Research Administration Practices (RAP) Sessions

Sponsor Requirements Certification and COI (Part 1)

Presented by:

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Introductions

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Agenda

• Why?
  • Brief history of the financial Conflict of Interest (fCOI) regulations
  • Purpose and key definitions of the fCOI policy
• Who?
  • Key offices and processes of COI @ MIT
  • Who needs to disclose
• How?
  • Brief overview of COI disclosure, review and management process
  • What are the COI requirements and processes during the lifecycle of a sponsored project and who plays a role?
  • Who does what at the proposal, award and post-award stages?
Brief History of events which triggered investigations leading to COI policy changes at NIH and NSF

1980: Bayh-Dole Act permits universities to own inventions created using federal grants.

1990: NIH and NSF regulations require research institutions to implement and enforce COI policies.


1999: Senate investigates major financial conflicts of interest in research at Emory, Harvard, University of Texas, and Stanford.

2008: New NIH regulations take effect and apply to all PHS-funded research. MIT creates COI Officer position and updates its COI policy to reflect new regulations. MIT policy is effective on August 24, 2012.

2011: Jesse Gelsinger died during first clinical trial for gene therapy. Dr. James Wilson, co-investigator, had financial interest in outcome of study and failed to disclose extent of adverse reactions during animal testing. Brought significant attention to FCOI.

2012: NIH creates rigorous standards for reporting, managing, and eliminating FCOIs in amended regulations.
The new regulations are a response to Congressional and HHS Office of Inspector General criticism of the NIH’s oversight of grantee compliance with COI rules and negative media accounts of financial relationships between pharma and device companies and academic researchers.

The changes aimed at increasing transparency and institutional and NIH oversight of financial interests of investigators in federally sponsored research.

Established new standards for disclosing (investigator), reviewing, managing and reporting (institution) financial interests in an effort to provide a reasonable expectation that the design, conduct, and reporting of research funded under grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

MIT updated its FCOI in Research policy in August 2012 and 2013 in response to the new regulations (PHS regs + NSF regs + MIT P&P = MIT’s FCOI in Research policy).
# 2011 PHS (NIH) Regulations Increase Institutional Oversight

<table>
<thead>
<tr>
<th>1995 Regulations</th>
<th>2011 Regulations</th>
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<tr>
<td>Investigators determine if financial interests and research are related</td>
<td><strong>Institution</strong> determines if financial interests and research are related</td>
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<tr>
<td>Disclose if financial interest above $10,000</td>
<td>Disclose if financial interest above $5,000; <em>any private equity</em></td>
</tr>
<tr>
<td>Disclose outside payments for activities like consulting, equity, stocks, royalties for intellectual property rights</td>
<td>Disclose outside payments for activities like consulting, equity, stocks, royalties for intellectual property rights <em>and travel reimbursement</em></td>
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<tr>
<td>No training requirement</td>
<td>Training <strong>required every 4 years</strong></td>
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<tr>
<td>If there are material changes in Significant Financial Interests, disclose annually.</td>
<td>If there are material changes in Significant Financial Interests, disclose <em>within 30 days of change and annually</em></td>
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<tr>
<td>No public accessibility of FCOIs</td>
<td>Public access of FCOIs <strong>upon request</strong></td>
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“When in doubt, disclose.” — Maria Zuber, MIT VPR
## Key COI Policy Definitions

<table>
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<th>Definition</th>
<th>Description</th>
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<tr>
<td><strong>Conflict of Interest (COI)</strong></td>
<td>Situation in which $$ or other personal considerations w/potential to compromise professional judgement or objectivity in the design, conduct or reporting of research</td>
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<td><strong>Significant Financial Interest (SFI)</strong></td>
<td>$$ interest that could reasonably appear related to Institutional Responsibilities; meets $ threshold for disclosure</td>
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<tr>
<td><strong>Financial Conflict of Interest (fCOI)</strong></td>
<td>SFI that could affect research design, conduct, or reporting of research</td>
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<tr>
<td><strong>Institutional Responsibilities</strong></td>
<td>Research, teaching, administration, etc.</td>
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<tr>
<td><strong>Investigator</strong></td>
<td>Researcher who is independently responsible for design, conduct, or reporting of research</td>
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<td><strong>Designated Official</strong></td>
<td>Helps determine if SFI is fCOI</td>
</tr>
<tr>
<td><strong>Institutional Official</strong></td>
<td>Vice President for Research, responsible for COI policy</td>
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Key Partners

