

**Town Hall Meeting on UMass
Conflict of Interest Policies
and Introducing the New
PHS/NIH Financial Conflict of Interest Regulations**

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Room 151 Computer Science Building

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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)

Outside Activities

- 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

Financial Conflict of Interest **Public Health Service Agencies**

- New policy effective April 6, 2012
- Applicable to any funding from the Public Health Service (PHS) – NIH, CDC, HRSA, SAMSHA, FDA, AHRQ
- Includes mandatory training (new requirement)
- 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 PHS regulation

PHS Financial Conflict of Interest Mandatory Training and Personnel

- All “Investigators” must be trained prior to engaging in research & every 4 years or if triggered by new activity
- Defines “Investigator” as PI on the grant application and any other personnel who would be *responsible for the design, conduct, or reporting of research* (may include consultants, subcontractors or unpaid collaborators depending upon role & responsibility)
- Lead PI is responsible for obtaining disclosures from all Investigators
- Disclosures cover Investigator plus spouse/domestic partner & dependent children

PHS Financial Conflict of Interest **Significant Financial Interest**

- Publicly Traded Entities - \$5,000 or more total income or equity in the preceding 12 month income (direct or indirect)
- Privately Held Entities – any equity interest, or \$5,000 in income (direct or indirect)
- Includes all travel reimbursements or sponsorships, including non-profits other than:
 - Federal, state or local government agency
 - Higher education institution or academic teaching hospital or medical center
 - Higher ed-affiliated research institute

PHS Financial Conflict of Interest Significant Financial Interest

Exclusions:

- Income paid by the University including Intellectual Property rights assigned to institution
- Investment vehicles (e.g., retirement funds where investigator does not directly control investment decisions)
- Certain income from government agencies

PHS Financial Conflict of Interest Disclosures

- All SFI that reasonably appear to be related to Institutional Responsibilities, not only a particular grant (excluding Phase I SBIR)
- Institutional Responsibilities means all of an Investigator's professional responsibilities on behalf of the University, for example:
 - research
 - teaching
 - clinical or professional practice,
 - academic activities
 - scholarly events
 - institutional committees and review boards

PHS Financial Conflict of Interest Disclosures

- Must Disclose to University:
 - Name of outside entity
 - Nature & value of financial interest (equity, consulting fees, etc)
 - Additional information requested to make the FCOI determination
 - For travel, must include purpose of the trip, destination, identity of sponsor, duration & monetary value (estimated if not known exactly)
- Must update if & when circumstances change (both SFI and Institutional Responsibilities)

PHS Financial Conflict of Interest Management

- University designated official(s) decide if there is a Conflict, based on disclosure
- SFI greater than \$10,000 considered by UMass System-Wide Conflicts Committee
- SFI less than \$10,000 may (or may not) be managed in a campus-defined process
- Oversight Committee appointed by VCRE or Conflicts Committee

PHS Financial Conflict of Interest Reporting

- Disclosures are confidential personnel information
- If an FCOI results, and is managed, it must be reported to the agency in a time & manner decided by the agency
- Publicly accessible within 5 business days of a written request if FCOI is still held by Investigator to include all information required in the report

PHS Financial Conflict of Interest 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)