

Frequently Asked Questions

Financial Conflict of Interest

Q: What is the purpose of this policy?

A: The Financial Conflicts of Interest Policy protects the objectivity and integrity of research done at the Institute and its individual Faculty and staff members. The Policy is designed to ensure that faculty and staff members identify, disclose, and appropriately manage or eliminate situations in which their personal or familial interests might otherwise compromise or appear to compromise their objectivity as teachers, researchers or administrators. An effective conflicts of interest policy helps both to safeguard the work and reputations of Institute faculty and staff members and to ensure the Institute's compliance with federal and other regulatory requirements relating to conflicts of interest. The Institute's Financial Conflict of Interest Policy can be found at www.harvardpilgrim.org/coi.

Q: Where can I find the regulations?

A: The Public Health Service 2011 Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR Par 50 Subpart F) can be found [here](#).

Q: What are my “institutional responsibilities”?

A: Institutional responsibilities are defined by the 2011 revised regulation as an Investigator's professional responsibilities on behalf of the institution, and as defined in the Institute's policy on Financial Conflict of Interest, which include, for example, activities such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Q: Who determines if a significant financial interest is a Financial Conflict of Interest?

A: The Conflict of Interest Management Committee makes the final determination of Financial Conflict of Interest. Committee members include:

- Vice President of Harvard Pilgrim's Corporate Compliance Programs
- Director of Harvard Pilgrim's Ethics Program
- A member of Harvard Pilgrim's Office of General Counsel
- Non- voting attendees (including the Senior Compliance Specialist, and consultants or individuals deemed necessary by the COIMC).

Q: What are some examples of management plans that may be utilized?

A: The Conflict of Interest Management Committee has responsibility for approving management plans.

Training

Q: Am I required to do COI training?

A: Yes, all Investigators and research personnel are required to complete COI training once every four years to comply with the Public Health Service COI regulations. The Institute is providing this training through a module in the CITI Training Program.

Q: How do I access the CITI training?

A: You can log in or register at www.citiprogram.com. Instructions on how to register and access the CITI COI module can be found on this website under Financial Conflict of Interest/Forms and Instructions.

Q: How long will the CITI training take?

A: The training will take approximately 20 minutes.

Q: When must I take the training?

The training must be *completed* prior to the submission of a new application for external funding.

Disclosure

Q: What do I have to disclose?

A: You must disclose ALL financial interests associated with your appointment or position at the Institute, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Q: Must I disclose the financial interests of my family?

A: Yes, this includes your spouse or domestic partner and dependent children.

Q: How often must I disclose my significant financial interests?

A: Disclosure reporting is required: 1) annually by Institute employees; 2) at the time of initial application for federally funded research, and 3) prior to any expenditure under a Federal award. Investigators are also required to update their disclosure within 30 days of discovering or acquiring a new Financial Interest.

Q: How do I create a research certification in Click Commerce?

A: Email the COI Administrator at COI_Administrator@harvardpilgrim.org, and cc your Grant Manager, with a request to set-up a research certification. Include the following in this email:

- Project ID (Grant # or # from Oracle)
- The full study title

- A list of all persons responsible for the design, conduct or reporting on your study (known as disclosers). Indicate the role for each discloser (e.g. PI, Co-I, etc.)

The COIA will create the certification and each discloser will be notified via email that action in their Click Commerce inbox is required. Disclosers will complete the certification as required.

Q: What are disclosure/reporting thresholds?

A: For the purpose of disclosure, the Institute, consistent with HMS policy for Faculty, requires reporting of all financial interests related to an Investigator's institutional responsibilities regardless of amount. For Federal reporting purposes, the Institute follows the PHS definition of Significant Financial interest under the 2011 revised regulation, requiring the Institute to report significant financial interests with an aggregated value of \$5,000 or greater to the PHS awarding component.

Q: What if I fail to disclose, either intentionally or unintentionally?

A: An Investigator must disclose a newly discovered SFI within 30 days so that the Institute can meet its federal reporting requirements. An unreported SFI must be evaluated by the Institute to determine whether the unreported SFI is a Financial Conflict of Interest. If FCOI is found, the Institute is required under the regulation to conduct a retrospective review to assess potential bias and report to the PHS Funding Component. Additional information about this process can be found in the Institute's COI policy.

Reporting

Q: What information will be made public pursuant to the new PHS regulation?

A: The following information about an Investigator's FCOI will be made publicly accessible by a written response to any requestor within five business days of a request:

- the investigators name
- the investigators title and role with respect to the research project
- the name of the entity in which the SFI is held
- the nature of the FCOI; and
- the approximate dollar value of the FCOI.

Requests should be sent to the following email address:

COI_Administrator@harvardpilgrim.org

FCOIs will also be externally reported to the funder, prime awardees and IRB, if applicable.

For Further Information

Please contact Deirdre Neylon, Administrative Specialist at [Deirdre Neylon @harvardpilgrim.org](mailto:Deirdre_Neylon@harvardpilgrim.org) or at 617-867-4321.