- OSATT
- RAS
- TLO
- VPR Conflict of Interest
- DLCI heads and administrators
- Deans’ Offices
- Office of Graduate Education
- Make Informed Decisions
- Protect Students & Educational Mission
- Collaborate 2 Innovate
- Reduce Administrative Burden
- Maintain Research Integrity

Key Partners
The 4 “P’s” critical in COI

- **People**
  - People are the drivers in fundamental research. Researchers have devoted their lives to this endeavor, therefore understanding the end goal of the researcher is a critical starting point.

- **Policy**
  - Policy is not what constrains us but what provides the structure to enable us to reach the end goal. Important to read the COI policy and ask questions.

- **Process**
  - Process implements the policy to gather and review information at key stages, determine appropriate steps to achieve the end goal: how to manage; what to change/eliminate; appropriate transitions; maintain separation…

- **Partnerships**
  - Partnerships with key MIT offices enable more balanced and mindful decisions. Many of our management strategies are ‘bespoke’, not a one-size-fits-all approach!
An Investigator’s first and primary responsibility is to support and advance MIT’s mission, rather than to advance his or her personal financial interests.

Research must be undertaken to advance scholarship and new knowledge and not an Investigator’s or the Investigator’s Family’s personal financial interest.

An Investigator must not attempt to influence the activities of colleagues and subordinates with the intent of enhancing the Investigator’s or the Investigator’s Family’s financial interests.

MIT’s resources, names and trademarks may not be used for personal benefit.

Investigators may not accept research sponsorship or gifts, in support of the Investigator’s Institutional Responsibilities from a for-profit privately-held Related Entity.

Investigators may not involve a student for whom the Investigator is a thesis supervisor in the Investigator’s Outside Professional Activities.

Investigators may not negotiate with MIT on behalf of a Related Entity, or negotiate with the Related Entity on behalf of MIT.

Investigators may not promote the use of products or services of a Related Entity in the course of the Investigator’s Institutional Responsibilities.
Outside Professional Activities (OPA)

Assesses Conflicts of Commitment with respect to Institutional Responsibilities: **TIME**

- Usually measured in time, disclosed via the annual OPA report; applies to MIT employees (faculty, staff) not students
- MIT faculty, staff and researcher ranks have prescribed consulting privileges
- Faculty disclose relationships with students, staff and use of MIT resources in carrying out OPA
- Prospective discussions with department heads prior to engaging in consulting, start-ups, engaging students and staff in OPA’s
- President owns policy

Financial Conflicts of Interest in Research (FCOI)

Assesses Financial Conflicts of Interest which could impact your MIT research: **MONEY**

- Usually measured in money disclosed via the COI disclosure on a rolling basis and proposal stage; applies to anyone who is responsible for the design, conduct or reporting of MIT research (Investigator)
- Disclose relationships (consulting, start-ups) based on financial thresholds (SFI’s), and relationship to awards
- DLC heads play key role in assessing COI risk
- Management plans put in place for those FCOI’s which can be effectively managed
- VPR owns policy
OK: Activities/Relationships which do not directly and significantly impact your ability to conduct your MIT research and educational responsibilities

- Institutional responsibilities
  - Service on MIT committees, uncompensated publication review, conferences, etc

- Consulting (“separate and distinct” between ongoing MIT research and consulting activities, OK to talk about published research results)

- Starting companies (no “direct”, “active” or “significant” line management responsibilities)

- Serve on SAB’s

Not OK: Activities/Relationships which could pose a risk to:

- Reputaion of MIT/researcher
  - Think long term, reputation hard to (re)build!

