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PREREQUISITES

Acronyms	
COI	Conflict of interest
FCOI	Financial conflict of interest
PHS	Public Health Service
GMAS	Grants Management Application Suite
OSP	Office for Sponsored Programs
SPA	Sponsored Programs Administration (in Harvard Medical School and Harvard T.H. Chan School of Public Health)
DIO	Designated institutional office

BACKGROUND

A new policy (HARVARD UNIVERSITY POLICY ON INDIVIDUAL FINANCIAL CONFLICTS OF INTEREST FOR PERSONS HOLDING FACULTY AND TEACHING APPOINTMENTS) was approved in May 2010, and later revised to include amendments relating to the Public Health Service (PHS) regulations. The U.S. Department of Health and Human Services (HHS) has issued a final rule in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). An Institution applying for or receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the revised regulatory requirements no later than 365 days after publication of the regulation in the Federal Register, i.e., **August 24, 2012**, and immediately upon making the Institution's Financial Conflict of Interest policy publicly accessible as described in 42 CFR part 50.604(a). Institutions must comply with the 1995 financial conflict of interest regulation until the Institution fully implements all of the regulatory requirements of the 2011 revised regulation.

To facilitate compliance with the new PHS Rule, a working group of representatives from the Office of the Vice Provost (OVPR), Office for Sponsored Programs (OSP), Harvard University Information Technology (HUIT), and Financial Systems Solutions (FSS), has implemented needed upgrades to the electronic form that collects annual disclosures under the University policy ("the annual FCOI system"), and GMAS. As part of these upgrades, all individuals covered by the University policy in Schools using the annual system, as well as PHS investigators in those schools, will report financial interests related to their University activities using the annual system.

Several outreach efforts have been made across the University to ensure that the identified population has completed their annual disclosures. The Harvard Medical School (HMS) and Harvard Business School (HBS) are not using the annual system.

IN A NUTSHELL

The enhancements made to GMAS in August of 2012 can be divided into three general categories:

- **Link to the annual FCOI system**
 - GMAS will pull in data from the annual FCOI system
- **Proposal Stage**
 - New Investigator flag
 - New COI approval screen
 - COI-related notifications sent to research team members
- **Award Stage**
 - Confirm research team after award notice is logged
 - COI-related notifications sent to research team members, COI Administrators, and Department Administrators

For details on the enhancements, visit the [Release Notes page](#).

LINK TO THE ANNUAL FCOI SYSTEM

A link has been established between the annual FCOI system and GMAS. The annual FCOI system is used by faculty to disclose, update, or modify their financial interests in relation to their research or institutional responsibilities. The system is available only to those faculty members identified as being required to comply under the University's COI policy or meeting the requirements of PHS investigator (primarily those individuals with teaching appointments). Other than this population, access is strictly limited to school DIO/COI administrators.

The URL for the annual system is: <https://fcoi.harvard.edu/>

As of August 2012, the annual FCOI system has been deployed to the following schools:

- Harvard School of Public Health (T.H. Chan)
- Faculty of Arts and Sciences (FAS)
- School of Engineering and Applied Sciences (SEAS)
- Harvard Divinity School (HDS)
- Graduate School of Education (GSE)
- Graduate School of Design (GSD)

As members are added to project research teams in GMAS, data from the FCOI system pulls into the COI approval. GMAS pulls back the following type of data and displays that data within the COI approval:

FCOI Data Field	Description	Example
Status	This is the status of the individual's disclosure.	No Disclosure
FCOI Participant	This Y/N field indicates whether or not the individual uses the FCOI system to report their financial interests.	Y/N
Disclosure on File	This Y/N field indicates whether or not the individual has a disclosure on file in the annual FCOI system.	Y/N
Interests Last Updated	This date indicates the last time the individual updated or entered their disclosure in the annual FCOI system.	7-14-2012

- GMAS also receives a nightly feed of disclosure updates from the annual FCOI system.
- GMAS also has a real-time check with the annual FCOI system when research team members are added and as users visit COI approvals.
- GMAS will send data as members are added to the research team and are not yet flagged in the annual FCOI system as needing disclosure.

PROPOSAL STAGE

This section details the COI-related functionality during the proposal stage. This section discusses requests and the research team. "Requests" in GMAS refer to a proposal for funding to an external sponsor, or a proposed change to an active segment (might be to an external sponsor or an internal request). Request types in GMAS include:

- Initial
- Continuation
- Supplement
- Competing Renewal

- Pre-Award expenditures
- Carryforward
- No-cost extension
- Equipment re-budget
- Re-budget restriction
- Subagreement at no additional cost
- IFI at no additional cost
- Termination
- Change PI
- Change Tub/Org
- New Account
- At-Risk Account

"Research team" is a GMAS phrase that refers to the people assigned to a project. The research team always includes the Principal Investigator (PI) and the fellow (if the project is a fellowship). Other relevant members can be added either during the proposal phase of the project or during the lifetime of the award.

