



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

Michelle D. Christy
Director, Office of Sponsored Programs

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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



Institutional Responsibilities and Determination of Relatedness

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

Conflict of Interest Officer

Department Lab or Center Head

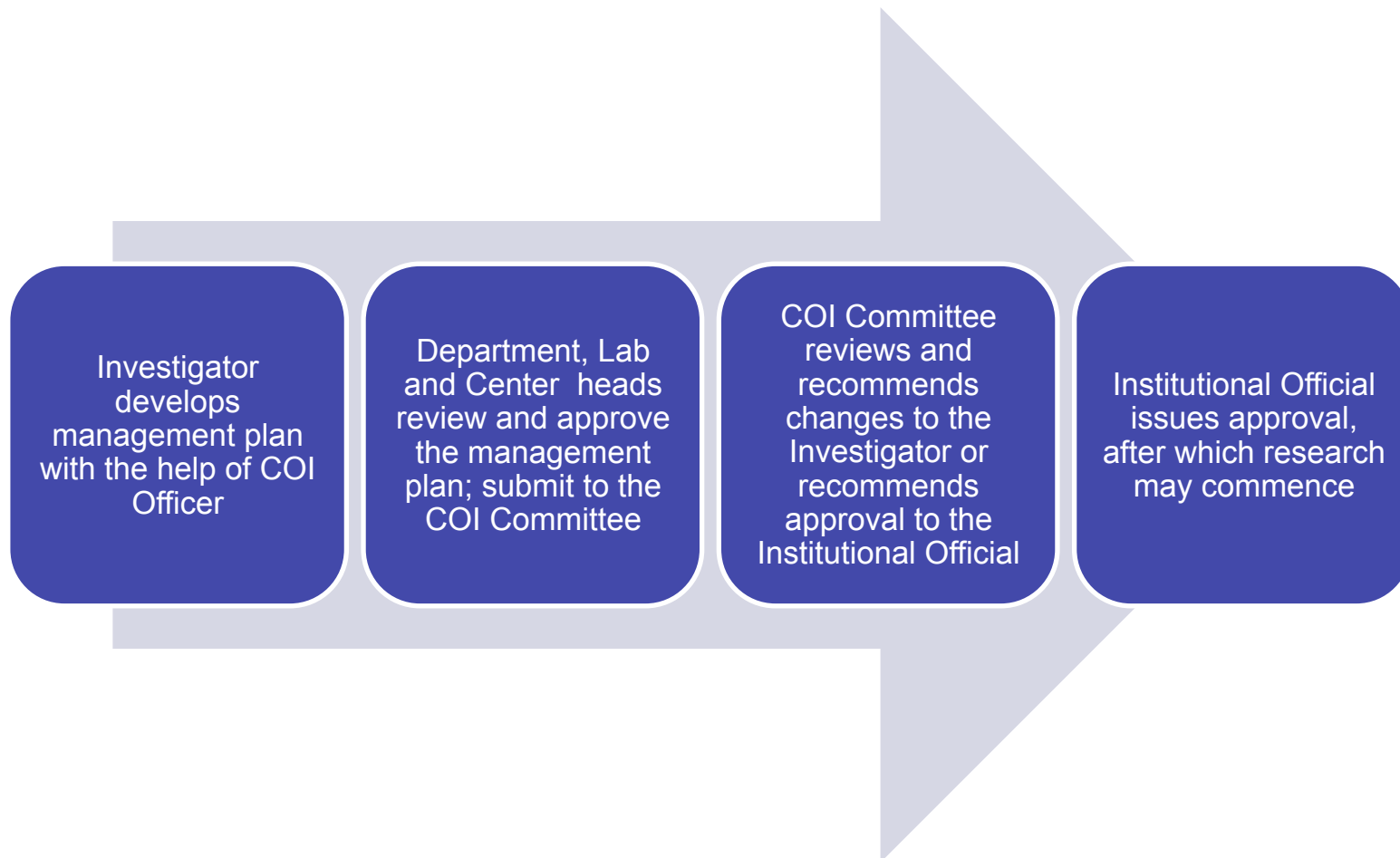
Goal: Handle as many disclosures as possible through administrative review.

