Conflict of Interest

July/August 2012
Agenda

- Policy
- Business Process
- GMAS Changes
University COI Policy - Overview

• Approved May, 2010
• Revised May, 2012
• Applies to anyone with a faculty or teaching appointment
• University-wide Application, but:
  – Each School has its own Implementation Plan
  – In general, individuals disclose their financial interests to the School in which they have a primary appointment
• Each School has a COI Officer (DIO or “designated institutional official”)
Public Health Service COI Policy

- Published August 25, 2011
- Takes effect August 24, 2012
- Applies to all PHS investigators (more on that later…) who apply for or receive funding from PHS agencies:
  - NIH, CDC, HRSA…
  - At HU, will also apply to any other sponsor that uses the PHS regs:
    - American Heart Association
    - American Cancer Society
    - Arthritis Foundation
    - Susan G. Komen Foundation
    - Alliance for Lupus Research
  - and National Science Foundation
- Some requirements extend to subrecipients
What and when do individuals need to disclose?

Minimum internal disclosure requirements under University policy are the same as PHS disclosure requirements*

At least annually and within 30 days of a new interest; before submitting a proposal for funding:

• **Significant financial interests (SFIs)**
  – Income and equity over $5,000
  – Equity in private entities over $0
  – Fiduciary and management roles

• If the SFI is in an entity that relates to their University responsibilities (research, teaching, committee service etc.)

  **Schools review SFIs and decide which (if any) are CONFLICTS**

  Then, management…

  *with the exception of travel
Travel

- PHS investigators **ONLY**
  - Must disclose the **occurrence** of any reimbursed or sponsored travel (but not the $ amount) **within 30 days of travel**
  - Exceptions included travel as part of a grant and travel sponsored by an institution of higher education (and some others)
Two Policies, Similar Requirements, Different Populations

University Policy
Faculty and individuals with teaching appointments

PHS Policy
Anyone applying for or receiving PHS funding
All PHS PIs
+ PHS Investigators
In a nutshell

*University and PHS*

Annually and before submitting a proposal:

DISCLOSURES ON FILE

*PHS Only*

Disclose Travel and

Before spending award money:

DISCLOSURES REVIEWED
Systems Solutions

- **University Disclosure System** (fcoi.harvard.edu)
  - FAS, SEAS, GSD, GSE, HSPH, Divinity
  - Other schools:
    - Own electronic system / paper system; or
    - Will use fcoi.harvard.edu in the future

- **GMAS Upgrades**

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University System will feed key information to GMAS
Business Processes

• 1. Defining Investigator
• 2. Research Team
• 3. fCOI Disclosures
• 4. Proposal Submission
• 5. Sub-agreements
• 6. Account Set Up
• 7. At Risk/Advanced Accounts
• 8. Non-Harvard Personnel
• Summary
Issue #1: Defining “Investigator”

- “…the project director or principal investigator or any other person, regardless of title, who is responsible for the design, conduct or reporting of research funded by the PHS, which may include consultants or collaborators”

- **Primary:** PI makes the decision on who is to be considered an “investigator”

- **Secondary:** Department grant administrators/OSP
  - Note: OSP, School, or department reviewers may request clarification around investigator status

- **Key Points:**
  - The definition has not changed
  - Include anyone who makes a substantive contribution
  - TBDs cannot be considered key personnel at proposal stage
  - Anyone who is an investigator will need to disclose fCOI at proposal stage
  - Key persons should always be listed as investigators
  - Could be anyone on the Research Team, not just the key persons
Issue #2: Identifying the Research Team
Who Are They?

• **Primary:** Department/PI
• **Secondary:** OSP

• **Key Points:**
  – Research team defined at proposal and at award stage
  – Research team will need to be reconfirmed at award stage by Department
  – Identify investigators early in the process
  – All disclosures must be on file at submission and on file and reviewed prior to award set up
  – TBDs cannot be considered key personnel at proposal stage
Issue #3: fCOI Disclosure on ALL Submissions

- **Primary:** PI
- **Secondary:** School fCOI Designated Institutional Official
- **Key Points:**
  - All faculty should have annual disclosure on file
  - fCOI system will feed information on disclosure status to GMAS
  - Faculty must disclose before submission if they haven’t done so already for all sponsors
  - Listed investigators on PHS submissions must disclose and will be prompted through the system once identified in GMAS

No more PI cert! All disclosures managed through the new university fCOI system
Issue #4: Proposal Submission

What does OSP need before a proposal under the new regulations can be submitted?