PROPOSAL STAGE PROCESS

The below process is intended to capture the basic steps at the proposal stage in GMAS. Each school may have additional processes to follow; please contact your OSP/SPA office with questions.

Step	Role / User	Action
1	Department	Enters proposal in GMAS. Add research team members.
2	Automated/GMAS	Investigators meeting the criteria (investigator, key personnel, HU COI policy) will receive e-mail notifying them that they have been added to a project and that they must disclose/update disclosures prior to proposal submission.
3	Investigators	Enters or updates disclosures in the annual FCOI system. For other schools not using the FCOI system, follow local COI procedures.

Step	Role / User	Action
4	Automated/GMAS	GMAS updated with updates from the annual FCOI system. For non-FCOI schools, the DIO/COI administrator will update GMAS accordingly.
5	COI Administrator/DIO	Reviews FCOI reports with status Needs Review alongside grant info in GMAS.
6	OSP/SPA Office	Submit proposal to sponsor once all COI approvals have been reviewed.

Initial request: Request type. Represents a proposal to an external sponsor for funding a specific sponsored research initiative. Creates a new project-segment in GMAS.

Competing renewal: Request type. Request to sponsor for financial or direct assistance to extend, for one or more additional budget periods. Indicates new period of performance and level of funding, should the request be awarded. Generates a new segment and fund in GMAS within existing project.

At-risk account request: Request type. At-risk accounts allow the PI to initiate spending on their project before the University receives and/or accepts an award. Such expenditures incurred are made at the department's risk.

THE INVESTIGATOR FLAG

- The investigator flag appears for projects adhering to the PHS regulations (see [sponsor list](#) below).
- T.H. Chan and University area projects cannot have research personnel flagged as investigator on non-PHS+ projects.
- HMS projects can have research personnel flagged as investigator on any project, regardless of sponsor.
- The flag will appear on the edit/create research team screen, and it will generate a COI approval for anyone set to yes for investigator.
- Research team members cannot be added to requests that are in *Submitted to Sponsor* or *Closed* status.

Investigator is defined as the **project director or principal Investigator** and **any other person**, regardless of title or position, **who is responsible for the design, conduct, or reporting** of research or proposed for funding, which may include, for example, **collaborators or consultants**.

See the NIH investigator definition [here](#).

INVESTIGATOR VS. KEY PERSONNEL

In GMAS, marking an individual as key personnel on a PHS+ project will automatically flag them as investigator.

Investigator definition:

Investigator is defined as the **project director or principal investigator** and **any other person**, regardless of title or position, **who is responsible for the design, conduct, or reporting** of research or proposed for funding, which may include, for example, **collaborators or consultants**.

NIH key personnel definition:

The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. "Zero percent" effort or "as needed" is not an acceptable level of involvement for senior/key personnel.

NON HUID RESEARCH TEAM MEMBERS

Individuals without Harvard IDs (HUID) are sometimes added to Harvard projects in GMAS. The most common examples are fellows who are not yet at the University, subcontractors, or consultants. These "non HUID" people may indeed be flagged as key personnel or investigators.

These "non HUID" people will:

- NOT receive email notifications from GMAS
- WILL generate a COI approval if flagged as key personnel or investigator. The COI approval for non-HUID research team members will default to a status of "Check status". This is due to the fact that GMAS cannot obtain COI information for non-HUID research team members. The COI Administrators/DIO will coordinate obtaining the appropriate documentation and update the GMAS COI approval accordingly.

INTER-TUB PROJECTS

Projects may include research team members with appointments in tubs other than the submitting department for a particular proposal. Researchers should follow their primary tub affiliation's COI processes and procedures.

TBDS

GMAS allows research team members added as TBD to be marked as key personnel or as an investigator. TBDs marked as key personnel cannot be included in system-to-system (S2S) proposals. TBDs will not generate the COI approval.

VIEWING FCOI DISCLOSURE DETAILS FROM THE PERSON PROFILE

To view a person's disclosure status from the FCOI system, navigate to the person's profile. The COI disclosure section will include the most recent data about that person's disclosure status and date last updated in the FCOI system. If the person is not a user of the FCOI system, their person profile will not include the COI disclose section.

COI disclosure Close 	
FCOI participant?	Yes
Disclosure on file in FCOI system?	No
Interests last updated:	

WHICH PROJECTS WILL INCLUDE THE INVESTIGATOR FLAG?

For T.H. Chan and University Area projects, the investigator flag will appear on any project with any of these organizations listed as the sponsor or prime sponsor:

- Public Health Service (includes NIH and all NIH agencies, CDC, HRSA, etc.)
- National Science Foundation
- American Heart Association
- American Cancer Society
- Arthritis Foundation
- Susan G. Komen Foundation
- Alliance for Lupus Research

This list of sponsors will be referred to as "PHS+" within this document. For a full list including all PHS "child" organizations, see [Appendix](#).

