

Complying with Conflict of Interest Policies and Regulations

Questions Frequently Asked by Research Administration Staff / Last Updated September 20, 2012

In July and August 2012, the Office of the Vice Provost for Research (OVPR), the Office for Sponsored Programs (OSP), the Faculty of Arts and Sciences (FAS), and Financial Systems Solutions (FSS) conducted a series of training sessions for research administrators on how to comply with conflict of interest policies and regulations. The slides used during the training sessions are available [here](#). The following questions were frequently asked during these sessions.

Please note: these FAQs supplement materials available [here](#). If you have questions that are not included in these FAQs, please send them to fcoihelp@harvard.edu.

FAQs for FACULTY AND INVESTIGATORS ARE AVAILABLE [HERE](#).

GMAS QUESTIONS?

If you have questions specific to conflict of interest functionality in the University's Grants Management Application Suite (GMAS), please click [here](#).

Questions

| | |
|--|---|
| What is the University Policy on Conflicts of Interest?..... | 2 |
| What is the "PHS Rule"? | 2 |
| What/who is a Designated Institutional Official? | 2 |
| Who is an Investigator? | 2 |
| Are key personnel always Investigators? Are Investigators always key personnel? | 3 |
| What do faculty and investigators have to disclose? | 3 |
| When do faculty and investigators need to disclose? | 3 |
| Can I add a "TBD" investigator to a proposal in GMAS?..... | 4 |
| What happens when an investigator joins a sponsored project while it is already in progress? | 5 |
| How are at-risk accounts handled? | 5 |
| Does the PHS Rule apply to internal proposals? | 5 |
| Does the PHS Rule extend to subrecipients?..... | 5 |
| What is the FDP Clearinghouse?..... | 5 |
| What is the PHS Rule's "travel requirement"? | 5 |
| How does a PHS investigator disclose travel? | 6 |
| Does Harvard extend the PHS Conflict of Interest Rule to other Sponsors? | 7 |

What is the University Policy on Conflicts of Interest?

On May 26, 2010, the President and Fellows of Harvard College approved a [University-wide policy on Individual Financial Conflicts of Interest](#). This policy, revised in May 2012, provides guidance for school deans, faculty and other individuals holding teaching appointments, in identifying, evaluating, and managing conflicts of interest.

The university-wide policy provides a framework for implementation that allows for some flexibility among the various Schools in recognition of their wide variance in culture, mission, and the nature of acceptable faculty interactions with external entities. Each School's approach to implementation of the policy is described in a School Implementation Plan.

The University Policy is supplemented by [Procedures](#) specific to the implementation of the August 25, 2011 Public Health Service Rule.

Faculty at the Medical School should refer to the website of the [HMS Office for Professional Standards and Integrity](#) for HMS-specific policies and procedures. In addition to complying with the Medical School's conflict of interest policy, Medical School faculty are also expected to comply with their hospital's conflict of interest rules.

What is the “PHS Rule”?

Since 1995, the federal government has regulated issues of financial conflict of interest in federally-funded research. On May 21, 2010, in response to criticism from the Office of Inspector General of the Department of Health and Human Services (DHHS) of compliance by both NIH and the university community, DHHS proposed substantial modifications to the 1995 regulation affecting institutions seeking and/or receiving Public Health Service (“PHS”) funds. These changes were finalized in August 2011 and went into effect on August 24, 2012. The PHS Rule is available online: [Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought](#) (42 CFR 50 Subpart F).

What/who is a Designated Institutional Official?

The [University Policy on Individual Financial Conflicts of Interests](#) (“the University Policy”) requires that each Dean designate an institutional official responsible for implementation of the University Policy at the School and for reviewing all internal disclosures of significant financial interests. These individuals are known as Designated Institutional Officials (DIOs) or Conflict of Interest Officers. Contact information for School officers is available [here](#). DIOs are responsible also for the review of disclosures in compliance with the PHS Rule.

Who is an Investigator?

An investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by an agency of the US Public Health Service (including the National Institutes for Health), the National Science Foundation and certain other sponsors¹, or proposed for such funding, including sub-grantees, contractors, or collaborators.

¹ Harvard University extends the PHS conflict of interest requirements, in part, to the American Heart Association, the American Cancer Society, the Arthritis Foundation, the Susan G. Komen Foundation, the Alliance for Lupus Research and any other entity that applies 42 CFR Part 50 – see http://vpr.harvard.edu/sites/vpr.harvard.edu/files/HU_Guidance_on_PHS_Rule_Implementation.pdf

An Individual may be considered an investigator regardless of their title. It will not be uncommon for post-doctoral scholars, for instance, to be considered investigators. In determining who is an investigator you should consult carefully with the Principal Investigator.

Are key personnel always Investigators? Are Investigators always key personnel?

Yes and no. Key personnel should always be investigators since key personnel are considered responsible for the design, conduct, or reporting of the research; however, an investigator does not have to be considered key personnel (although this might be the case).