Those that require specific understanding of detailed scientific areas will need the input of the DLC Head

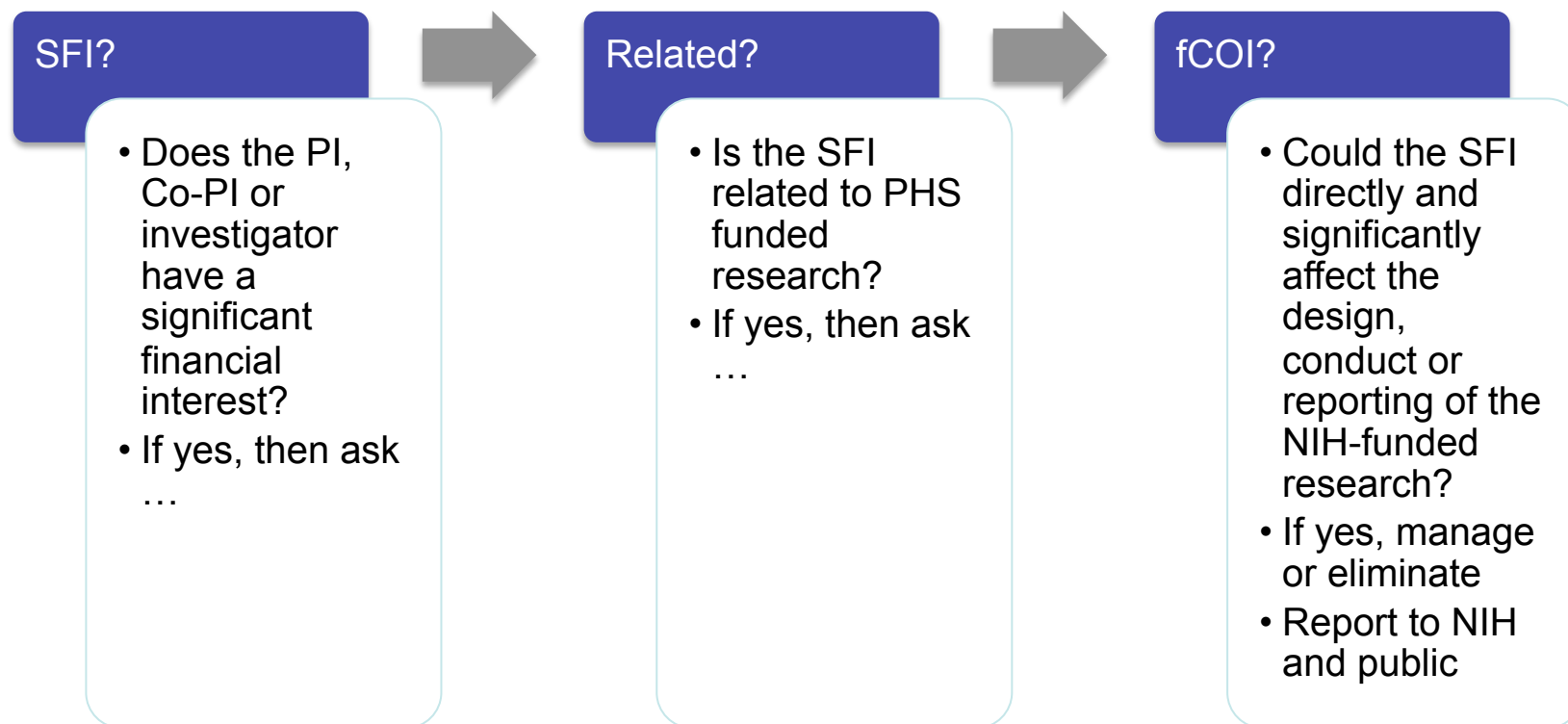
Options for Resolving Conflicts

- *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



Process for Determining fCOI



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

The screenshot shows the CoeusLite interface for managing proposals. The main navigation bar includes 'Coeus Home', 'My Proposals', 'My COI', 'Inbox', 'My ARRA', and 'Logout'. Below this, there are links for 'All Proposals', 'Proposals In Progress', 'Create New Proposal', 'Proposal Search', and 'Grants'. The left sidebar contains a menu with options like 'Proposal Summary', 'General Info', 'Organization', 'Investigators/Key Persons >>', 'Credit Split', 'Special Review', 'Abstract', 'Science Code', 'Others', 'YNQ', 'Proposal Roles', 'Questionnaire', 'Test Questionnaire', 'Grants.Gov', 'Budget', 'Upload Attachments', 'Validate', 'Submit for Approval', and 'Print'.

The main content area displays details for a proposal by Wood, Carol J. The 'Investigator/Key Study Personnel Details' section includes a form with the following fields:

- Name: [Text Box]
- Commons User Name: [Text Box]
- Unit: [Text Box] [Search](#)
- Proposal Role: Co-Investigator (dropdown)
- % Academic Year Effort: [Text Box]
- Email: [Text Box]
- Fax: [Text Box]
- Multi PI:
- % Summer Year Effort: [Text Box]
- Phone: [Text Box]
- Mobile: [Text Box]
- % Effort: [Text Box]
- % Calendar Year Effort: [Text Box]

At the bottom of the form, there are 'Save' and 'Send Notification' buttons. A red arrow points to the 'Send Notification' button.