All HMS projects will display the investigator flag regardless of sponsor.

ADDING RESEARCH TEAM MEMBERS

For all initial and competing renewal requests users have the opportunity to add research team members. The PI will always default onto the project as key personnel and cannot be deleted. Select **Add research team** member to include additional research team members for the project. For PHS+ initial and competing renewal requests, the screen for adding research team members will look like this:

Create request

Add research staff member

Project ID	06297523-01	Fund no.	
Title	Singing in the Rain: A Study in Audio and Hydrodynamics		
P.I.	Kelly, Gene		
Sponsor	NIH		
Dates	07-01-2013 to 06-30-2014		

[Help with this page](#)

If a specific person has been assigned to this role, enter his/her name below. If not, check TBD box.

Answer all questions below for this role.

Investigator is identified as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research. Any research team member who meets this criteria should be set to "yes" for the investigator question.

Research team member

***Role**

***Person** **Lookup** TBD (To be determined)

*** Will this member be involved with human subjects?** Yes No

*** Is this individual considered key personnel?** Yes No

*** Is this member responsible for the design, conduct or reporting of the proposed research?** Yes No

*required field

Any fields with an asterisk must be answered before navigating away from this screen.

THE COI APPROVAL

The COI approval will generate if a research team member is:

- ✔ Marked as an Investigator (GMAS)
- ✔ Covered by the University COI policy (FCOI annual system)

For non-PHS+-sponsored projects:

- For the University Area and T.H. Chan, the COI approval will only generate if the research team member is covered under the University COI policy.

Conflict of Interest Approval for Kelly, Gene

The Conflict of Interest Approval status can only be updated by the appropriate Conflict of Interest Administrator/Designated Institutional Officer. The Conflict of Interest Administrator/Designated Institutional Officer identified on the administrative team should be contacted if the status of this approval is not accurate.

Current Approval Status	
Status:	No Disclosure
FCOI participant:	Yes
Disclosure on File	No
Date Received	<input type="text"/>

Approval Details

Generated By:	r5484792
Generation Date:	12-14-2012
Reason Generated	Investigator

Approval Status History

Date	Status	Updated By
------	--------	------------

Comments:

Documents 0 Document(s) Open

Callout 1: This section pulls data in real-time from FCOI system, if applicable
•Only the DIO/COI Admin can edit
•Will default to *Needs Review* or *No Disclosure*








Callout 2: This section is GMAS-generated and indicated why the COI approval is being generated (ex. person has been flagged as investigator)

Callout 3: This section automatically updates when the FCOI system is updated or when this COI approval is modified

Note: only the COI Administrator/DIO and Central Special Users can edit the Comments field.

COI approvals generated prior to August 2012 will be referred to as "COI Legacy."

COI APPROVAL STATUSES AND WHAT THEY MEAN

COI Approval Statuses	Description
Needs Review	<ul style="list-style-type: none">  Awards should not move forward with COI approvals in this status.  Proposals can move forward with COI approvals in this status. • <i>Needs Review</i> is the GMAS-generated default for research team members who have a disclosure on file.
No Disclosure	<ul style="list-style-type: none">  Proposals and awards should not move forward with COI approvals in this status. • Disclosures do not exist for the individual.
Disclosure on file (Only applies to T.H. Chan and University Area non-PHS+ projects)	<ul style="list-style-type: none">  Proposals and awards can move forward with COI approvals in this status. • A disclosure is on file for the individual.
No Interests	<ul style="list-style-type: none">  Proposals and awards can move forward with COI approvals in this status. • Disclosure is present, but no interests relate to the project. • COI Administrator/DIO assigns this status.
Under Review	<ul style="list-style-type: none">  Awards should not move forward with COI approvals in this status.  Proposals can move forward with COI approvals in this status • Disclosures for this individual are being reviewed by the COI Administrator/DIO. • COI Administrator/DIO assigns this status.

COI Approval Statuses	Description
Managed	<ul style="list-style-type: none"> ✔ Proposals and awards can move forward with COI approvals in this status. • Disclosures exist and have been reviewed and managed. • COI Administrator/DIO assigns this status.
Reviewed – No Conflict	<ul style="list-style-type: none"> ✔ Proposals and awards can move forward with COI approvals in this status. • Disclosures exist have been reviewed and managed. • COI Administrator/DIO assigns this status.
Eliminated	<ul style="list-style-type: none"> ✔ Proposals and awards can move forward with COI approvals in this status. • Disclosures exist and any interests have been eliminated for this project. • COI Administrator/DIO assigns this status.
N/A	<ul style="list-style-type: none"> ✔ Proposals and awards can move forward with COI approvals in this status. • This approval was generated in error. • COI Administrator/DIO assigns this status.
Check status	<ul style="list-style-type: none"> ✘ Awards should not move forward with COI approvals in this status. ✘ Proposals and awards should not move forward with COI approvals in this status. • Used as the default status for any non-HUID research team member who is flagged as an investigator.

