



# Conflict of Interest Town Hall Meetings



Summer 2012

# Purpose of the Town Hall Meetings

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- ▶ Summarize
  - ▶ MSU Conflict of Interest Policy revisions
  - ▶ New PHS (i.e., NIH) regulations for Investigators
- ▶ Address
  - ▶ Impacts on faculty and sponsored projects investigators
  - ▶ Faculty and staff requirements
- ▶ Provide Information Sources
- ▶ Respond to Questions

# MSU Conflict of Interest Policy

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- ▶ Revision approved by the Board of Trustees on April 13, 2012 after review and comment by Faculty Governance
- ▶ Updated for two key reasons:
  - ▶ To be consistent with national trends
    - ▶ Association recommendations (e.g., [AAMC](#), [AAU](#), [FASEB](#), [IOM](#))
    - ▶ Best practices at peer institutions (CIC, AAU, others)
  - ▶ To comply with Federal requirements

# Federal Requirements

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- ▶ MSU must comply with sponsor requirements concerning the reporting and review of personal Significant Financial Interests (SFIs) of Investigators and their immediate families as possible conflicting interests:
  - ▶ [42 Code of Federal Regulations \(CFR\) Part 50 Subpart F](#), Promoting Objectivity in Research for Public Health Service (PHS) grants or cooperative agreements;
  - ▶ [45 CFR Part 94](#), Responsible Prospective Contractors for PHS research contracts;
    - ▶ NIH [Financial Conflict of Interest](#)
  - ▶ [21 CFR Part 54](#), Financial Disclosure by Clinical Investigators;
  - ▶ [Section A. Conflict of Interest Policies in Chapter IV Grantee Standards](#) of NSF's Award and Administration Guide; and
  - ▶ Certain non-profit organizations (e.g., [American Heart Association](#), [American Cancer Society](#), [Arthritis Foundation](#), [Susan G. Komen Foundation](#), and the [Alliance for Lupus Research](#))

# Purpose of Sponsor Requirements & Policy

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- ▶ To promote objectivity in research and scholarship
  - ▶ To ensure there is no reasonable expectation that the **design, conduct, or reporting** of research and other scholarly projects will be biased by any personal financial interest of an Investigator that might appear to conflict with their university obligations

# PHS Requirements - MSU Responsibilities

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- ▶ Establish a Policy and associated Guidelines
- ▶ Train Investigators before they **engage** in research
- ▶ Solicit and reviewing disclosures of Investigators' **Significant Financial Interests (SFIs)**
  - ▶ **Reasonably related to the Investigator's Institutional Responsibilities**; not just a specific sponsored project

# PHS Requirements - MSU Responsibilities

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- ▶ Determine whether an Investigator's SFI is related to research/scholarly activities and, if so related, whether the SFI is a **Financial Conflict of Interest (FCOI)**.
  - ▶ *A Financial Conflict of Interest exists when MSU, through its designated official(s), reasonably determines that a SFI could directly and significantly affect the design, conduct, or reporting of a research/scholarly project.*
- ▶ Develop and implement management plans, as needed, to manage SFIs and FCOIs for MSU Investigators and Subrecipient Investigators, if necessary
  - ▶ *Manage means taking action to address a conflicting interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.*

# Examples: Management Plan

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## ▶ Must:

- ▶ Report any change concerning a SFI or initiation of any new activity on behalf of MSU that relates to the **Entity** or Organization in which there is a SFI as soon as it occurs
- ▶ Request approval to undertake outside work for pay according to the [Outside Work for Pay Policy](#)
- ▶ Disclose the personal interest to students, fellows, trainees, and other research workers supervised as an institutional activity when their efforts are related
- ▶ Disclose the personal interest in publications and academic presentations from the Investigator's laboratory/working group where such disclosure is appropriate and required
- ▶ Report proposed use of MSU equipment and facilities in support, including routine testing services ([Guidelines for Provision of Technical Testing Services to Entities in which MSU Employees Hold a Financial Interest](#)), to ensure appropriate review and approval
- ▶ Forward purchase requests for equipment to support collaborative efforts to the Chair for review and approval
- ▶ Meet annually with Chair to review the extent of personal SFI's, their relationship to institutional activities, and this management plan



# Examples: Management Plan

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## ▶ May not:

- ▶ Represent the Entity in direct negotiations with MSU, except in exigent circumstances approved by the Vice President for Research & Graduate Studies following consultation with the Provost
- ▶ Unless waived by the Dean based on written justification and endorsement by the Chair,
  - ▶ Serve as the dissertation or thesis chairperson of any graduate committee for a student:
    - Employed concurrently by the Entity
    - Appointed or employed by MSU to carry out routine technical services for the Entity

# PHS Requirements - MSU Responsibilities

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- ▶ Submit initial and annual FCOI reports to Federal sponsors in accordance with requirements;
  - ▶ *Report refers to MSU's report of identified FCOIs to sponsors as required.*
- ▶ When non-compliance by investigators is discovered:
  - ▶ Complete a retrospective review and update any previously submitted FCOI report, if required after the retrospective review is complete
  - ▶ Prepare a mitigation report when bias is found through this retrospective review
- ▶ Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions

# Changes in MSU Policy

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- ▶ Clarifies who the Policy applies to
- ▶ Establishes an Annual Disclosure Requirement
  - ▶ All significant financial interests and other opportunities for tangible personal benefit related to institutional responsibilities
  - ▶ NSF & PHS Investigators by August 24, 2012
  - ▶ All others by January 2015
- ▶ Establishes Responsibilities for the COI Officer (previously COI Information Officer)
- ▶ Establishes Responsibilities for a Conflict Review Committee
- ▶ Formalizes compliance with NSF/PHS requirements
- ▶ Maintains Disciplinary Procedures for Non-compliance

# Changes in MSU Policy

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- ▶ Applies general PHS-mandated Institutional Responsibilities, for all, except for:
  - ▶ Training requirement
  - ▶ Inclusion of payments by the following as a SFI:
  - ▶ Disclosure of **Sponsored/Reimbursed Investigator Travel** by:
    - ▶ Non-profit organizations (e.g., the American Cancer Society or the Association of American Medical Colleges);
    - ▶ Research institutes not affiliated with an institution of higher education.
    - ▶ Foreign governments at all levels;
    - ▶ Foreign institutions of higher education;
    - ▶ Foreign academic teaching hospitals and medical centers; and Foreign research institutes.

# Training Requirement

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- ▶ This training tutorial must be:
  - ▶ Completed before you engage in conducting research related to any PHS-funded project (August 24, 2012);
  - ▶ Completed immediately by a PHS Investigator new to MSU; and Repeated:
    - ▶ At least every four years thereafter;
    - ▶ When MSU revises its financial conflict of interest policy or procedures in any manner that affects the requirements of PHS Investigators; and
    - ▶ When MSU finds that an Investigator is not in compliance with MSU's Financial Conflict of Interest (FCOI) requirements or an established management plan.

# Investigator Compliance

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- ▶ **Effective August 24, 2012,**
  - ▶ *All PHS and NSF Investigators must annually Disclose all personal Significant Financial Interests (SFIs) that relate to their Institutional Responsibilities.*
  - ▶ *Investigators must also update their Annual Disclosure within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI or a change in a SFI (e.g., new sponsored/reimbursed travel by PHS investigators).*

# Investigator Compliance

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- ▶ **Investigator** refers to the Principal Investigator(s), Project Director(s), Senior/Key Personnel, and any other person, regardless of title or position, who is deemed responsible for the design, conduct, or reporting of research, including Investigators working for subgrantees, contractors, consortium participants, collaborators, or consultants.
- ▶ **Disclose** means to provide requested information about the nature of personal SFIs to MSU through a web portal.
- ▶ **Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of MSU, which include research, teaching/education, outreach, and service activities, both within and outside the University, in the general area of expertise for which the Investigator is appointed.

# Investigator Compliance

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- ▶ To comply with the Policy, you must know which personal Significant Financial Interests must be Disclosed.
  - ▶ **Significant Financial Interest** means a financial interest (anything of monetary value, whether or not the value is ascertainable ) consisting of one or more of various types of financial interests when aggregated over the previous twelve months exceeds \$5,000 (or other specified limits).
  - ▶ SFIs include not only your personal interests, but also financial interests held with or by your immediate family (spouse, domestic partner, dependent child(ren), and other dependents) and with or by any legal entity that you or your family owns or controls.



