Agenda

PART I
- New Conflict of Interest Policy

PART II
- Proposal Prep changes
  - New Certification Questions
  - PI Self Certification
  - Validations and Routing Preventions
  - Approval
  - Resources Available
- Next User Group meeting
- Q&A
New MIT Conflict of Interest Policy

- All PIs disclose for all proposals
- New definition of SFI for MIT
  - New SFI disclosure threshold ($5,000)
  - Reporting of publicly traded stock decreases (only disclose when the value of equity interest exceeds $100,000 and there reasonably appears to be a relationship between the business and the Investigator’s research)
- Designated Official
- COI Officer
A financial interest received alone or in combination with his or her spouse and/or dependent children that reasonably appears to be related to the Investigator’s institutional responsibilities.
Disclosure and Review Process

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.
Process for Determining fCOI

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

- Is the SFI related to PHS funded research?
  - If yes, then ask …

- 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
PART II: Proposal Preparation Changes

Agenda:
- Changes to Certification Questions and COI
- Who is required to certify and disclose?
- How to Certify/Disclose
  - For Aggregators
  - For investigators and key persons
- Routing Preventions
  - COI Disclosure Status
- Proposal Review and Approval
- Helpful Hints/Resources
Proposal Preparation Changes

- **Changes to Certification Questions and COI**
  - Proposal Certification Questions previously done by proxy are no longer available to be done “by proxy” (possible future enhancement).
  - Content of Certification Questions is also changing to now include several COI screening questions which when completed constitute a disclosure.
    - HOWEVER, if a potential conflict is identified in any one of the screening questions a more complete disclosure is required. The certifier will be presented a link to the new COI module.
    - This means, no more YNQ – all questions are now in Certification except YNQ 33 – re-route will be a Questionnaire presented when re-routing.
  - **NOTE**: Proposals cannot route to OSP until Certifications and Disclosures are complete.
  - New Questions
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?
New Certification Questions (cont’d)

- 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 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-publicly 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.
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.
Who is required to Certify and Disclose?

- **For NIH:**
  - All investigators, Co-Investigators, and *NIH key persons* **EXCEPT:** “Subaward Investigator,” “Other Significant Contributor” and “Consultant” will be required to certify.
  - **NOTE:** System looks for exact spelling of these terms above!
  - They must now **self-certify** in Coeus Lite (How, in a minute…)
    - **NOTE:** Certifying in lite requires MIT Certificates. Any **non-MIT** investigators, Co-Investigators, and NIH Key Persons will be 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](http://ist.mit.edu/accounts/guest)
Who is required to Certify and Disclose?

- For all other sponsors **right now**:
  - All Investigators and Co-Investigators
  - These people must now **self-certify** in Coeus Lite (How, in a minute…)
  - **NOTE:** Certifying in Coeus Lite requires MIT Certificates. Any non-MIT Investigators, Co-Investigators as described above will also be required to complete certification in Coeus Lite.
    - DLC will need to sponsor the PI/Co-I 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](http://ist.mit.edu/accounts/guest)
How to Certify/Disclose

- Aggregators will no longer be able to certify by proxy
  - Signed Certification uploads are no longer required
- Aggregators will now “Send Certification Request” to Investigator/Key Person from the proposal in Coeus
- Investigator/Key Persons receive the Certification Request email, access Lite system via link provided, Complete questions presented themselves
- Aggregators may submit/route proposals for approvals ONLY once certifications (& disclosures if necessary) are complete
How to Certify/Disclose

Aggregator actions in Lite:

1. Proposal Summary
   - General Info
   - Organization
   - Investigators/Key Persons
   - Credit Split
   - Special Review
   - Abstract
   - Science Code
   - Others
   - YNQ
   - Proposal Roles

2. Questionnaire
   - Test Questionnaire

3. Grants.Gov
   - Budget
   - Upload Attachments
   - Submit for Approval

4. Print
   - Delete Proposal

- Investigator: Hensler, Judith
- Agency/Sponsor: 000590 : NSF
- Title: KD Test of PI self Cert
- Proposal #: 00012467 (In Progress)
- Proposal Period: 05/01/2015 - 05/31/2016
- Deadline Date:

Investigators/Key Study Personnel Details
- Investigator/Key Study Personnel Name is a searchable field, it cannot be entered.
- Unit is required for Key Person Role is required.
- Employee Search
  - Name: [Select: All | None]
  - Last Notification:

Send Certification Request
- Select: Hensler, Judith
- Send
- Close

List of Investigators/Key Study Personnel
- Name: Hensler, Judith
- Department: Mechanical Engineering
- MPI Role: Principal Investigator
- % Effort:
  - T: 0.0
  - A: 0.0
  - S: 0.0
  - C: 0.0
- Certify

COI Disclosure Status
- Remove
- Details
How to Certify/Disclose

Aggregator actions in Premium:

1. Click on "Action" and select "Send Notification".

2. Select the individuals (Haskell, Edward and Hensler, Judith) and check their names.

3. Click "Send" to send the notifications.
Aggregators will receive email notifications (as long as notifications are “on” or may check system for completion:}
Proposal Prep Changes

- **Investigator Actions:**
  1. Follow Link
  2. Answer certification questions in Lite

- Message from webpage:
  The "PI Proposal Certification Questions" questionnaire is complete.
Proposal Prep Changes

- Key Person Actions:
  - Follow link in email notification and answer certification questions in Lite (notice they are the COI screening questions).
Proposal Prep Changes

- If a potential conflict is identified in any one of the screening questions a more complete disclosure is required. Link to COI will be provided. (COI Demo in a minute)
Proposal Prep Changes

- Proposals cannot be routed for approval until...
  - All PIs, Co-Is and NIH 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) (COI status check next slide…)
  - 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.)

- Changes to System Validations
  - Signed Certification upload no longer required
COI Disclosure Status

<table>
<thead>
<tr>
<th>Person Name</th>
<th>Role</th>
<th>COI Disclosure Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lewin, Walter H G</td>
<td>Principal Investigator</td>
<td>Review-In-Progress</td>
</tr>
<tr>
<td>Hansman Jr, Robert J</td>
<td>Co-Investigator</td>
<td>In-Progress</td>
</tr>
</tbody>
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Proposal Prep Changes
### Proposal Review and Approval

This screen is now available from the left hand navigation menu prior to routing as well.

*Note: Full Proposal Details link

*Note: Red text
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…
Helpful Tips

- **Talk with your Investigators**
  - Ask your Investigators about upcoming application deadlines
  - Ask about their travel plans…
    - If they are not available to certify a proposal it will not route
  - Confirm Investigators and key people have MIT certificates on their computers
    - If they are not able to certify a proposal it will not route

- **Initiate Proposal as early as possible**
  - capture Investigators/Key people early
  - send Certification Requests early

- **Remember, tomorrow, 8/15/12 - no more paper proposals accepted by OSP**
Getting 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 Grewal, Michelle Christy and Tom Duff)
  - Questions about the Conflict of Interest Policy
- Coeus-help@mit.edu

Keep lines of communication open – let us know what questions you have or what we can do to help
Proposal Quickcards - Coming soon!

For Aggregators:
- Coeus Lite and Premium: Investigator/Key Person Notify
- System Validations – update

For Investigators:
- Proposal Certify/COI Screening questions

For Approvers:
- Coeus Lite: Proposal Review and Approval

COI Quickcards – Also Coming soon!
Next User Group Meeting

- Repeat of Today’s Presentation
  - August 22\textsuperscript{nd}, in Singleton Auditorium (46-3002) from 1:30pm – 2:30pm

- Announcements via Coeus-User-Group mailing list

- SEPT 12, 2012 Coeus Lite Non-grants.gov Proposal Prep class to be given
Q & A

Questions?

Email coeus-help@mit.edu

Sign up for the coeus-user-group mailing list: http://osp.mit.edu/coeus/help-and-training/user-group/mailing-list