For any research team members with an HUID who are not participants of the annual FCOI system, the COI approval will default to *Needs Review*.

AWARD STAGE

On at least a daily basis, OSP and the Longwood SPA offices log sponsor notices that are received by the University. Details about the notice, including date received and the actual terms and conditions themselves are captured in GMAS. GMAS triggers an email notification and to-do to Department Administrators to confirm the research team for any notices awarding initial or competing renewal requests for all sponsors.

AWARD STAGE PROCESS

The below process is intended to capture the basic steps at award stage in GMAS. Each school may have additional processes to follow; please contact your OSP/SPA office with questions.

Step	Role / User	Action
1	OSP/SPA Office	Receives notice from sponsor in response to request for funding. If not funded, update request status to <i>Not Funded</i> and end here. If funded, logs notice of award in GMAS.
2	Automated / GMAS	Anyone in the Department Administrator role in GMAS receives a to-do and email when the award notice is logged notifying them that the research team needs to be confirmed. Email notification will include name of project and a link to the request homepage. GMAS will populate the research team from the original initial or competing renewal request.
3	Department Administrator	Verifies research team in GMAS accurately reflects investigators on project and confirms TBD investigators, adding or removing members, if applicable. Confirm research team via segment homepage by selecting Confirm research team .
4	Automated /GMAS	Research team members flagged as investigator, key personnel or under the University COI policy will have Conflict of Interest approval and receive email notifications: <ul style="list-style-type: none"> • New investigators automatically added to annual FCOI reporting system and notified to complete disclosure. • Existing investigators emailed to update their disclosures.
5	Investigators	Enters or updates disclosures in the annual FCOI system. For other schools not using the FCOI system, follow local COI procedures.

Step	Role / User	Action
6	Automated / GMAS	GMAS updated with updates from the annual FCOI system. Email notification sent to the COI Administrator/DIO to review approvals in <i>Needs Review</i> status.
7	COI Administrator / DIO	Reviews disclosures and project information. Updates COI approval accordingly.
8	OSP/SPA Office	Reviews all COI approvals. Sets up award if all approvals are in appropriate status.

CONFIRMING THE RESEARCH TEAM

Once OSP/SPA has logged a sponsor notice against an initial or competing renewal request, all Department Administrators assigned to the project will receive an email notification and a GMAS to-do. The email and to-do will include the project title, a link to the segment homepage, and instructions indicating that the research team must be confirmed.

Below is an example of the **Confirm research team** button on the segment homepage:

The screenshot shows a web interface for a project segment. At the top, the title is "Singing in the Rain: A Study in Audio and Hydrodynamics" with project details: "Project: 6297523 - 07-01-2013 to 06-30-2014" and "Segment 01: 07-01-2013 to 06-30-2014 : Fund". Below the title are two buttons: "Create request" and "Confirm research team", with a yellow arrow pointing to the latter. A navigation menu on the right includes "Revisions", "Segment documents", "Administrative team", "Sponsor contacts", "Equipment", "Perm file", "Budget upload", "Event history", "5 entries", "Segment to-do's", "7 total", "7 due", and "0 overdue". The main content area displays "Project Information" for project no. 06297523-01, which is in a "Pending" state. It lists details such as Tub (370, FCOR^FAS Core), Org (32000, FCOR^Psychology), Title, Principal Investigator (Kelly, Gene), Sponsor (NIH), and various funding and award information.

Selecting the **Confirm research team** button will bring Department Administrators to a new screen. The research team defaults in from the originating request and can be modified to delete or add additional research team members.

Research Team

Project ID	06297523-01	Fund no.	
Title	Singing in the Rain: A Study in Audio and Hydrodynamics		
P.I.	Kelly, Gene		
Sponsor	NIH		
Dates	07-01-2013 to 06-30-2014		

This screen includes all current research team members who have been identified.

All editable fields on the screen are required.

If you are a Department Administrator who navigated to this screen by selecting the <Confirm research team> button, selecting <Ok> will confirm that the research team is accurate, includes all known research team members, and will generate email notifications, as needed.

Name	Role	Key personnel	Investigator	Human Subjects
Kelly, Gene	Principal Investigator	Yes	Yes	No ▾

Add team member X **Lookup**

*required fields **Cancel** **OK**

Upon selecting **OK**:

- The research team will be confirmed.
- Research team members flagged as investigators, key personnel or under the University COI policy will receive email notifications
 - New investigators automatically added to annual FCOI reporting system and notified to complete disclosure.
 - Existing investigators emailed to update their disclosures.
- The Department Administrator's to-do will be removed.

HAS THE RESEARCH TEAM BEEN CONFIRMED?

