Agenda

• Where we left off in Workshop 1
  – Who is an Investigator
• Conflicts of Interest Policy
• Changes in Proposal Process
  – Timeline
  – Who needs to Certify
  – New Certification Process and Questions
• New Award Process
• Training Requirements
Outstanding questions from Workshop 1

• When does the policy take effect?
• Who does it apply to?
• Process and timing for Key Person verification?
• System questions?

• What do you want to be sure we cover today?
Definition of Investigator

MIT policy defines Investigators as those individuals who are *independently responsible* for the design, conduct and reporting of research. The definition of senior/key person and Investigator are closely related. When determining whether an individual should be listed as a senior/key person, PIs should consult the guidance provided in the MIT Investigator Matrix [http://osp.mit.edu/compliance/new-conflict-of-interest-policy/who-is-an-investigator](http://osp.mit.edu/compliance/new-conflict-of-interest-policy/who-is-an-investigator)
COI Policy Changes (for ALL Investigators)

- All PI’s disclose for all proposals
- New definition of SFI for MIT
  - Threshold decreases from $10K to $5K for all
  - Less reporting of stock – limited situations
- 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
What is a Significant Financial Interest (SFI)

- A Significant Financial Interest is a financial interest received or held by an Investigator, alone or in combination with his or her Family (and not expressly excluded below), which exceeds $5,000 in the form of:
  - Payment for services (e.g., consulting, Board positions, or shares when they are provided in lieu of services)
  - Any equity from a privately held company
  - Stock in a publicly traded company, but only when:
    - the company sponsors your research, or
    - the company’s business reasonably appears to be related to your research, and the stock value is > $100K
A SFI Does Not Include

• Remuneration from MIT;
• Remuneration from authorship of academic or scholarly works;
• 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; U.S. research institutes affiliated with institutes of higher education, academic teaching hospitals, and medical centers; and
• Equity Interests in or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions for these vehicles.

Foreign institutions are not excluded!
A Financial Interest is not a Conflict of Interest

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

- **Related?**
  - Is the SFI related to your research at MIT?
  - 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
Disclosure and Review Process

All Investigators

Investigator discloses SFIs, describes how it is or is not related to his/her research

Designated Official considers Investigators disclosure, determines whether the SFI is related to the research; and where it is related, submits disclosure to COI Committee

COI Committee reviews disclosure and determines if there is a FCOI, makes recommendations to Institutional Official as to whether it can be managed

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”

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

Conflict of Interest Officer

Department Lab or Center Head
What is a Financial Conflict of Interest (FCOI)

- Financial Conflict of Interest means a Significant Financial Interest that MIT reasonably determines could directly and significantly affect the design, conduct, or reporting of research.
  - # SFIs disclosed, only # cases need management
Transition Timeline

Up until 8/14
Paper, email and Coeus proposals accepted in OSP.

8/15
All proposals in Coeus. Current Coeus Certify and COI process (DLC uploads signed Cert) PI uses current COI module

8/20
New Self-Certification and COI process turned on (PI, etc. to self-certify/disclose in Coeus) details to follow…
Compliance with Minimum Burden Possible

- PIs, Co-PIs provide proposal information electronically, upfront – **PI Certification in Coeus** – no more paper – for all proposals
  - COI screening questions will satisfy the NIH and NSF requirements most of the time
  - Only the PI can answer these questions – certificate based
  - Proposal Certification can be completed at any time after your department initiates a proposal in Coeus
- Please tell your department administration about proposals early in the process so you’ll have plenty of time to complete the proposal certification
Compliance with Minimum Burden Possible

• New COI disclosure module for annual disclosures and full proposal and award disclosures, when needed
• Faculty Advisory Committee on COI reviewed the screens, provided feedback, we revised and improved
• Next opportunity – combining OPA and COI disclosures before the next annual OPA process
• Master Disclosure, updated at least annually
Changes to Questions and COI

- New Proposal Certification questions will need to be completed by the Investigator online, in Coeus Lite.
- Proposal Certification questions now include several COI screening questions and, when completed, constitute a disclosure.
- If a potential conflict is identified in any of the screening questions (the Investigator answers “Yes”), a complete disclosure is required.
- Proposals cannot route to OSP until Certifications and Disclosures are complete.