• **Primary**: OSP

• **Secondary**: Department grant administrators

• **Key Points**: (to recap)
  
  – ALL investigator disclosures MUST be on file prior to submission, per regulatory mandate
  
  – Start identifying investigators early in the process
  
  – Alert OSP early if you anticipate challenges in this area
  
  – GMAS will integrate with University fCOI system once an investigator is identified
Issue #5: Subagreements

- **Primary**: Department grant administrators
- **Secondary**: OSP
- **Key Points**:
  - Subrecipients must verify in writing that their fCOI policy meets PHS regulations
  - If they do not have a compliant fCOI policy, relevant investigators must disclose through Harvard via PDF and be manually uploaded by DIO

Subagreements and submissions fall under the same standards as the prime
Issue #6: Award/Account Set Up
What does OSP need BEFORE it can set up an award?

• **Primary:** OSP
• **Secondary:** Department/PI, school fCOI official
• **Key Points:**
  – All investigators on the research team must have an approved fCOI disclosure in place before ANY money can be spent
  – Includes subs, consultants, others
  – GMAS will require confirmation of research team and relevant investigator status by department at award stage
  – Award will not be set up without all disclosures reviewed and finalized, per federal law
Issue #7: At Risk Accounts

What does OSP need BEFORE it can set up an at-risk account?

• Primary: OSP

• Secondary: Department/PI, school fCOI official

• Key Points:
  – At risk will be handled as stringently as full award set up
  – Accounts will not be set up until full and approved disclosures are on file
Issue #8: Individuals with No Harvard ID

• **Primary:** Department/PI
• **Secondary:** OSP
• **Key Points:**
  – May include post-docs, consultants, subs, key unpaid collaborators, other incoming PIs
  – Will be held to the same fCOI regulations as other investigators
  – Will disclose via PDF to the school DIO
  – DIO will upload into system and then GMAS will update as well
  – Allow time to collect manually before submission and at award stage
Summary of Business Processes

• Key Points:
  – Investigator disclosures now required
  – GMAS and university fCOI system will interface
  – Start the process early
  – Sub-awards and contractors must disclose as well
  – Start the process early
  – Awards CANNOT be set up without fCOI disclosure and FULL review
  – Investigators should be all key personnel as well as identified others, per the PI
  – Start the process early
Overview of GMAS Changes

GMAS will have a link to the FCOI system where faculty disclose their financial interests for review by COI Administrators

**Proposal Stage**
- New criteria for generating COI approval: PHS Investigator
- New COI approval screen
- COI-related notifications sent to research team members and COI Administrators

**Award Stage**
- Confirm research team after award notice is logged
- COI-related notifications sent to research team members, COI Administrators, and Department Administrators

You will see the changes in GMAS on August 20, 2012
Proposal Process

- Dept Admin
  - Creates request in GMAS
  - Adds research team members, indicating “investigator” as appropriate

- Investigator
  - Receives email notification to disclose/update in FCOI system

- DIO/COI Admin
  - Receive report to review “Needs review” approvals
  - Review all COI approvals, update status

- OSP/SPA
  - Once all COI approvals reviewed/appropriate status, proposals submitted
Proposal Stage - The COI Approval

• The COI approval will generate on PHS+ proposals if a research team member is:
  - Marked as PHS investigator
  - Marked as key personnel
  - Covered by the University COI policy

• Non-PHS+ Proposals
  - University area will only generate COI approvals for research team members who fall under the University Policy
  - HMS and SPH will generate COI approvals for research team members marked as “key personnel”
When adding a research team member...

The percent effort recorded in GMAS is self-reported, not verified. See the Academic Faculty Salary and Effort Certification Form and the Summer Salary Certification Report Form for the official record for University wide percent effort information.

Delete personnel

Member details

- **Role**: Research Assistant
- **Full name**: Aaron, Ashley

Approvals

- **Will this member be involved with human subjects?**
- **Is this member considered key personnel?**
- **Is this member an investigator as termed by PHS regulations?**

Salary and fringe benefit costs

- **Period information**: 01-01-2013 to 12-31-2013
- **% Effort**: 
- **Salary ($00)**: 
- **Fringe ($00)**: 
- **Total ($00)**: 
- **Key Personnel**: 

**required fields**
When adding a research team member...

Below is a list of research team members associated with this project. To add member, select <Add team member>. To view or update information on research team member in list, select Role link.