Until the research team has been confirmed, no research staff members will receive COI approvals and notifications. This (along with the disclosures themselves) may hold up account set up. There are two ways to find out whether or not the research team has been confirmed:

- From the sponsor notices dashboard
- From the segment homepage

SPONSOR NOTICES DASHBOARD

The sponsor notices dashboard is accessed through the GMAS homepage via the **Sponsor Notices** link. The dashboard shows all sponsor notices that have been received by OSP and the SPA offices, but not yet awarded. In other words, the notice is in but the Action Memo has not yet been issued.

The Team Confirmed column indicates whether or not a Department Administrator has confirmed the research team. The COI Reviewed column indicates whether or not the DIO has reviewed the COI approvals for the project.

Sponsor Notices

This dashboard lists Sponsor Notices that have been received by Harvard but have not been awarded. Select the Date Received by Harvard to navigate to the list of sponsor notices in a segment.

Area: ALL
 Tub: X
 Search

Page: 2014-06-14-2012-10-03 Go to page 1 - 20 of 372 records Next20>

Project#	Fund	Date Received by Harvard	Type	PI	Sponsor	Start Date	Title	Sponsor award no.	Org	Team Confirmed	COI Reviewed
06169786-01		06-14-2014	Initial request	Chance, Kerry	Amer Council of L...	07-01-2012	New Faculty Fellowship	No Award Nbr	31850 FCOR*Anthro - Gen...	No	Yes
06295585-01		11-28-2012	Initial request	Cross, Whitney	NH	02-01-2013	Testing WC	No Award Nbr	31240 FCOR*CCB Org Res	Yes	No
00000866-05	111050	11-27-2012	Supplement	Willett, Walter	NH/NCI	08-01-2009	Risk Factors for Breast Can...	SR01CA050385-24	23480 SPH*Nutrition	Yes	Yes
06277030-01		10-15-2012	Initial request	Seltzer, Margo	NSF	06-01-2013	CSR: Medium Collaborative R...	No Award Nbr	28741 SEAS*Computer Sci...	Yes	No
06294618-01		10-15-2012	Initial request - ...	Rebello, Steven	NH	01-01-2013	Steve testing R2R COI	No Award Nbr	23610 SPH*Maternal+Chil...	Yes	No
06124488-01		10-15-2012	Initial request	Tobias, Deirdre	NH	07-01-2012	Parity, birth-interval, and...	No Award Nbr	23480 SPH*Nutrition	Yes	No

SEGMENT HOMEPAGE

The Research staff section of the segment homepage will indicate whether or not the research team has been confirmed.

Seg 01 : Singing in the Rain: A Study...

Singing in the Rain: A Study in Audio and Hydrodynamics Project: 6297523 - 07-01-2013 to 06-30-2014
Segment 01: 07-01-2013 to 06-30-2014 : Fund

Create request open all | close all

Project Information	• project no. 06297523-01 Pending	
Tub	370, FCOR^FAS Core	
Org	32000, FCOR^Psychology	
Fund		
Title	Singing in the Rain: A Study in Audio and Hydrodynamics	
Principal Investigator	Kelly, Gene	
Sponsor	NIH	Prime sponsor
Sponsor type	US Federal Government	Prime sponsor type
Award number		Prime award number
Funding instrument		
Project type	Basic research and all other	
ARRA(Stimulus)funding?		
Institutional authorities?		
SNAP?		
Additional award information		
School specific information		
Dates and dollars	• anticipated 07-01-2013 to 06-30-2014	Open
Accounts	• 1 total 1 proposed 0 active 0 closed	
Subagreements	• 0 total 0 pending 0 active	
Requests	• 1 total 1 pending 0 awarded	Open
Sponsor notices	• 1 total 1 pending 0 reviewed & applied	Open
Research staff	• 1 total Team confirmed - Yes	

Revisions
Segment documents
Administrative team
Sponsor contacts
Equipment
Perm file
Budget upload
Event history
5 entries
Segment to-do's
7 total
7 due
0 overdue

SETTING UP ACCOUNTS

The OSP and SPA offices are responsible for setting up accounts once the research team has been confirmed. Pre-award staff from those offices are responsible for checking that all required individuals have a COI approval in the appropriate status prior to setting up accounts. If a user from OSP/SPA attempts complete sponsor notice review without research team confirmation, they will receive a warning message.

DURING THE AWARD

ADDING RESEARCH TEAM MEMBERS DURING THE LIFE OF THE AWARD

Investigators may come on or off of an award after it has been activated. To add someone to the research team:

1. Search for the project in GMAS.
2. Navigate to the Segment homepage.
3. Select **Research staff**.
4. Select **Edit Research Team**. You will be prompted to enter the following data fields:
 - **Role**
 - **Full name**
 - **Will this member be involved in human subjects?**
 - **Key personnel**
 - **Investigator** (will appear only for those PHS+ projects)
5. New COI approvals will be generated.

AT-RISK REQUESTS

The COI workflow and "confirm research team" process applies to at-risk account requests.

