NIH Conflict of Interest Workshop 1

July 26, 2012
August 1, 2012
August 7, 2012
Agenda

• The When:
  – When do these regulations take effect?

• The Who:
  – Definition of Investigator
  – Definition of Key Person
  – Relationship between Investigator and Key Persons
  – Resources and Questions

• The How:
  – Reviewing and tracking Key Persons
    • In preparation for COI annual disclosure process
    • On ongoing basis prior to new appointments and salary distributions
    • Changing Key Person effort with NIH
    • System demo of My Awards Module and Key Person Maintenance
When do the regulations take effect?

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
Note the Issue Date

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Issue Date: 08/24/2012

Grant Number: XXXXXXX

Principal Investigator(s):

Project Title: Synthesis and Study of Complex Natural Products

WILLIAM J. BARRETT
MASSACHUSETTS INSTITUTE OF TECHNOLOGY
77 MASSACHUSETTS AVENUE
E19-750
CAMBRIDGE, MA 02139

Award e-mailed to: nih-award@mit.edu

Budget Period: 08/01/2012 – 07/31/2013
Project Period: 08/10/2005 – 07/31/2014

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $333,540 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to MASSACHUSETTS
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.

“Key Person” = “Investigator”
Always an Investigator & Key Person

- Principal Investigator (PI) or Project Director (PD)
- Co-Investigator
- Graduate and Postdoctoral Fellows on Fellowships
  - Sponsor for Graduate and Postdoctoral Fellows
- Subrecipient PIs and Senior/Key Personnel
Never an Investigator & Key Person

- Graduate and Postdoctoral Fellows on **Training Grants**
- Other significant contributors (OSCs)
- Unpaid Collaborators
- Paid Collaborators at Other Institutions
May be an Investigator & Key Person

- Postdocs on research grants
- Graduate Students (RAs)
- Consultants
- Paid Collaborators at MIT

Lead PI must make the determination.
Investigator Matrix & Guidance Materials

• Take a look through the Matrix

<table>
<thead>
<tr>
<th>Title and/or Role</th>
<th>Senior/Key Personnel</th>
<th>Investigator</th>
<th>MIT Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI/PD Project Director or Principal Investigator</td>
<td>Always</td>
<td>Always</td>
<td>Includes multi-PIs.</td>
</tr>
<tr>
<td>Co-Investigator</td>
<td>Always</td>
<td>Always</td>
<td>Are named at the PD/PI’s discretion. Are involved with the PD/PI in the scientific development or execution of a project. May include research scientists, senior research scientists and senior postdoctoral associates, although this is not common. The designation of a co-investigator, if applicable, does not affect the PD/PI’s roles and responsibilities.</td>
</tr>
</tbody>
</table>

• Small groups: Compile list of questions/areas for clarification
• Large group: Question read-out, explanations from experts
Changing Key Person effort with NIH

Require Prior Approval

- 25% or greater reduction of effort of key person in Notice of Award

Report in Progress Report

- 25% or greater reduction in effort of key person in proposal
- Not named as key person by NIH

Prior approval for increase of effort not required.

NoA Section IV: Special Terms and Conditions

Treatment of Program Income:
Additional Costs

SECTION IV – EY Special Terms and Conditions – 5R01EY011289-27

FUNDING LEVEL
This award is issued in accordance with the NIH fiscal policies described in NIH Guide Notice NOT-OD-12-036.

SALARY CAP
None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the applicable salary cap. Current salary cap levels can be found at the following URL: http://grants1.nih.gov/grants/policy/salcap_summary.html

KEY PERSONNEL:
In addition to the PI, any absence, replacement, or substantial reduction in effort of the following individual(s) below, requires the written prior approval of the National Institutes of Health awarding component.
When to Review and Track Key Persons

- Now, beginning July 30 in preparation for the annual disclosure process that begins on August 15
- Prior to receipt of a new or continuation award
  - New JIT process
- On an ongoing basis whenever key persons change
Who can maintain key persons?

- All PIs and Co-Is will have access to view their awards through My Awards in CoeusLite
  - PIs have authorization to view/edit key persons through Key Person Maintenance functionality on their accounts
- DLC administrators at the Unit/Department level
SYSTEM WALK-THROUGH
# Access My Awards in CoeusLite

The image shows a section of a webpage with a table titled "Award List". The table contains rows for different awards, each with details such as Award Number, Account Number, PI, Lead Unit, Title, Sponsor, Status, Start Date, and Key Person Confirmed.

- **Award Number**: 020460-001
  - **Account Number**: 6988888
  - **PI**: Haskell, Edward
  - **Lead Unit**: 150001
  - **Title**: Theobromine and Dopamine Production
  - **Sponsor**: NIH
  - **Status**: Hold
  - **Start Date**: 2013/01/01
  - **Key Person Confirmed**: Yes

- **Award Number**: 020461-001
  - **Account Number**: 6976543
  - **PI**: Haskell, Edward
  - **Lead Unit**: 150001
  - **Title**: Elevating Phenethylamine Concentration through Coc ...
  - **Sponsor**: American Confectionery Society
  - **Status**: Active
  - **Start Date**: 2013/01/01
  - **Key Person Confirmed**: No

- **Award Number**: 020463-001
  - **Account Number**: 6777777
  - **PI**: Haskell, Edward
  - **Lead Unit**: 150001
  - **Title**: Theobromine Neurotoxicity Levels and Cocoa Consumption
  - **Sponsor**: NIH
  - **Status**: Hold
  - **Start Date**: 2013/09/01
  - **Key Person Confirmed**: Yes

The webpage also highlights that users can access their awards through CoeusLite by clicking on the "My Awards" tab. The "Award Search" and "Export to Excel" options are also visible at the top of the table.
Review the Award Summary to Confirm you have Accessed the Correct Award
Confirm Appropriate Key Persons

Add Key Person

Existing Key Persons

- Cleaver, Theodore
  - Unit No.
  - Unit Name
  - Title/Project Role: Remove, Confirm
- Mondello, Larry
  - Unit No.
  - Unit Name
  - Title/Project Role: Remove, Confirm
Remove Listed Personnel Who Are Not Key Persons
Adding a Key Person

**Add Key Person**

Name: Mondello, Larry
Title/Project Role: Research Scientist
Email: larrym@mit.edu
Unit: 150001
Unit Name: Center for Coeus Training
Phone: 617-2531000

**Existing Key Persons**

<table>
<thead>
<tr>
<th>Name</th>
<th>Unit No.</th>
<th>Unit Name</th>
<th>Title/Project Role</th>
<th>Confirm Timestamp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaver, Theodore</td>
<td></td>
<td></td>
<td>Senior PostDoctoral Associate Remove</td>
<td>2012-07-23 08:43:47 by eddieh</td>
</tr>
</tbody>
</table>
Confirm No Key Persons on Award

<table>
<thead>
<tr>
<th>Name</th>
<th>Unit No.</th>
<th>Unit Name</th>
<th>Title/Project Role</th>
<th>Confirm Timestamp</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Key Persons on this award</td>
<td></td>
<td></td>
<td></td>
<td>Confirm</td>
</tr>
</tbody>
</table>
Next Steps

• Setup departmental authorizations for Key Person Maintainer
  – AO/FO request via coeus-help@mit.edu

• Review departmental reports and determine process for coordinating with PIs

• Contact your Contract Administrator for assistance
Where to go for help

Workshop 1 Recap

- The When
- The Who
- The How
- Workshop 2: August 9 or August 13