Below the form is a table titled 'List of Investigators/Key Study Personnel' with columns for Name, Department, LU, MPI, Role, % Effort (T, A, S, C), and COI Disclosure. The table contains one entry for Wood, Carol J.

Name	Department	LU	MPI	Role	% Effort				COI Disclosure
					T	A	S	C	
Wood, Carol J	• Massachusetts Institute of Technology	<input checked="" type="checkbox"/>		Principal Investigator	0.0	0.0	0.0	0.0	Remove

PI Screening Questions

Proposal Persons
 Barrigar, Wendy
 Certification
 ✓ PI Certification

Advanced Summary
 Investigator: Barrigar, Wendy Proposal #: 00012354 (In Progress)
 Agency/Sponsor: WB Another Test Proposal Proposal Period: 10/01/2012 - 09/30/2014
 Title:
 Direct Cost Under Recovery Indirect Cost Cost Share Total Cost Period

PI Certification
 Certification for : Barrigar, Wendy

Question	More	Less
1) Have you lobbied, or are you aware of anyone has lobbied government officials in support of this project? Lobbying includes oral or written communications to government officials regarding the adoption of program funds, or execution of program funds that would specifically support this project.	More	Less
2) Is your current space sufficient to carry out this project, and those already proposed?	More	Less
3) Do you plan to carry out part of this work in any space other than that of the department, lab or center submitting this proposal?	More	Less
4) Will you need to appoint individuals in a department, lab or center other than the one submitting this proposal?	More	Less
5) Will you need to appoint visitors at MT in order to carry out this project?	More	Less
6) Visiting students?	More	Less
7) Visitors from the sponsor?	More	Less
8) Other visitors such as collaborators?	More	Less
9) Could the work contemplated in this project reasonably appear to affect a company or other organization in which you hold a Significant Financial Interest? A Significant Financial Interest is defined as stock, controlling, or other remuneration of \$1,000 or more, which you have received in the last 12 months, or expect to receive in the next 12 months, or any equity interest in a non-publicly traded company.	More	Less
10) Do you have a Significant Financial Interest that could reasonably appear to affect the design, conduct or reporting of this research?	More	Less
11) Under this project, do you anticipate any purchases from or contractual arrangements with a company or other organizations in which you hold a Significant Financial Interest?	More	Less
12) Do you have a Significant Financial Interest in the sponsor of this project?	More	Less
13) Will you receive any information, software or equipment that requires restricted access or use by researchers of some nations?	More	Less
14) Will any part of this project be performed outside of the US? (including seaboard arrangements, but including attendance at conferences)	More	Less
15) Will you deliver equipment, materials or information including software, outside the US?	More	Less
16) Will you receive any equipment, materials or information (including software) from non-US parties?	More	Less
17) Describe any non-US activities (text box)	More	Less