- Integrity of MIT’s educational mission
  - Students are here to graduate on time, post-docs are here to train, faculty are here to teach and mentor

- Sponsored research funding (industry and other sources)
  - Research integrity and transparency is critical to building sponsor relationships

- Ability of staff/subordinate to carry out institute responsibilities
  - We’re here to support MIT’s mission not ensure an individual’s/company’s financial success

- MIT IP
  - Do not want to compromise IP rights and obligations related to MIT research

Mitigating risk is important—timely discussions and communications with the Department Head and COI Officer to help think things through can be an effective means of mitigating risk. Informed decision making is the goal!
How COI disclosures are made?

1. Do you have a Significant Financial Interest (SFI) in this sponsor? A SFI is defined as salary, consulting, or other remuneration of $5,000 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; or stock holdings in a company that is related to your area of research, and exceeds $100,000?
   - Yes
   - No

2. Could the work contemplated in this project reasonably appear to affect a company or other organization in which you have a SFI?
   - Yes
   - No

3. Does this project contemplate any purchases from or subawards to a company or other organization in which you hold a SFI?
   - Yes
   - No

4. If the sponsor for this proposal is Federal - Have you lobbied, or are you aware of anyone who has lobbied government officials in support of the project?
   - Yes
   - No

5. If you have not already done so, please read the policy before you Create or Revise a disclosure as you will be asked during the disclosure process to certify that you have read the policy and understand it.
Under MIT policy, **all Investigators are required to disclose SFI’s**. An **Investigator** is an individual who is *independently responsible* for the design, conduct or reporting of research - usually only the PI and Co-PI but also a Key Person.


An Investigator is solely responsible for the content and certification of the disclosure. MIT’s COI disclosure module does not allow proxies.
All SFI’s: A financial interest that meets any of the criteria for significance set forth below and is received or held by the Investigator and/or his or her Family:

- Aggregate of Remuneration $5K from U.S. or foreign publicly traded entities, U.S. or foreign privately held entities, U.S. or foreign non-profit entities and foreign governmental/academic institutions or organizations
- Equity Interests $5K in U.S. or foreign publicly traded entities if entity sponsoring your research
- Equity Interests $100K in U.S. or foreign publicly traded entity if entity’s business appears to be related to your Institutional Responsibilities
- ANY Equity Interest in a U.S or foreign privately held entity (your start-up for instance, regardless if value of shares is $0!)
- Income $5K received from IP rights from entity other than MIT
- Sponsored Travel (PHS Investigators only) is considered an SFI and counts towards aggregate

What needs to be disclosed?
Required to disclose “Sponsored Travel” which means all travel which meets the definition is now considered an SFI. Looking back 12 months at time of proposal and ‘running’ thereafter.

- Just travel (hotel, meals, transportation, etc...)
- If aggregate per entity adds to $5k over last 12 months
- Travel and consulting
- If aggregate per entity adds to $5k over last 12 months
- Travel by Investigator and his/her Family
- Investigator completes a separate disclosure for each traveler ‘type’

“Sponsored Travel (applies only to PHS Investigators) means (a) travel expenses paid to an Investigator or travel paid on an Investigator’s behalf, by a single entity in any 12-month period and (b) travel reimbursed to or paid on behalf of an Investigator’s Family by a single entity in any 12-month period ONLY if such travel reasonably appears to be related to the Investigator’s Institutional Responsibilities. See the PHS Addendum for more information.”
What does not need to be disclosed

- Any Remuneration from MIT (salary, royalties)
- Any Remuneration from authorship of academic or scholarly works, regardless of the source
- Remuneration from seminars, lectures, or teaching engagements sponsored by, or from advisory committees or review panels for, U.S. Federal, state, or local governmental agencies; U.S. institutes of higher education (e.g. Whitehead Institute and Broad Institute); U.S. research institutes affiliated with institutes of higher education, academic teaching hospitals, and medical centers
- Equity Interests in or income from investment vehicles, such as mutual funds and retirement accounts (401K) in which you don’t directly control the investment decisions
- Any travel paid through MIT (from grants, or other sources)
An Investigator need not disclose Sponsored Travel paid for or reimbursed by:

- MIT (e.g. paid from MIT funds or from sponsored awards funds managed at MIT)
- U.S. Federal, state or local governmental agencies
- U.S. Institutes of higher education
- U.S. Research institutions affiliated with institutions of higher education
- U.S. Academic teaching hospitals and medical centers
COI Review Process

SFI Disclosed in Coeus → COI Officer Reviews → COI Officer Approves

Designated Official Reviews to help determine relatedness

Designated Official can be either the Conflict of Interest Officer or, in complex cases, a faculty member appointed to the role by the Investigator’s Department, Lab, or Center Head; School Dean
Red light! A few complex disclosures will rise to level of FCOI and will require a management plan to be drafted with help of COI Officer, Investigator and Designated Official (to help determine relatedness).

