

HARVARD
UNIVERSITY



Conflict of Interest

July/August 2012

Agenda

- Policy
- Business Process
- GMAS Changes

WWW.VPR.HARVARD.EDU

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

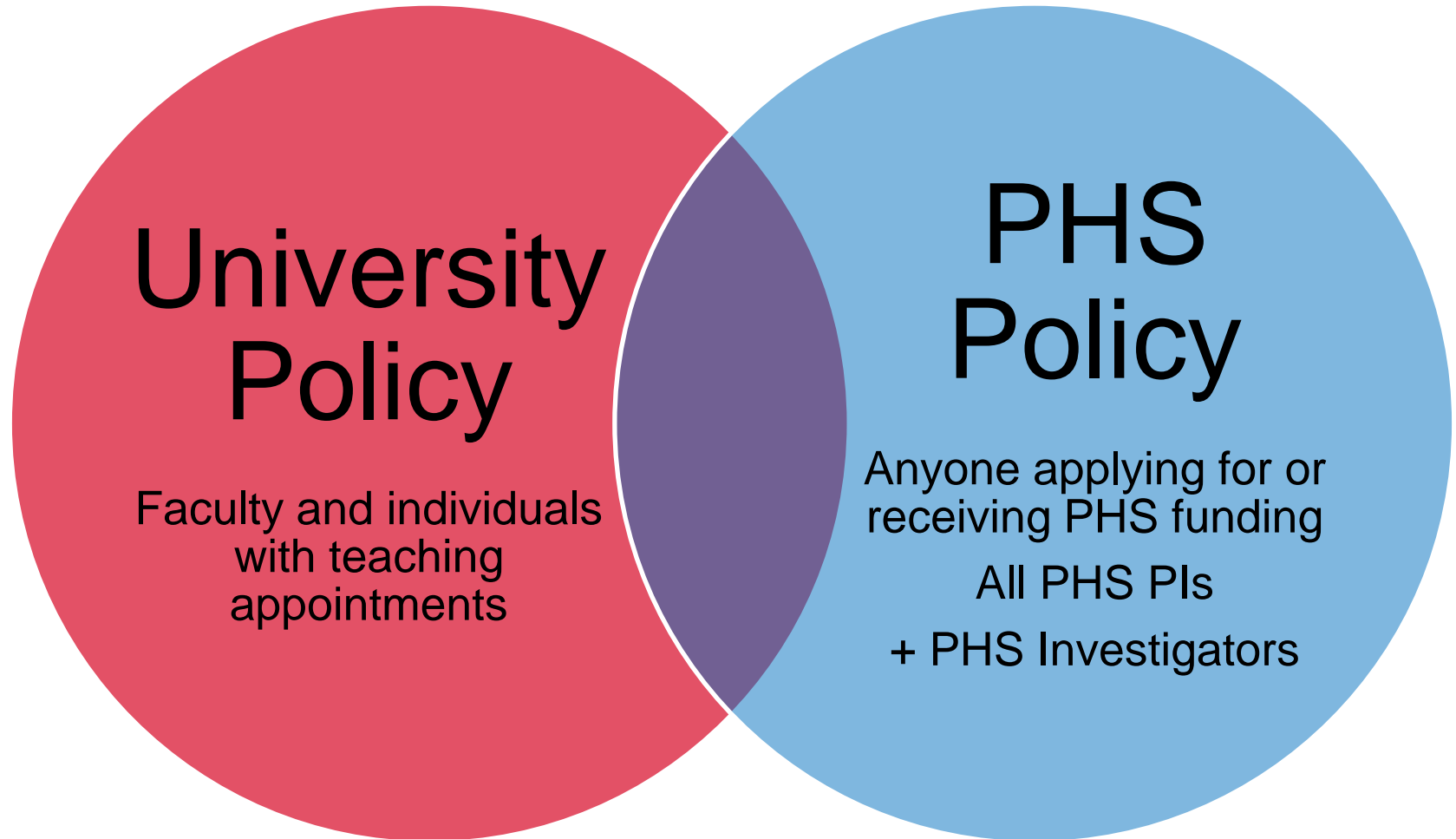
Then, management...