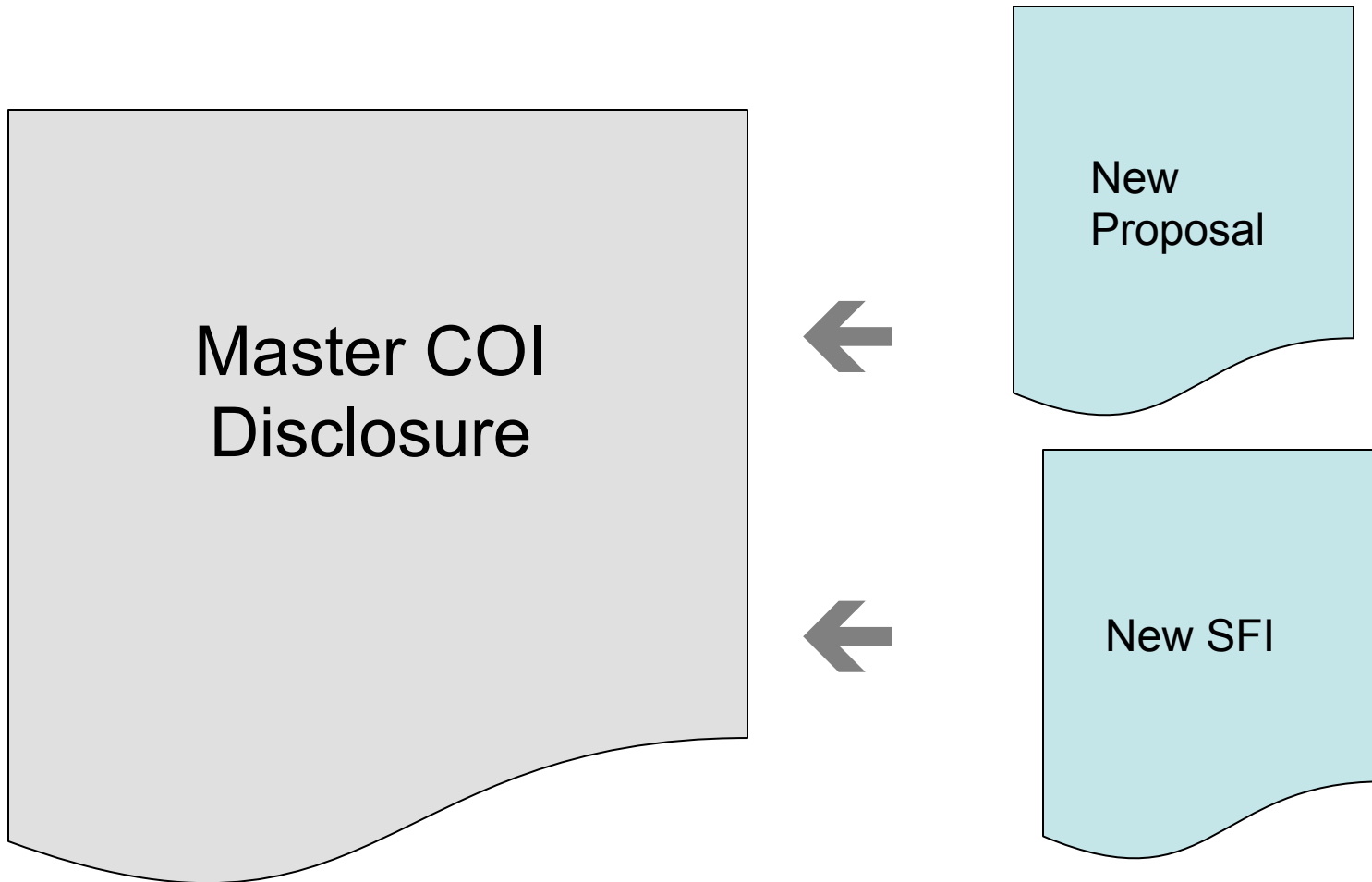
Print

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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

Master COI Disclosure



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

NIH
Investigators

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

All Investigators

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

NIH
Administrators

Two-part Workshop

- Workshop 1:
 - Offered July 26, August 1, August 7
- Workshop 2:
 - Offered August 9, August 13

All
Administrators

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>)

MIT Financial Conflict of Interest
Policies and Procedures

Search: **GO**

Guiding Principles Definitions MIT Policy Disclosure Requirements PHS Requirements

- Policy Statement
- Definitions
- Guiding Principles
- Application of Guiding Principles
- Disclosure Requirements
- Review, Evaluation and Resolution
- Disclosure to Third Parties
- Disciplinary Action
- Record Retention
- Appendix A - PHS Addendum

Introduction

This Policy is intended to assist MIT researchers in applying and complying with MIT's requirements regarding financial conflicts of interest in research, and with the requirements of sponsors, including the Public Health Service (PHS). PHS includes the National Institutes of Health (NIH), among other agencies. Specifics regarding the PHS requirements are set forth in [Appendix A](#) of this Policy.

Every researcher has an obligation to become familiar with, and abide by, the provisions of this Policy. If a situation raising questions of conflict of interest arises, a researcher should discuss the situation with MIT's Conflict of Interest Officer or the Vice President for Research. The Vice President for Research is responsible for ensuring implementation of this Policy.

News

Effective August 15, 2012 -

The U.S. Department of Health and Human Services (HHS) has issued a final rule in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). An Institution applying for or receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the revised regulatory requirements no later than 365 days after publication of the regulation in the Federal Register, i.e., Aug. 24, 2012, and immediately upon making the Institution's Financial Conflict of Interest policy publicly accessible as described in 42 CFR part 50.604(a). [Read more...](#)

Related Links

- CITI Training
- NIH COI page
- FCOI FAQs
- COI Tutorial
- Summary of Major Changes
- NIH Guide Notice

MIT MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Claude Canizares, Vice President for Research
77 Massachusetts Avenue, Room 3-234
Cambridge, MA 02139-4307 | (617) 253-1000
<http://web.mit.edu/industry/vp-research.html>