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<table>
<thead>
<tr>
<th>Role</th>
<th>Research member</th>
<th>Involvement with human subject?</th>
<th>Key personnel</th>
<th>PHS Investigator?</th>
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<tbody>
<tr>
<td>Principal Investigator</td>
<td>Rebello, Steven Michael</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
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<td>Consultant</td>
<td>Keuthen, Emily</td>
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<td>Consultant</td>
<td>Ezzati, Majid</td>
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<td>Data Collector</td>
<td>Toon, Michael R.</td>
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<td>Analyst</td>
<td>Cross, Whitney Leigh</td>
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<tr>
<td>Lab Assistant</td>
<td>Simmons, Beth Ann</td>
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<td>Project Coordinator</td>
<td>Duraisingh, Manoj T.</td>
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<td>No</td>
<td>Yes</td>
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<td>Analyst</td>
<td>Pharr, George Mathews</td>
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## COI Approval

### Conflict of Interest Approval for Duraisingh, Manoj T.

**Instructional Text:** (This would be changed once I get the text)

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<th>Current Approval Status</th>
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<tbody>
<tr>
<td>Status:</td>
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<tr>
<td>FCOI participant:</td>
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<td>Disclosure on File:</td>
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<table>
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<th>Approval Details</th>
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<td>Generated By:</td>
<td>r5437330</td>
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<tr>
<td>Generation Date:</td>
<td>07-18-2012</td>
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<td>Reason Generated</td>
<td>PHS Investigator</td>
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<th>Approval Status History</th>
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<tr>
<td>Date</td>
<td>07-18-2012</td>
</tr>
<tr>
<td>Status</td>
<td>No Disclosure</td>
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<td>Updated By</td>
<td>System</td>
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</table>

**Statuses:**
- Eliminated
- No Interests
- Needs Review
- Under Review
- Managed
- Reviewed - No Conflict
- No Disclosure
- N/A

- This section pulls data in real-time from FCOI system, if applicable.
- Only the DIO/COI Admin can edit.
- Will always default to "Needs Review".

- This section is GMAS-generated and indicated why the COI approval is being generated (ex. person has been flagged as investigator).

- This automatically updates when FCOI is updated or when this COI approval is modified.
Award Process

OSP/SPA
- Logs sponsor notice
- Scans/uploads award documents to GMAS

Dept Admin
- Receives email/to-do to confirm/add/modify the research team
- Confirm research team

DIO/COI Admin
- Receive email notification to review “Needs review” approvals
- Review all COI approvals

Investigator
- Enters/Updates disclosures in FCOI system

OSP/SPA
- Once all COI approvals reviewed/appropriate status, account(s) set up

These changes represent the most significant impact to business process
After OSP/SPA logs the sponsor notice...

<table>
<thead>
<tr>
<th>Request homepage</th>
<th>Project ID</th>
<th>Fund no.</th>
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<tbody>
<tr>
<td>Title</td>
<td>Simone testing</td>
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<tr>
<td>P.I.</td>
<td>Alpen, Simone</td>
<td></td>
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<tr>
<td>Sponsor</td>
<td>NIH</td>
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<tr>
<td>Dates</td>
<td>01-01-2013 to 12-31-2013</td>
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**Log a notice** | **Revise to resubmit** | **Request closeout** | **Confirm research team**

**Request attributes**

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<tr>
<th>Request number</th>
<th>5436465</th>
<th>Retroactive</th>
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<tr>
<td>Type</td>
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<tr>
<td>Status</td>
<td>Submitted to sponsor</td>
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</tr>
</tbody>
</table>

**Request information**

- Tub: 370, FCOR^FAS Core
- Org: 32000, FCOR^Psychology
- Title: Simone testing
- Project type: Basic research and all other
- Principal investigator: Alpen, Simone
- Sponsor: NIH
- Sponsor type: US Federal Government
- Prime sponsor
- Prime sponsor type
- OMB A21 functional code: Organized Research (A02)
- Discipline: Agricultural Sciences
After OSPO/SPA logs the sponsor notice

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<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Key Personnel</th>
<th>PHS Investigator</th>
<th>Human Subjects</th>
<th>Appointment</th>
<th>Start date</th>
<th>End date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbara, Suhy, Abazi, Gani</td>
<td>Principal Investigator</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>12 months</td>
<td>01-01-2013</td>
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</tr>
<tr>
<td>Abba, Ashley</td>
<td>Consultant</td>
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<td>No</td>
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<td>01-01-2013</td>
<td>12-31-2013</td>
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<tr>
<td>Abbate, Michael</td>
<td>Data Collector</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>12 months</td>
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<tr>
<td>Rebello, Steven</td>
<td>Developer</td>
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<td>Wrangham, Richard</td>
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Questions & Answers