Please note that the National Institutes of Health (NIH) define key personnel as:

“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.”

What do faculty and investigators have to disclose?

All investigators and any individual with a faculty or teaching appointment must submit, in the form prescribed by their School, an internal confidential disclosure of their and their family members’ significant financial interests in the preceding twelve months in any related outside entity. Investigators and individuals with a faculty or teaching appointment must update disclosed information at least annually and:

- Within 30 days of the discovery of a new significant financial interest; and
- Prior to: accepting gifts, submitting an application for a sponsored project, or initiating a technology licensing agreement.

School Implementation Plans should specify the format for investigator disclosures. Schools are encouraged to use the fCOI IT system to collect disclosures and the GMAS system to monitor compliance with disclosure requirements at the proposal and award stage of a sponsored project. If not using these systems, Schools must have in place another system that meets the requirements of the University policy and the PHS Rule.

When do faculty and investigators need to disclose?

Faculty and investigators must disclose significant financial interests at least annually and as determined by a School’s Implementation Plan. They must also update disclosed information (e.g. a change in value of a previously reported interest) at least annually and within 30 days of the discovery or acquisition of a new financial interest. Faculty and investigators must have disclosed significant financial interests prior to accepting gifts, submitting an application for a sponsored project, or initiating a technology licensing agreement.

Investigators currently receiving or planning to apply for funding from the US Public Health Service must disclose the occurrence of sponsored or reimbursed travel within 30 days of the date of travel completion.

Can I add a “TBD” investigator to a proposal in GMAS?

No. All investigators must be named in order for the University to be able to collect a financial interest disclosure from them. Since an unnamed person cannot submit a disclosure, and OSP will not submit a proposal to a sponsor without all investigator disclosures on file, you should name all investigators.

Do Investigators need to update their disclosures every time they are added to a research team in GMAS?

No. When an individual is added to a research team on a proposal in GMAS – and if they are an investigator or have a faculty or teaching appointment – they will receive an email prompting them to file a disclosure if they have not done so already or update a previously submitted disclosure if they have acquired or discovered a new significant financial interest. If there has been no change to their previously disclosed significant financial interests (i.e. they do not have a new interest to report) then no action on their part is needed.

If a faculty member never has any sponsored research, must s/he submit a disclosure of financial interests?

Yes. Under the University Conflict of Interest policy, any individual with a faculty or teaching appointment must submit a disclosure of significant financial interests in related outside entities at least annually and must update that disclosure within 30 days of the discovery or acquisition of a new significant financial interest.

Do all research team members need to file a financial interest disclosure prior to proposal submission to all sponsors?

Yes and No. Individuals with faculty and teaching appointments must have a disclosure on file with their School prior to submitting a proposal to any sponsor (this is a requirement of the University policy). Investigators must have a disclosure on file prior to submitting a proposal to an agency of the US Public Health Service (PHS) or the National Science Foundation². For HMS and SPH, disclosures must be on file for all investigators or key personnel for all sponsors.

Can the Office for Sponsored Programs submit a proposal if an investigator’s disclosure is marked as “no disclosure” in GMAS?

No. Proposals cannot be submitted until all investigator disclosures are on file regardless of the circumstances.

Can the Office for Sponsored Programs submit a proposal if an investigator’s disclosure is marked as “needs review” in GMAS?

Yes. At proposal stage, all individuals with faculty and teaching appointments, and investigators on PHS and NSF proposals, must have submitted a disclosure of significant financial interests. The DIO needs to review the disclosure, identify and manage any conflicts, and report conflicts to the sponsor *at award stage* (i.e. prior to award set-up).

² Investigators must also file disclosures prior to submitting a proposal to the American Heart Association, the American Cancer Society, the Arthritis Foundation, the Susan G. Komen Foundation, the Alliance for Lupus Research and any other entity that applies 42 CFR Part 50 – see footnote 1, and http://vpr.harvard.edu/sites/vpr.harvard.edu/files/HU_Guidance_on_PHS_Rule_Implementation.pdf

What happens when an investigator joins a sponsored project while it is already in progress?

The investigator must be added to the research team in GMAS and their disclosure must be completed with any SFI managed, reduced, or eliminated and training completed prior to engaging in research on the project.

How are at-risk accounts handled?

At-risk accounts are handled in the same manner as awards. All investigators must have completed disclosures with any SFI managed, reduced, or eliminated and training completed prior to the at-risk account being set-up.

Does the PHS rule apply to internal proposals?

The PHS rule could apply depending on the original source of the funding from which the internal award will be made. It is advisable to confirm with the school/department to which you are applying.

Does the PHS Rule extend to subrecipients?

Yes. The regulation is applicable to each Institution that applies for PHS grants or cooperative agreements for research or submits a proposal for a research contract whether in response to a solicitation or otherwise and, through the implementation of the regulation by each Institution, to each Investigator participating in such research. Additionally, Harvard extends the PHS Rule to subrecipients on NSF awards and awards funded by Sponsors that apply 42 CFR Part 50.

