

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 conducted 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 policy and procedure on Financial Conflicts of Interest of Researchers and Research Staff can be found at www.hphcinstituteosp.org/fcoi.

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 (COIMC) makes the final determination of Financial Conflict of Interest. Committee members include:

- Chief Compliance Office of Point32Health's Corporate Compliance Programs
- Executive Director of Harvard Pilgrim Health Care Institute
- A member of Harvard Pilgrim's Office of General Counsel
- Non- voting attendees (including the Research Compliance Program Manager, and consultants or individuals deemed necessary by the COIMC).

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

A: The COIMC 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.org. 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 initiate a research certification in Cayuse?

A: The certification will automatically be created for all research personnel when the SPA is submitted in the Cayuse system. Notices will be sent to the email address associated with the employee's network email. Users will click on their profile, then access COI Disclosures in the drop-down menu.

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@point32health.org

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

Cayuse

Q: Do I have to keep entering my outside interests for each research-based disclosure?

A: No, but you do have to have it entered & submitted at least once in order for your outside interest to appear with each future disclosure. If you have outside activities or financial interests, you must answer “yes” in the **Outside Activity Details** section, and re-identify the category of disclosure (equity, intellectual property, etc.). When you move to the next section of your applicable interest’s category, you will see the details of your previously disclosed financial interests and you will be prompted to review the details of your outside activities before submitting. If your information does not auto-fill, please refresh the page by pressing function f5 or refresh.

Q: What if my outside interests do not relate to the proposed research?

A: In the **Study Information** section, you can answer “no” if your outside interests are not related to the proposed research. If you answer “yes” the next questions will require that you identify which outside interest is related to the research study you are disclosing on, and you will need to describe how they overlap. If you answer “no”, you still are required to keep your outside interests active in your COI disclosure. You will do this

in the **Outside Activity Details** section. You must answer “yes” in the Outside Activity Details section if you have any outside financial interests, and re-identify the category of disclosure (equity, intellectual property, etc.). When you move to the next section of your applicable interest’s category, you will see the details of your previously disclosed financial interests auto-populate, and you will be prompted to review the details of your outside activities before submitting.

For Further Information

Please contact Deirdre Neylon, Project Coordinator at:

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