Step #	Role / User	Process
1	Department User or OSP/SPA Office	Create at-risk account request from an existing project. Route for signatures.

The COI workflow and "confirm research team" process applies to at-risk account requests.

Step #	Role / User	Process
2	Automated/GMAS	Once all required signatures are obtained and the request moves to <i>Authorized</i> status, anyone in the Department Administrator role in GMAS receives a to-do and email notifying them that the research team needs to be confirmed. Email notification will include name of project and a link to the segment homepage. GMAS will populate the research team from the original initial or competing renewal request.
3	Department Administrator	Verifies research team in GMAS accurately reflects investigators on project and confirms TBD investigators, adding or removing members, if applicable. Confirm research team via segment homepage by selecting Confirm research team .
4	Automated/GMAS	Research team members flagged as investigator, key personnel or under the University COI policy will have a Conflict of Interest approval and receive email notifications: <ul style="list-style-type: none"> • New investigators automatically added to annual FCOI reporting system and notified to complete disclosure. • Existing investigators emailed to update their disclosures.
5	Investigators	Enters or updates disclosures in the annual FCOI system. For HMS, investigators must upload/submit their COI Disclosure Statement to SPA which requires visiting the Outside Activity Reporting System to update or report outside activities. For other schools not using the FCOI system, follow local COI procedures.
6	Automated/GMAS	GMAS updated with updates from the annual FCOI system. Email notification sent to the COI Administrator/DIO to review approvals in <i>Needs Review</i> status.
7	COI Administrator/DIO	Reviews disclosures and project information. Updates COI approval accordingly.
8	OSP/SPA Office	Reviews all COI approvals. Sets up at-risk award(s) when all approvals are in appropriate status.

GMAS COI NOTIFICATIONS: WHO GETS WHAT WHEN

The grid below provides information regarding the automatic GMAS email notifications during the COI process

#	Trigger	Sent To	Subject	Body Text
1	Generation of COI approval for FCOI participant research team member	Research team member	Submit/Update Conflict of Interest Disclosure for Proposal Submission	<p>You have been added to the research team for the following project: Title: insert project name Principal Investigator: insert PI last name, first name</p> <p>If you have already submitted a disclosure of financial interests, and have no updates to make, no additional action is needed for this project.</p> <p>If you have not submitted a disclosure of financial interests, or have updates to make (i.e. you have new financial interests to disclose), please submit the information to the Financial Conflict of Interest system. For more information on the University's Conflict of Interest Policy, please visit the Office of the Vice Provost.</p> <p>If you have any questions or concerns please contact your School's Designated Institutional Official for guidance.</p>

The grid below provides information regarding the automatic GMAS email notifications during the COI process

#	Trigger	Sent To	Subject	Body Text
2	Generation of COI approval for non-FCOI participant research team member with HUID	Research team member	Submit/Update Conflict of Interest Disclosure for Proposal Submission	<p>You have been added to the research team for the following project: Title: insert project name Principal Investigator: insert PI last name, first name</p> <p>If you have already submitted disclosure of financial interests and have no updates to make, no additional action is needed for this project.</p> <p>If you have not submitted a disclosure of financial interests, or have updates to make (i.e. you have new financial interests to disclose), please submit or update the information in accordance with your School's submission process</p> <p>Harvard Medical School Investigators: please see guidance below</p> <p>All Other Investigators: If you are not familiar with your School's process for collecting financial interest disclosures, please contact your Central Sponsored Administrator or Designated Institutional Official.</p> <p>Training only needs to be completed once every four years or immediately if 1) the institution changes the policies in such a way that changes your reporting obligations, 2) you are new to the institution, or 3) you are not in compliance with the PHS regulations or a management plan promulgated under those regulations.</p>

The grid below provides information regarding the automatic GMAS email notifications during the COI process

#	Trigger	Sent To	Subject	Body Text
3	Research team is confirmed and research team member is an FCOI participant with COI approval status = No Disclosure	Research team member	Financial Interest Disclosure Needed	<p>You are on the research team for the following project which has been awarded:</p> <p>Title: insert project name Principal Investigator: insert PI last name, first name</p> <p>Please complete a disclosure of financial interests at Financial Conflict of Interest system so that Harvard may set up the award referenced above.</p> <p>For more information on the University's Conflict of Interest Policy, please visit the Office of the Vice Provost for Research web site.</p> <p>If you have any questions, please contact your School's Designated Institutional Official.</p>

The grid below provides information regarding the automatic GMAS email notifications during the COI process

#	Trigger	Sent To	Subject	Body Text
4	Research team is confirmed and research team member is an FCOI participant with COI approval status of No Disclosure	Research team member	Review Needed	<p>You are on the research team for the following project which has been awarded:</p> <p>Title: insert project name Principal Investigator: insert PI last name, first name</p> <p>If you have any updates to your previously submitted disclosure of financial interests in the Financial Conflict of Interest system (i.e. new financial interests to disclose) please submit an update immediately. If you have previously submitted a disclosure of financial interests and have no updates to make, no additional action is needed for this project.</p> <p>For more information on the University's Conflict of Interest Policy, please visit the Office of the Vice Provost for Research web site.</p> <p>If you have any questions, please contact your School's Designated Institutional Official.</p>