*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



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**

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

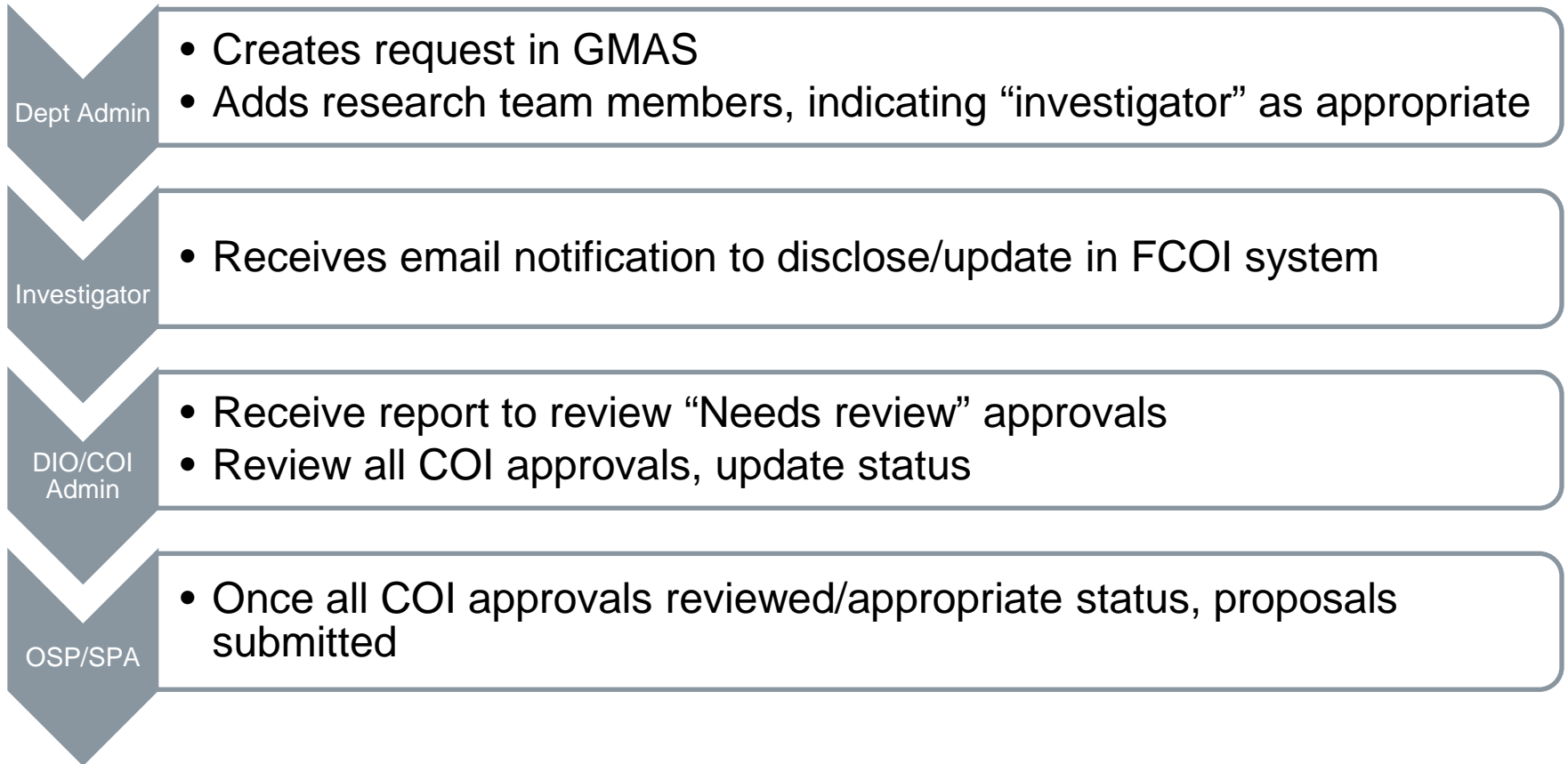
- New criteria for generating COI approval: PHS Investigator
- New COI approval screen
- COI-related notifications sent to research team members and COI Administrators

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



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. . .

Edit research personnel

Project ID 06173340-01 **Fund no.**
Title Steve testing COI 7242012
P.I. Rebello, Steven
Sponsor National Science Foundation
Dates 01-01-2013 to 12-31-2013

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.