Note: There Are No Proxy Certifications
Who is required to Certify and Disclose?

NIH
- Principal Investigators, Co-Investigators and Key Persons need to certify.
- Exceptions: Subaward Investigator, Other Significant Contributor and Consultant will NOT be required to certify.
  - These roles must be entered exactly as shown here, so the system will exclude them.

NSF
- Principal Investigators and Co-Investigators
Who is required to Certify and Disclose? (cont’d)

• For Solicitation-specific COI requirements:
  – This is a work in progress
Who is required to Certify and Disclose? (cont’d)

• Principal Investigators, Co-Investigators, Key persons who are not MIT employees are also required to complete certification in Coeus Lite
  – DLC will need to sponsor the PI/Co-I/Key Person to get them a kerberos and certificate
  – To do this they will need to submit this IS&T form in advance: http://ist.mit.edu/accounts/guest
SCREENSHOTS: CHANGES TO PROPOSAL PROCESS
Notifying Investigators to certify – Coeus Lite
Notifying Investigators to certify – Coeus Premium

1. Send Certification Request

2. Select Investigator(s) and Send

3. All Notifications are Sent.
Investigator Certification

Please certify the proposal by clicking on the following link: PI: Levin, Walter H G Lead Unit: 155600; Kavli Inst for Astrophysics and Space Research Proposal Number: 80012419

Sponsor: NASA - Washington (USE FOR PROPOSALS ONLY) Deadline Date:

Title: The Physics of Space

Sponsor Announcement:

You have been named as investigator for the above referenced project. Please use the link given below for the project details.

https://coeus-dev.mit.edu/coeusdl/proposalPersonsCertify.do?proposaNo=00012419&personId=00000716

Please select the link below to update COI information.


CoeusLite requires an MIT personal web certificate.

For information about obtaining MIT personal web certificate please go to http://web.mit.edu/a/help/cert/
Proposal Specific Certification Questions

• Is your current space sufficient to carry out this project, and those already proposed?
• 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?
• Will you need to appoint individuals in a department, lab or center other than the one submitting this proposal?
• Will you need to appoint visitors at MIT in order to carry out this project?
• Will you use animal subjects?
• Will you use human subjects?
Export Control Certification Questions

- Will you receive any information, software or equipment that require restricted access or use by researchers of some nationalities?
- Will any part of this project be performed outside of the US? (Including subaward arrangements, but excluding attendance at conferences)?
- Will you ship equipment, materials or information including software, outside the US?
COI Screening PI Certification Questions

• If the sponsor for this proposal is Non-Federal – Do you have any financial relationship with this sponsor (e.g. consulting, board position, salary)? If this is a non-publically traded company, any equity is considered a financial relationship.

• 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?
COI Screening PI Certification Questions

• 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 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-publically traded company.
For Federal Sponsors Only Certification Question

- For Federal Sponsors – 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.
Final Certification Question

• The information that I have contributed to this proposal is true, complete and accurate to the best of my knowledge. I understand that federal sponsors reserve the right to impose criminal, civil or administrative penalties for false, fictitious or fraudulent statements included in this proposal. I agree to accept responsibility for the scientific conduct of the project, including providing reports to the sponsor, as required. If this proposal includes a subaward to another organization, I confirm that subaward costs appear reasonable given the statement of work.
Viewing PI certification answers and impact on Yes/No questions
Proposals cannot be routed for approval until...