The grid below provides information regarding the automatic GMAS email notifications during the COI process

#	Trigger	Sent To	Subject	Body Text
5	Research team is confirmed and research team member is not an FCOI participant with a HUID	Research team member	Submit/Update Financial Interest Disclosure	<p>You are on the research team for the following project which has been awarded:</p> <p>Title: insert project name Principal Investigator: insert PI last name, first name</p> <p>If you have already submitted a disclosure of financial interests and have no updates to make (i.e. no new financial interests to disclose), no additional action is needed for this project.</p> <p>If you have not submitted a disclosure of financial interests or have updates to make (i.e. new financial interests to disclose), please submit or update the information in accordance with your School's submission process. (If you are not familiar with your School's process for collecting financial interest disclosures, please contact your School's Designated Institutional Official. For more information on the University's Conflict of Interest Policy, please visit the Office of the Vice Provost for Research web site.)</p>

The grid below provides information regarding the automatic GMAS email notifications during the COI process

#	Trigger	Sent To	Subject	Body Text
6	Research team is confirmed and any research team members have an approval status of Needs Review	COI Administrator	Review COI Disclosure(s) for ProjectTitle	<p>Harvard has received notice that PROJECT (with link to segment homepage) has been awarded. Please review the disclosures of the following research team members.</p> <p>Lists Research Team Member Name for research team members whose COI Approvals are in "Needs Review" status.</p> <p>Please review the disclosure(s) as soon as possible to prevent a delay in account set-up and allowability of costs.</p>
7	Notice has been logged associated to an initial request or a competing renewal and the segment status is <i>Pending</i>	Department Administrator	Confirm Research Team for ProjectTitle	<p>A notice has been logged for the following project:</p> <p>Project ID: insert project ID Title: insert project name as link to Segment Home Screen Principal Investigator: insert PI last name, first name.</p> <p>Please confirm the Research Team is accurate. The Research Team should include all individuals who are responsible for the design, conduct, or reporting of the proposed research.</p>

The grid below provides information regarding the automatic GMAS email notifications during the COI process

#	Trigger	Sent To	Subject	Body Text
8	When at-risk account request is in <i>Authorized</i> status	Department Administrator	Action required: Confirm Research Team for ProjectTitle	<p>An at-risk request has been authorized for the following project:</p> <p>Project ID: <i>insert project ID</i> Title: <i>insert project name</i> as link to Segment Home Screen Principal Investigator: <i>insert PI last name, first name.</i></p> <p>Please confirm the Research Team is accurate. The Research Team should include all individuals who are responsible for the design, conduct, or reporting of the proposed research.</p>

FAQS

Q: If there are multiple people in the Department Administrator role, will everyone receive a notification at award time to confirm the research team?

A: Yes.

Q: What data does GMAS pull in from the annual FCOI system? Will grant managers see specific details about an investigator’s financial disclosures?

A: GMAS will pull in the following data fields:

- Status of FCOI disclosure - whether or not the individual has recorded their disclosures and, if so, the status of the disclosure
- FCOI participant - whether or not the individual is covered under the University's COI policy
- Date of when the disclosures were last recorded in the annual FCOI system

No details about the disclosures themselves will be transmitted from the annual FCOI system to GMAS.

Q: Which sponsors are following the PHS COI regulations?

A: See the full list [here](#).

Q: Who can create new initial requests and competing renewals in GMAS?

A: Departmental users with Department Administrator and Lab Administrator roles can create initial requests and competing renewals. Central Administrators can also create initial and competing renewal requests.

Q: What happens if OSP or the SPA office tries to set up the account and the research team has not been confirmed?

A: If an OSP or SPA office representative attempts to complete the review of a notice, they will receive a warning message.

Q: What happens to initial or competing renewals that are midstream when GMAS goes live with these enhancements?

A: For PHS+ proposals in process, users will get a warning when selecting **Lock & Route for Signatures**. The warning will prompt users to answer the investigator question for all research team members. Once they answer the Investigator question for each research team member, they can **Lock & Route for Signatures**.

ADDITIONAL RESOURCES

List of School COI Officers: <http://vpr.harvard.edu/sites/vpr.harvard.edu/files/COI%20Contact%20Us.pdf>

Office of the Vice Provost for Research Conflicts of Interest page: <http://vpr.harvard.edu/content/conflicts-interest>

National Institutes of Health Financial Conflict of Interest page, including FAQs: <http://grants.nih.gov/grants/policy/coi/>

[GMAS Release Notes](#)

[GMAS Glossary](#)

Need GMAS access? Check out [this page](#) for more information.