# Investigator Compliance

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- ▶ The Policy requires that Significant Financial Interests be disclosed by private organization or entity when you:
  - ▶ Receive income or payments of any kind
  - ▶ Own greater than 1% of a single outside entity or have ownership interests (e.g., stock)
  - ▶ Serve as a trustee for a trust or estate, or have a beneficial interest in a trust or estate
  - ▶ Are indebted to or have provided a loan
  - ▶ Have intellectual property rights or which generate income of any value
  - ▶ Have unvalued options for stock or ownership of any value in a private company
  - ▶ Serve on a governing or advisory board, or in a fiduciary or managerial role, for, or as a general partner with or without pay
  - ▶ Receive gifts -- goods, property, or services, like transportation, resort or hotel accommodations, or other recreational or personal amenities (greater than \$250 when combined)

# Investigator Compliance

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- ▶ The following financial interests **DO NOT** need to be reported:
  - ▶ SFIs **unrelated** to your MSU Institutional Responsibilities;
  - ▶ MSU Salary, remuneration by MSU, or other payments at MSU's behest (including from an MSU-approved practice plan); and
  - ▶ Financial interests arising solely by means of investment in a mutual, pension, or other institutional investment fund over whose management and investments neither you nor any immediate family member has control.

# Investigator Compliance

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- ▶ The following financial interests **DO NOT** need to be reported:
  - ▶ Indebtedness from a bank, credit union, or other commercial lender; and
  - ▶ Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels paid by U.S.:
    - ▶ Federal, state, or local government agencies;
    - ▶ Institutions of higher education;
    - ▶ Academic teaching hospitals and medical centers; and
    - ▶ Research institutes affiliated with an institution of higher education.

# Investigator Compliance

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- ▶ PHS Investigators have **added disclosure responsibilities:**
  - ▶ The definition of SFI (Investigator & immediate family) also includes payments for seminars, lectures, service on committees or review panels, or other educational activities by:
    - ▶ Non-profit organizations (e.g., the American Cancer Society or the Association of American Medical Colleges);
    - ▶ Research institutes not affiliated with an institution of higher education.
    - ▶ Foreign governments at all levels;
    - ▶ Foreign institutions of higher education;
    - ▶ Foreign academic teaching hospitals and medical centers; and Foreign research institutes.

# Investigator Compliance

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- ▶ PHS Investigators (they alone)  
**must also disclose** (and update within 30 days)  
Reimbursed or Sponsored Travel by trip  
(dates/duration; destination; purpose).
- ▶ ***Reimbursed or Sponsored Travel*** means *travel expenses reimbursed or paid on behalf of the Investigator related to their institutional responsibilities by:*
  - ▶ Non-profit organizations (e.g., the American Cancer Society or the Association of American Medical Colleges);
  - ▶ Research institutes not affiliated with an institution of higher education;
  - ▶ Foreign governments at all levels;
  - ▶ Foreign institutions of higher education;
  - ▶ Foreign academic teaching hospitals and medical centers; and
  - ▶ Foreign research institutes.

# Training Portal

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- ▶ Register at <https://noncredit.msu.edu>
  - ▶ Offering Catalogs > RCR > Financial Conflict of Interest
- ▶ Will announce availability to Investigators within a week
- ▶ PHS Investigators must complete training by:
  - ▶ Attending one Town Hall
  - ▶ Completing the On-line Training Module
- ▶ NSF and other Investigators – strongly recommended

# Disclosure Portal

- ▶ Through the OSP/CGA web site at <http://osp.msu.edu> under **CONFLICT OF INTEREST**

The screenshot displays the OSP & CGA Home page. The navigation menu includes Home, Preaward, Postaward, Forms, Industry, and Portal. The main content area is titled "My Personal Interests: Annual Disclosures". A sidebar menu on the left is expanded to show "Conflict of Interest" options, with "Report My Interests" highlighted by a red dashed box. The main content area features a navigation bar with buttons for "Annual Disclosures", "Financial Entities", "Sponsored/Reimbursed Travel", "Proposals", and "Awards". Below this is a "Manage Annual Disclosures" section with a button for "Start New Annual Disclosure (7/1/2011 - 12/31/2012)" also highlighted by a red dashed box. A table below shows a reporting cycle with the text "There is no Annual Disclosure Information".

| Reporting Cycle                           | Certified On | Actions |
|---|--------------|---------|
| There is no Annual Disclosure Information |              |         |

- ▶ Training module emphasizes the details of this process
- ▶ After August 24, proposals will not be submitted if this is not completed by Investigators

# Please Sign the Attendance List

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- ▶ Presentation will be posted at <http://www.ora.msu.edu/>
- ▶ Questions