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Delete personnel

Member details

* **Role**

* **Full name** Aaron, Ashley

* **Appointment**

* **Start date** (mm-dd-yyyy)

* **End date** (mm-dd-yyyy)

Approvals

	Yes	No
* Will this member be involved with human subjects?	<input type="radio"/>	<input checked="" type="radio"/>
* Is this member considered key personnel?	<input type="radio"/>	<input checked="" type="radio"/>
* Is this member an Investigator as termed by PHS regulations?	<input checked="" type="radio"/>	<input type="radio"/>

Salary and fringe benefit costs

[Calculate salary](#)

Period information	% Effort	Salary (\$..00)	Fringe (\$..00)	Total (\$..00)	Key Personnel
Period 1 01-01-2013 To 12-31-2013	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="checkbox"/>

Member has fellowship

*required fields

[Cancel](#)

[OK](#)

When adding a research team member. . .

projects people organizations receipts reporting receivables inbox to-do's documents portfolio

Seg 01 : COI reason generated test | Request List | Request Home | Research Team

Research Team

Project ID	06171297-01	Fund no.
Title	COI reason generated test	
P.I.	Rebello, Steven	
Sponsor	NIH	
Dates	01-01-2013 to 12-31-2013	

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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Role	Research member	Involvement with human subject?	Key personnel	PHS Investigator?
Principal Investigator	Rebello, Steven Michael	No	Yes	Yes
Consultant	Keuthen, Emily	No	Yes	No
Consultant	Ezzati, Majid	No	Yes	No
Data Collector	Toon, Michael R.	No	No	No
Analyst	Cross, Whitney Leigh	No	No	Yes
Lab Assistant	Simmons, Beth Ann	No	No	No
Project Coordinator	Duraisingh, Manoj T.	No	No	Yes
Analyst	Pharr, George Mathews	No	No	Yes



COI Approval

Edit approval

Project ID 06171297-01 **Fund no.**
Title COI reason generated test
P.I. Rebello, Steven
Sponsor NIH
Dates 01-01-2013 to 12-31-2013

Conflict of Interest Approval for Duraisingh, Manoj T.

Instructional Text (This would be changed once i get the text)

Current Approval Status

Status: No Disclosure
FCOI participant: Yes
Disclosure on File No
Interests Last Updated

- 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”

Approval Details

Generated By: r5437330
Generation Date: 07-18-2012
Reason Generated PHS Investigator