APPENDIX

Full List of Sponsors Following the PHS COI Policy

Below is the full list of all sponsors selected by Harvard University to follow the Public Health Services Conflict of Interest policies. This list includes all of the Public Health Service "child" organizations including NIH, CDC, etc.

Full Name	Abbreviation
ACF/Child Care Bureau	
ACF/Office of Refugee Resettlement	
Administration for Children and Families	
Administration for Children, Youth and Families/Head Start Bu	
Administration on Aging - Public Health Service	
Alliance for Lupus Research	
American Cancer Society	ACS
American Cancer Society/MA Division Inc.	
American Heart Association	AHA
American Heart Association Northeast	AHANE
American Heart Association/Mass	AHAMA
Arthritis Foundation	
CDC - Public Health Service	CDC

Full Name	Abbreviation
CDC/Association of Teachers of Preventive Medicine	CDC/ATPM
CDC/CID-Public Health Service	CDC/CID
CDC/Coordinating Office for Terrorism Preparedness and Emergency Response	CDC/COTPER
CDC/National Center for Environmental Health	CDC/NCEH
CDC/National Center for Immunization and Respiratory Disease	NCIRD
CDC/NCCDPHP-Public Health Service	CDC/NCCD
CDC/NCHHSTP - Public Health Service	NCHHSTP
CDC/NCIPC- Public Health Service	CDC/NCIPC
CDC/NCZVED	
CDC/NIOSH - Public Health Service	CDC/NIOSH
Center for Medicare and Medicaid Innovation	
Centers for Medicare and Medicaid Services	
Department of Health and Human Services	DHHS
DHHS/Assistant Secretary for Preparedness and Response	ASPR
DHHS/Food and Drug Administration	

Full Name	Abbreviation
DHHS/Office for the Assistant Secretary for Planning and Eva	
DHHS/Office of Acquisition Management	
DHHS/Office of Research Integrity	
DHHS/Office of the Surgeon General	OSG
DHHS/Office on Women's Health	
DHHS/Substance Abuse and Mental Health Services Administration	SAMHSA
FDA/Center for Devices and Radiological Health	FDA/CDRH
FDA/Office on Women's Health	
H. Lee Moffitt Cancer Center and Research Institute	
Health Care Financing Administration	
Health Resources & Services Administration	HRSA
HRSA - Public Health Service	HRSA/PHS
HRSA Maternal & Child Health Bureau - Public Health Service	HRSA/MCHB
HRSA/BHP - Public Health Service	HRSA/BHP
HRSA-HIV/AIDS Bureau-Public Health Service	HRSA/HIV

Full Name	Abbreviation
Indian Health Service	IHS
National Center for Health Statistics	
National Radio Astronomy Observatory	
National Science Foundation	NSF
NIH	NIH
NIH/DRG	NIH/DRG
NIH/FIC	NIH/FIC
NIH/NCATS	NIH/NCATS
NIH/NCCAM	NIH/NCCAM
NIH/NCI	NIH/NCI
NIH/NCRR	NIH/NCRR
NIH/NEI	NIH/NEI
NIH/NHGRI	NIH/NHGRI
NIH/NHLBI	NIH/NHLBI
NIH/NIA	NIH/NIA
NIH/NIAAA	NIH/NIAAA

Full Name	Abbreviation
NIH/NIAID	NIH/NIAID
NIH/NIAMS	NIH/NIAMS
NIH/NIBIB	NIH/NIBIB
NIH/NICHD	NIH/NICHD
NIH/NIDA	NIH/NIDA
NIH/NIDCD	NIH/NIDCD
NIH/NIDCR	NIH/NIDCR
NIH/NIDDK	NIH/NIDDK
NIH/NIEHS	NIH/NIEHS
NIH/NIGMS	NIH/NIGMS
NIH/NIMH	NIH/NIMH
NIH/NIMHD	NIH/NIMHD
NIH/NINDS	NIH/NINDS
NIH/NINR	NINR
NIH/NLM	NIH/NLM
NIH/OAR	NIH/OAR

Full Name	Abbreviation
NIH/ODS	ODS
Office of Minority Health-Public Health Service	
Office of the Civilian Volunteer Medical Reserve Corps	MRC
Office of the Director, NIH	NIH/NDPA
Public Health Service	
Public Health Service - AHRQ	AHRQ
Public Health Service - OASH	
Public Health Service - OASH/OMH	
Public Health Service - SAMHSA/CMHS	SAMHSA/MHS
Public Health Service - SAMHSA/CSAP	SAMHSA/SAP
Public Health Service - SAMHSA/CSAT	SAMHSA/SAT
Public Health Service NIAID/AIDS Repository	
Southeast Regional Center of Excellence for Emerging Infections and Biodefense	SERCEB
Susan G. Komen Breast Cancer Foundation	
Yerkes National Primate Research Center	