Accordingly, Harvard must take reasonable steps to ensure that Investigators working for such entities comply with the regulation, either by requiring the Investigators to comply with the Harvard's policy or by requiring the entities to provide appropriate assurances to Harvard. Subrecipients/subcontractors must report identified FCOIs to Harvard; Harvard must report to the PHS or NSF the existence of any conflicting interests arising from subrecipients/subcontractors and assure that the interest has been managed, reduced, or eliminated in accordance with the regulation.

What is the FDP Clearinghouse?

The [FDP Clearinghouse](#) is a site that provides a central location for educational institutions and other entities to document that they are in compliance with the PHS Financial Conflict of Interest (FCOI) rules and regulations. It is a helpful way to verify the compliance of our potential subrecipients with these regulations. If the institution appears on this site, we do not have to ask them to complete a separate form to certify their compliance.

If the subrecipient falls under Harvard's policy (i.e., they do not have their own policy in place), how do we ensure the training requirement is completed?

At proposal stage, a PDF document of the required training will be sent to the subrecipient by the department. The subrecipient will certify that they understand and have read the training document. This will constitute compliance with the training requirement.

What is the PHS Rule's "travel requirement"?

The PHS requires that investigators applying for or receiving funding from an agency of the PHS make certain disclosures about their reimbursed and sponsored travel. Harvard does NOT extend this requirement to the National Science Foundation or other sponsors. As described in Appendix A of the University's COI policy, the requirement is as follows:

Any investigator receiving funding from the U.S. Public Health Service (PHS) must disclose to their Dean or designee the occurrence of any reimbursed or sponsored travel (i.e. that which is paid on behalf of the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Please note that investigators must disclose travel within 30 days of concluding such travel (see next question, below).

How does a PHS investigator disclose travel?

School Implementation Plans will specify the details of the disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Schools may require that Investigators disclose their planned or anticipated reimbursed or sponsored travel in a prospective manner (e.g. over the next twelve months) at the time of the annual update of financial interests, with a requirement to update the travel disclosure annually. However, Investigators must disclose new (unanticipated) sources of travel within 30 days of such travel.

The school's Dean or designee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest in regard to the PHS-funded research.



If a School uses the online disclosure system at fcoi.harvard.edu, investigators may disclose their travel directly through the system by clicking on the “New Travel Disclosure” tab in the left hand side bar (they will only be able to see this tab if they have been identified as a PHS investigator in GMAS).

If the travel funds flow through Harvard as part of a sponsored award, does travel need to be disclosed?

No, travel does not need to be disclosed if the PHS investigator is traveling on funds from a sponsored award that was issued to Harvard.

If a PHS investigator uses her Harvard corporate credit card for travel, gets reimbursed directly from an outside organization, but then reimburses the funds back into a Harvard-managed account, such as her Harvard start-up account, must she disclose the travel under the PHS Rule?

Yes, while the funds do go through Harvard, it is the investigator that is directly reimbursed, not the University, and so this travel must be disclosed to the University.

Does Harvard extend the PHS Conflict of Interest Rule to other Sponsors?

Yes and no. Harvard extends the PHS Rule, in part, to projects proposed for funding or funded by the National Science Foundation (NSF), the American Heart Association, the American Cancer Society, the Arthritis Foundation, the Susan G. Komen Foundation, the Alliance for Lupus Research and any other entity that applies 42 CFR Part 50. Note that some school specific implementation plans extend rule to all sponsors. Please check with your specific school for details. A full description of what elements of the Rule apply to other sponsors is available [here](#) and the following table provides a summary of the scope of application of some of the key elements of the PHS Rule:

| | | PHS (NIH) | | NSF + | | OTHER SPONSORS | |
|-------------------|--|-----------|---------------|---------|---------------|----------------|---------------|
| | | Faculty | Investigators | Faculty | Investigators | Faculty | Investigators |
| PRIOR TO PROPOSAL | Individual files annual disclosure of Significant Financial Interests (SFI) with School DIO if not already filed | ○ | ○ | ○ | ○ | ○ | |
| PRIOR TO AWARD | DIO reviews SFI disclosure and determines whether SFIs = conflicts; puts a management plan in place | ○ | ○ | ○ | ○ | | |
| | Individual completes conflict of interest training | ○ | ○ | ○ | ○ | | |
| | DIO/OVPR reports conflict(s) to Sponsor | ○ | ○ | ○ | ○ | | |
| | OVPR makes information about conflict available to public upon request | ○ | | | | | |
| ANYTIME | DIO reviews SFI disclosure and determines whether SFIs = conflicts; puts a management plan in place | | | | | ○ | |
| | Individual files disclosure of reimbursed or sponsored travel with School DIO/updates within 30 days of travel | ○ | ○ | | | | |
| | Individual updates annual disclosure of SFIs within 30 days of the discovery or acquisition of a new SFI | ○ | ○ | ○ | ○ | ○ | |