Implementation of MIT’s New Conflict of Interest Policy: Changes Affecting Administrators and Principal Investigators

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Agenda

• Changes coming this summer for ALL Investigators
  – COI Policy Changes
  – Changes necessary to support COI policy:
    • Online PI Certification and streamlined SFI
disclosure for all proposals
    • New COI Module
Agenda

• Changes specifically tied to the new NIH COI regulations
  – Rolling implementation
  – COI policy expands to include all “Investigators”
  – Mandatory training Requirement
  – Disclose of reimbursed/sponsored travel
  – Disclosure process becomes ongoing
  – Additional oversight of subawardees
  – Expanded reporting to NIH requirements and public reporting of fCOI’s to the public
  – Change in award acceptance process
COI Policy Changes (for ALL Investigators)

• All PI’s disclose for all proposals
• New definition of SFI for MIT
  – SFI disclosure threshold decreased – $10K to $5K
  – Reporting of publicly traded stock decreases
• New role of Designated Official defined in the policy
• COI Officer – new position dedicated to the management of COI, assists with disclosure review, helps PIs and Department, Lab and Center heads
Disclosure and Review Process

1. **Investigator** discloses SFIs, describes how it is or is not related to his/her research.
2. **Designated Official** considers Investigators disclosure, determines whether the SFI is related to the research; and where it is related, submits disclosure to COI Committee.
3. **COI Committee** reviews disclosure and determines if there is a FCOI, makes recommendations to Institutional Official as to whether it can be managed.
4. **Institutional Official** makes final determination on FCOI and whether it can be managed; COI Committee informs Investigator of determination and next steps.
Institutional Responsibilities and Determination of Relatedness

“Designated Official” = individual tasked with reviewing disclosures for “relatedness”

Conflict of Interest Officer

Department Lab or Center Head

Goal: Handle as many disclosures as possible through administrative review.

Those that require specific understanding of detailed scientific areas will need the input of the DLC Head
Options for Resolving Conflicts

• **Elimination.** A Financial Conflict of Interest may be eliminated by divestiture of Equity Interests; termination of the relationship that gives rise to the Significant Financial Interest (such as consulting); abandoning the proposal; terminating the sponsored project; and similar measures.

• **Management.** If the Investigator does not want to eliminate a Financial Conflict of Interest or the appearance of a Financial Conflict of Interest and the Institutional Official determines that it can be managed, the Investigator must develop a written management plan. The Conflict of Interest Officer will assist the Investigator in developing the plan.
Management Process

- All Investigators
  - Investigator develops management plan with the help of COI Officer
- Department, Lab and Center heads review and approve the management plan; submit to the COI Committee
- COI Committee reviews and recommends changes to the Investigator or recommends approval to the Institutional Official
- Institutional Official issues approval, after which research may commence
Process for Determining fCOI

**SFI?**
- Does the PI, Co-PI or investigator have a significant financial interest?
  - If yes, then ask ...

**Related?**
- Is the SFI related to PHS funded research?
  - If yes, then ask ...

**fCOI?**
- Could the SFI directly and significantly affect the design, conduct or reporting of the NIH-funded research?
  - If yes, manage or eliminate
  - Report to NIH and public
Changes necessary to support COI policy

Online PI Certification and streamlined COI disclosure for all proposals

- All PIs and CO-PIs
  - Complete proposal specific questions
  - Complete COI screening questions

- NIH and NSF PIs save time – they only need to complete a full disclosure if answers to questions require additional information

- All PIs who have a potential fCOI must complete a full disclosure
Changes necessary to support COI policy

• Certification questions must be completed before the proposal can be routed
• Aggregators will prompt PI Certification from within the proposal (questions can be answered at any time after the department initiates a new proposal in Coeus)
• That’s why …. all proposals need to be created and/or routed in Coeus by August 15th
Status of Coeus Transition

Proposals created/routed in Coeus:

• July 2011 – 46.5%
• May 2012 – 79%
• August 2012 – 100%
Notification for online PI Certification
PI Screening Questions
New COI Module

• A new COI module has been developed in CoeusLite
  – Revised existing module to capture new information

• Usability was conducted with several PIs (part of our COI Faculty Advisory Group), and several changes were made

• Master Disclosure, updated at least annually
All Investigators

OSP Forum

Master COI Disclosure

New Proposal

New SFI
New NIH Regulations

“Old” policy
• SFI => $10,000 or >5% of privately held company
• Regular updates of SFI required
• High level reporting to NIH annually

“New” policy
• SFI => $5,000, 0% equity in privately held company
• New travel reporting
• Reporting of SFIs within 30 days
• Training of all Investigators
• Detailed reporting to NIH annually
• Detailed reporting to the public
Rolling Implementation

New Awards and Competing Renewals with issue dates on or after 8/24/2012

Before the start of new awards:
- PIs and Investigators need to complete training and need to disclose SFIs
- Disclosures need to be reviewed and decisions made

Continuing Awards

Before current awards are revised:
- PIs and Investigators need to complete training and need to disclose SFIs
- Disclosures need to be reviewed and decisions made
COI policy expands to include all “Investigators”

Definition of Investigator:
The project director or principal investigator and any other person, regardless of title or position, who is independently responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

At MIT, it now includes Principal Investigator, Co-Investigator, and Key Persons.
Mandatory Investigator Training Requirement

• Required before an Investigator begins work on the project
• Provided through CITI
  – Module 1 - Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules
  – Module 2 - Institutional Responsibilities as They Affect Investigators
  – Module 3 - MIT Specific Policies
  – Module 4 - Conflicts of Commitment, Conscience, and Institutional Conflicts of Interest (optional)
Disclosure of Reimbursed Travel

• Must disclose reimbursed or sponsored travel paid by institutions other than
  – MIT
  – US government agencies,
  – US institutions of higher education,
  – US academic teaching hospitals, medical centers, or
  – US research institutes affiliated with an Institution of higher education

• Disclosures will be completed through MyCOI in CoeusLite
Disclosure process becomes ongoing

- New SFIs must be reported within 30 days
- Travel disclosures must be reported within 30 days
Additional Oversight of Subawardees

- Subawardees must have a policy that complies with PHS regulation
- Subawardees report fCOIs to MIT within 45 days
- MIT reports fCOIs of subawardees to NIH within 60 days
Reporting Requirements

• Initial fCOI must be reported:
  – Prior to the expenditure of funds
  – Within 60 days from new disclosure

• Annual fCOI Report:
  – At time of submission of annual progress report including multi-year funded progress reports, or
  – At time of extension

• Retrospective review to determine bias when there is noncompliance
  – Mitigation report (if bias is found)
Public Accessibility

- Identified fCOIs must be made available to the public
  - Via public website, or
  - Within 5 business days of written request for information
Change in Award Acceptance Process

- Verification of proposed Key Persons
- Full disclosure and completion of review
- Training requirements met
Key Dates

July 26
- Key person verification process begins in preparation for Annual COI disclosure

August 6
- New JIT/Award setup process begins

August 15
- Annual Disclosure process begins in new MyCOI module

August 24
- All NIH awards with issue date on or after today are subject to new requirements

August 15
- All proposals route in Coeus
- All PIs complete PI Certification and streamlined COI disclosure in Coeus for all proposals
- New MyCOI module
Additional Information

Two-part Workshop
• Workshop 1:
  – Offered July 26, August 1, August 7
• Workshop 2:
  – Offered August 9, August 13

Upcoming Coeus User Group
• Offered August 14, August 22

NIH Administrators should plan to attend one session of each workshop but do not need to attend the Coeus User Group in August
New COI website (http://coi.mit.edu/research)