- All PIs, Co-Is and Key Persons have completed online proposal certification
- Full COI disclosures have been submitted (when required because an Investigator answered “Yes” to one of the COI screening questions)
- There is an inconsistency between special review answers in the proposal and the answers in the certification questions
- Other Proposal Validations (NSF Code missing, Award # missing from Renewal, Revision, Continuation, etc.)
How Certifications will be completed

• Proposal Aggregators will “Send Certification Request” to Investigator/Key Persons from the proposal in Coeus
• Investigators and Key Persons will receive a Certification notification email with a link directly to Coeus Lite and the certification questions
• If a potential conflict is identified in any one of the COI screening questions a more complete disclosure is required. A link to My COI will be provided
New Award Process

• New and continuation awards with *Issue Dates* on or after August 24, 2012 will be put in hold until
  – Key persons are verified (confirmed, removed)
  – PIs, Co-Is, and key persons complete training
  – PIs, Co-Is, and key persons complete full COI disclosure; COI Officer review is complete
  – All other existing hold issues are resolved
    • pending protocols, cost sharing template, etc.)

Plans underway to initiate award setup during JIT
Mandatory Investigator Training Requirement#

• Required before an Investigator begins work on the project

• Provided through CITI – Takes 45-60 minutes

• 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)

Retraining requirement every four years
Mandatory Investigator Training Requirement

- Training records feed from CITI to SAP Enterprise Learning and Coeus nightly
- My Awards will be updated after initial upgrade to display training and disclosure completions
- Email notification of training requirement and how to access training will be sent to key persons who have been ‘confirmed,’ PIs and Co-Is when CITI modules are available
- After initial implementation, key persons will receive automated email immediately upon ‘confirmation’
My COI Module System Demo

MIT policy requires that MIT officers, faculty, and staff and others acting on its behalf avoid, ethical, legal, financial, and other conflicts of interest and ensure that their activities and interests do not conflict with their obligations to MIT. Disclosure of financial interests enables MIT to determine if a financial interest creates a conflict of interest or the appearance of a conflict of interest. The existence of a conflict or the appearance of one does not imply wrongdoing and does not necessarily mean that a researcher may not retain his or her financial interest and undertake the affected research. Often MIT can work with the researcher to manage a conflict or the appearance of a conflict so that the research can continue in a way that minimizes the possibility of bias and preserves the objectivity of the research. Proper management depends on full and prompt disclosure.

My COI provides the ability to disclose and maintain your Significant Financial Interests; identify potential areas of concern related to your proposals and awards; and, disclose reimbursed travel (for NIH compliance).

### Significant Financial Interest (SFI)

An Investigator must disclose any new Significant Financial Interest within a reasonable period (generally 90 days) following the date on which the Significant Financial Interest is acquired or arises.

In this section, you can disclose new SFI as well as view, edit, and make "inactive" any existing SFI.

#### Master Disclosure

Investigators must disclose their Significant Financial Interests annually. During the annual disclosure process you must complete four steps:

- Answer Screening Questions
- Review and update all SFIs
- Describe how your projects are related to your SFIs
- Certify the information is complete

As of August 15, 2012, you must create a Master Disclosure. Once the Master Disclosure has been reviewed, the grayed out options below will become available and you can view or update your Master Disclosure.

#### Create Annual Disclosure

- View Completed Master Disclosure
- Revise / Update Master Disclosure

#### Travel Disclosures (NIH only)

NIH Investigators must disclose travel paid on his/her behalf (either directly or through reimbursement) related to his or her Institutional Responsibilities within 30 days, unless the travel is reimbursed by: MIT; U.S. Federal, state or local governmental agencies; U.S. Institutes of higher education; U.S. Research institutes affiliated with Institutes of higher education; and U.S. Academic teaching hospitals and medical centers.

Travel paid by for-profit entities, foreign governments, universities and research institutes or non-profit organizations that are not U.S. Institutes of higher education must be disclosed.

#### Create New Travel Disclosure

- View Completed Travel Disclosures

### New Proposal Disclosures

Prior to submitting a proposal for funding, Investigators must answer a few Conflict of Interest Screening questions. If the answers to any of those questions indicate a need for follow up, Investigators are directed to create a full proposal specific disclosure within My COI.

#### Create New Proposal Disclosure

- New Award Disclosures

When an award is received for which the Investigator has not completed a full proposal disclosure, he or she must create a new award disclosure (for those sponsors that require COI disclosures). Additionally, when an Investigator joins an existing research project, he or she must create a new award disclosure and disclose any existing Significant Financial Interests prior to commencing participation.