Yellow light! A small number of disclosures may require more details, will work with Investigator to further understand issues presented.

Green light! All disclosures reviewed in confidence by COI Officer, majority will be approved on first review.
An SFI is not automatically an fCOI

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

Related?
- Is the SFI related to his/her research at MIT?
- If yes, then ask...

FCOI?
- Could the SFI directly and significantly affect the design, conduct or reporting of the research?
- If yes, manage or eliminate the conflict (real or perceived)

Disclosures submitted
  SFI's reported
  fCOI's
  Managed or eliminated
1) Research investigator receiving intellectual property-related royalties (e.g., patented medical device) or otherwise holding rights on IP (e.g., patent) that is involved in the research (usually assessed or improved)

2) Research investigator receives compensation from or has equity (e.g., stocks or stock options) in an entity that is interested in or involved in the research (usually sponsoring it or providing resources)
Proposal Stage
COI Screening questions & disclosure
What is the Kuali Coeus/COI Connection?

1. Do you have a Significant Financial Interest (SFI) defined as salary, consulting, or other remuneration of $5,000 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, or stock holdings in a company that is related to your area of research, and exceeds $100,000?
   - Yes
   - No

2. Should the work contemplated in this project reasonably appear to affect a company or other organization in which you have a SFI?
   - Yes
   - No

3. SFI Screening Questions replies from KC
Create Proposal in KC / Notify Key Personnel cont’d

Three of the certification questions are SFI screening questions: 10, 11, and 12:

10. Do you or a Family member have a Significant Financial Interest in this sponsor? A Significant Financial Interest (SFI) is defined as salary, consulting, or other remuneration of $5,000 or more (received from an entity other than MIT), 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; or stock holdings in a company that is related to your area of research, and exceeds $100,000. Family is defined as your spouse or domestic partner and dependent children.

11. Could the work contemplated in this project reasonably appear to affect a company or other organization in which you or a Family member have a SFI?

12. Does this project contemplate receiving/using any materials/data (data sets, confidential information) or making any purchases from or subawards to a company or other organizations in which you or a Family member hold a SFI?

13. If the sponsor for this proposal is Federal - Have you lobbied, or are you aware of anyone who 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.
Proposal Stage

Create proposal in KC
Notify Key Personnel (PI)
PI (KP) answers 3 COI-specific certification questions
If PI (KP) answers yes to any COI certification question, CA triggers COI review
COI Officer Preliminary Review
CA submits proposal

Legend
- Department responsibility
- PI responsibility
- CA responsibility
- COI responsibility

PI makes changes to the proposal if required.
If you have additional COI questions, please contact coi-help@mit.edu
February 7 10:00 – 11:00 am Register on Atlas
How to meet COI requirements at Proposal and Award stage:

• Sponsor and Solicitation specific requirements
• Non-MIT personnel (does not have an MIT Kerberos)
• KC personnel roles and certification requirements
• Award hold for COI requirements
Financial Conflicts of Interest in Research

MIT has a responsibility to generate positive learning opportunities for its students, preserve the integrity of the research enterprise and gain and maintain the public's trust. A robust process for discussion, disclosure, and management of real or perceived conflicts of interest (COI) is an important part of meeting that responsibility.

Online resources: www.coi.mit.edu
We are providing a **QR Code** for you to access a **RAS-ED feedback survey** via your phone or mobile device.

I will also provide the link [https://mit.co1.qualtrics.com/jfe/form/SV_6SxzH2KJW SKXCyq](https://mit.co1.qualtrics.com/jfe/form/SV_6SxzH2KJW SKXCyq) to access the form via the web and in a follow up email.