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

Approval Status History

Date	Status	Updated By
07-18-2012	No Disclosure	System

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

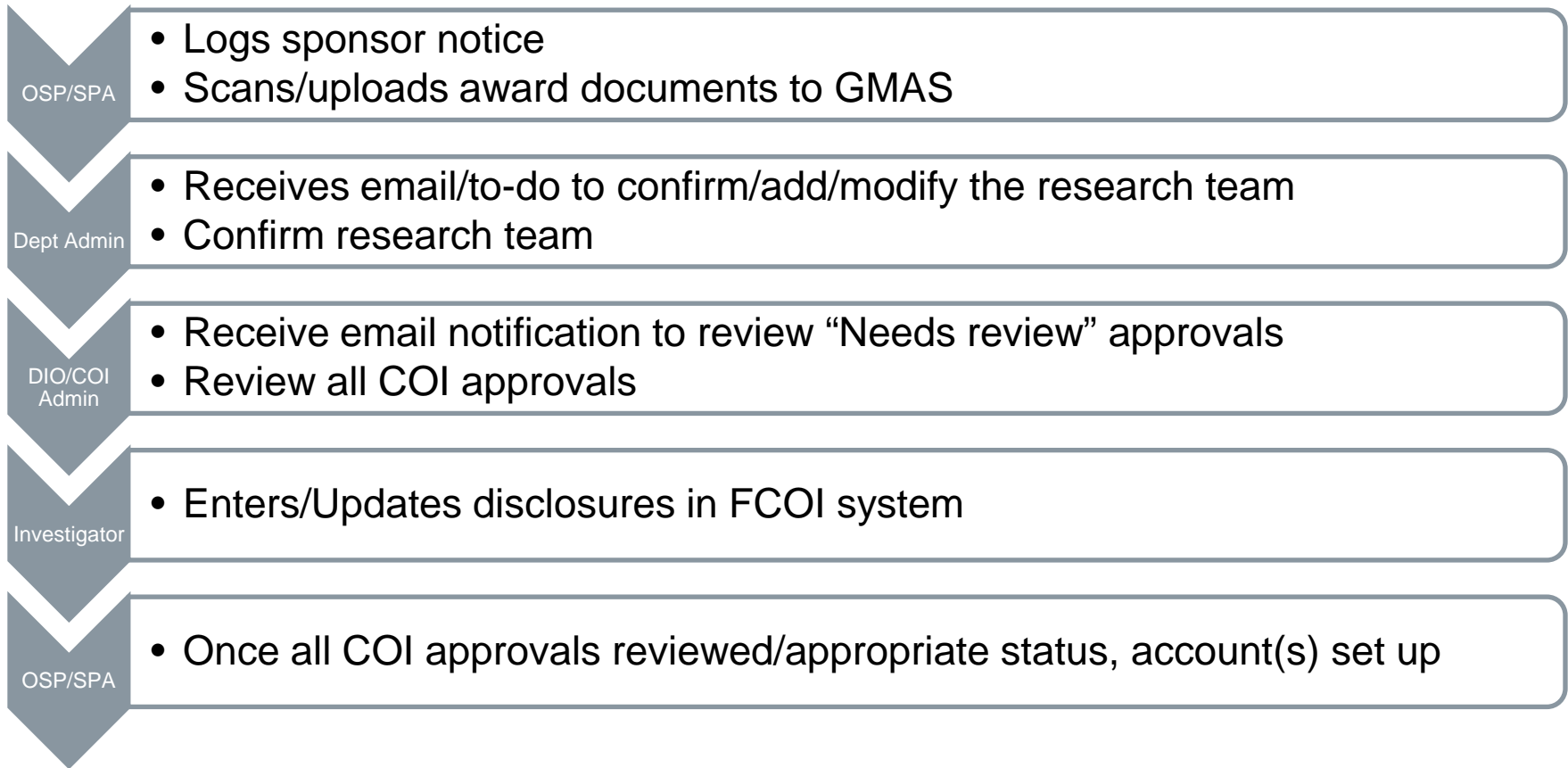
Comments:

Cancel

Statuses

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

Award Process



These changes represent the most significant impact to business process

After OSP/SPA logs the sponsor notice...

Request homepage

Project ID 06170035-01 Fund no.
 Title Simone testing
 P.I. Alpen, Simone
 Sponsor NIH
 Dates 01-01-2013 to 12-31-2013

[Log a notice](#)

[Revise to resubmit](#)

[Request closeout](#)

[Confirm research team](#)



open all | close all

Guidance links

[HMS Proposal Checklist](#)
[OSP Proposal Information](#)

Administrative team

Submissions

1 submissions
 0 pending submission

Related History

[▶ View segment revision history](#)

Forms and letters

[Letter of Intent](#)
[Human Subjects Completion](#)
[No Cost Extension Confirmation](#)

Request attributes			
Request number	5436465	Retroactive	No
Type	Initial request		
Status	Submitted to sponsor		
Request information			Edit
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

projects | people | organizations | receipts | reporting | receivables | inbox | to-do's | documents | portfolio

Seg 01 : HMS COI test | Request List | Request Home | Research Team

Research Team

Project ID 06167912-01 **Fund no.**

Title HMS COI test

P.I. Abbara, Suhny

Sponsor NIH

Dates 01-01-2013 to 12-31-2013

Below is a list of research team members associated with this project.

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Name	Role	Key personnel	PHS Investigator	Human Subjects	Appointment	Start date	End date
Abbara, Suhny	Principal Investigator	Yes	Yes	No	12 months	01-01-2013	12-31-2013
X Abazi, Gani	Analyst	Yes	Yes	No	Choose	01-01-2013	12-31-2013
X Aaron, Ashley	Consultant	Yes	No	No	Choose	01-01-2013	12-31-2013
X Abbate, Lauren C.	Data Collector	Yes	No	No	12 months	01-01-2013	12-31-2013
X Rebello, Steven Michael	Developer	No	No	No	Choose	01-01-2013	12-31-2013
X Wrangham, Richard W.	Analyst	No	No	No	12 months	01-01-2013	12-31-2013



Add team member X **Lookup**

*required fields

Cancel

OK

Questions & Answers