#### Create New Award Disclosure

View or Edit a Disclosure in Process

A disclosure in process is one that:

- You started but were unable to finish
- You completed (master, proposal, award, or travel), but has not yet been reviewed

The disclosures will be separated into disclosures that can be viewed and those that can be edited. If you need to edit your Master Disclosure after it has been reviewed, select "Revise/Update Master Disclosure".
Annual Disclosure

CoeusLite

Disclosure View

Step One
Screening Questions

Step Two
Significant Financial Interests

Step Three
Relationships

Step Four
Certify

MY COI Home

Financial Disclosure by Haskell, Edward
Name: Haskell, Edward
Department: 150001.Center for Coeus Training
Faculty: Yes

User Name: eddieh
Phone: 617-2531000
Email: eddieh@mit.edu

Step One: Screening Questions

You answer “No” to all of the questions, your disclosure will be complete and you will be taken to Step Four for final certification.

You answer “Yes” to any of the questions, you will need to complete Step Two, Significant Financial Interest, and Step Three, Relationships.

Continue
My COI Disclosures

• Create Annual / Master Disclosure as first disclosure
• Proposal and Award Disclosures follow four step process similar to Annual Disclosure
• Annual Disclosure:
  – Step 1: Screening Questions
  – Step 2: Significant Financial Disclosure
  – Step 3: Relationships
  – Step 4: Certify

• Note: Once you “Create” a new disclosure, you must use the View or Edit a disclosure in Process button to modify and certify for review.
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
Travel Disclosure in My COI

<table>
<thead>
<tr>
<th>Travel Disclosure by Haskell, Edward</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong> Haskell, Edward</td>
</tr>
<tr>
<td><strong>User Name:</strong> eddieh</td>
</tr>
<tr>
<td><strong>Department:</strong> 150001:Center for Coeus Training</td>
</tr>
<tr>
<td><strong>Faculty:</strong> Yes</td>
</tr>
<tr>
<td><strong>Phone:</strong> 617-2531000</td>
</tr>
<tr>
<td><strong>Email:</strong> <a href="mailto:eddieh@mit.edu">eddieh@mit.edu</a></td>
</tr>
</tbody>
</table>

Please enter the following information for your trip (Note: travel reimbursed through MIT does not need to be disclosed under PHS policy)

- **Trip Name:**
- **Destination:**
- **Purpose of Travel:**
- **Organization Reimbursing or Sponsoring Travel:**
- **Duration (days):**

[Continue]
Disclosure process becomes ongoing

• New SFIs must be reported within 30 days
• Travel disclosures must be reported within 30 days
What Do PIs need to do?

- **August 7**
  - Review new COI policy
  - [http://coi.mit.edu/research](http://coi.mit.edu/research)

- **August 15**
  - ALL PIs

- **August 20**
  - Complete Master COI disclosure prior to new proposal submission

- **September 4**
  - Online PI Certification & Disclosures for all proposals

- **NIH PIs**
  - Complete Master COI disclosure prior to receipt of new or continuation funding or new proposal submission
  - Online PI Certification & Disclosures for all proposals
  - Complete CITI training on PHS COI regulations prior to receipt of new or continuation funding

*Necessary to bring them into the Annual/Master disclosure process*
Important Dates and Next Steps

- Coordinate with your PIs to complete key person verification (ideally by 8/20)
- Establish a process for ongoing key person maintenance in your area
- Encourage your PIs & key persons to complete their Master/Annual as soon as the system goes live
- Encourage your PIs & key persons to complete their CITI training (when available)
Where to go for help

• Ask your contract administrator…
  – Questions about prior approvals and changes in key person effort
  – Applicability of the new regulation
  – Proposal preparation and routing and approval questions
  – Award setup questions
• COI-help@mit.edu (Rupinder, Michelle and Tom D)
  – Questions about the Conflict of Interest Policy
• Coeus-help@mit.edu
  – System issues and authorizations

Keep lines of communication open – let us know what questions you have or what we can do to help
QUESTIONS?