gratuities to State employees

• Addresses misuse of position, “self-dealing”, nepotism, false claims & improper disclosure of confidential information

• Appearance of a conflict of interest – susceptible to improper influence
Financial Conflict of Interest
NSF & Other Federal Funding Agencies

• Established, existing policy – mandated by NSF Grant Policy Manual (previously applied to NSF & NIH)

• Requires disclosure & management of circumstances involving Significant Financial Interest (SFI), defined as those financial interests totaling $10,000 or 5% equity or more when aggregated over the previous 12 month period

• Disclosure to Head/Chair, Dean & VCRE annually or as needed for revisions/changes
Financial Conflict of Interest
NSF & Other Federal Funding Agencies

• Proposals submitted should include a disclosure of potential or actual COI

• VCRE, as institutional officer for COI, reviews & determines if conflict exists; an ad hoc committee may be formed to assist in this analysis

• Mandates a “Management Plan” to address any potential COI

• Requires reporting to awarding agency of the existence, but not the details of, any conflict of interest