Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs

Policy and Procedure

TITLE: Financial Conflicts of Interest of Researchers and Research Staff

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PURPOSE:

To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research, including research funded under Public Health Service (PHS) grants or cooperative agreements, will not be biased by conflicting financial interests of researchers and research staff.

PERSONS AFFECTED:

This policy & procedure (P/P) applies to all Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim Health Care Institute, LLC (HPHCI) (collectively, HPHC/I) researchers and research staff ("investigators") responsible for the design, conduct, or reporting of research. This includes, but is not limited to, faculty, fellows, project managers, and data analysts. This also applies to contingent workers.

This policy also applies to sub-recipients, subcontractors or collaborators of HPHC/I involved in PHS research activities unless the home institution of the sub-recipient, sub-contractor, or collaborator has its own written policy on conflict of interest that is in accordance with 42 CFR 50, Subpart F.

POLICY:

HPHCI recognizes that a financial conflict of interest may arise due to the nature and scope of research activities. A financial conflict of interest may be actual, potential or perceived, and, if not properly identified and managed, could compromise the integrity of the research and reputation of HPHCI and its employees. HPHCI employees who are Harvard Medical School (HMS) Faculty must also comply with applicable HMS policies and requirements for reporting outside activities and conflicts of interest.

DEFINITIONS:

Business
Any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint-stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes.

Conflict of Interest Management Committee (COIMC)
The HPHCI committee that is made up of the HPHCI Vice President, Administration & Finance, an attorney from the Point32Health Office of the General Counsel, and the Point32Health Chief Compliance Officer with the authority to review disclosures of significant financial interests, determine whether a significant financial interest is a financial conflict of interest related to PHS-funded research, and develop and implement management plans.

Design, Conduct or Reporting of Research
Oversight, decision-making or participation, in research that includes creating the structure, roles, and/or protocol of a research project; participating in the execution of the research roles and protocol; participating in the publishing, presentation, or discussion of the research results.

Disclosure of Financial Interests
An investigator's disclosure of financial interests to an Institution. Disclosure reporting is required:

1. annually;
2. at the time of initial application for federally funded research;
3. within 30 days of discovering or acquiring a new financial interest; and
4. prior to any expenditure under a federal award.

Financial Interest
Anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI)
A significant financial interest that HPHCI reasonably determines could directly and significantly affect the design, conduct, or reporting of research.

Financial Conflict of Interest Report
An Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial Conflict of Interest Management Plan
A detailed plan developed by the HPHCI COIMC that outlines the actions necessary to manage, reduce, or eliminate a FCOI to ensure, to the extent possible, that the design, conduct and reporting of research will be free of bias.

Immediate family Member(s)
An individual's spouse, domestic partner and/or dependent children.

Institution
Any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for or that receives, PHS research funding.

Institutional Responsibilities
The investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as IRBs or Data and Safety Monitoring Boards.

Investigator
The principal investigator or project director and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborations or consultants, also referred to as "researcher" and "research staff" in this P/P.

Manage
Taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Noncompliance
Intentional or unintentional failure to comply with PHS regulations or this policy, including but not limited to: failure to report one or more financial interest; failure to comply with a FCOI management plan established by the COIMC; failure to update one's financial interests; and failure to adhere to the mandates of this policy.

Public Health Service (PHS)
The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH) and the Food and Drug Administration (FDA).

PHS Awarding Component
The organizational unit of the PHS that funds the research that is subject to this policy.

PI/PD
The principal investigator or project director of a PHS-funded research project; the PI/PD is included in the definition of senior/key personnel and investigator in this policy.

Reporting
The requirement for HPHC to notify PHS funding agencies and the public of information related to FCOI and management plans.

Research
A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research;

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

For definition of "research" under the FDA regulations, see the definition for "clinical investigation" in Glossary.

Senior/key personnel
The PI/PD and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this policy.

Significant Financial Interest (SFI)
A financial interest of the investigator and/or immediate family member(s) that reasonably appears to be related to the investigator's institutional responsibilities that meets one or more of the following criteria established by the PHS:

a. Financial Income: payments or anything of monetary value from a single entity that when aggregated for the investigator and immediate family member(s) for the past 12 months or expected over the next 12 months exceeds $5,000. This includes salary and other payments by the entity (e.g. consulting fees, honoraria, paid authorship, etc.);

b. Equity Interest: for a publicly traded business, an equity interest (e.g., stock, stock options, or other ownership interest) that when aggregated for the investigator and immediate family member(s) exceeds $5,000. For a non-publicly traded business, any equity interest in such business, regardless of the amount, even if the value of the equity is unknown;
c. Intellectual Property Interest: any income (regardless of amount) related to intellectual property rights and interests (patents, copyrights, etc.).
d. Travel: any reimbursed or sponsored travel, related to institutional responsibilities, which was paid on the investigator's behalf, even if the exact value of the travel is unknown.

Exclusions:

- Payments by or ownership in an entity that is unrelated to your institutional responsibilities (e.g., a geneticist does not need to report payments received for playing the saxophone at a local watering hole).
- salary, royalties, or other remuneration paid by the Institution to the investigator, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- any ownership in mutual funds, retirement accounts or other investment vehicles where you do not directly control the investment decisions;
- Any ownership in or payments from your own private clinical practice.
- Situations where the only relationship is through this institution or a Harvard affiliate institution (such as sponsored research agreements) do not need to be reported. For example, if you receive sponsored research support from a pharmaceutical company to conduct research at this institution or a Harvard affiliate institution, and you have no other relationship to that company, there is no need to report it.
- salary support, honoraria or other income paid by Harvard, an affiliated institution, or any other academic teaching hospital, medical center, or a research institute that is affiliated with a charitable institution of higher education located in the United States. Paid and unpaid relationships and positions with foreign institutions must be reported;
- Payments from a local, state or United States federal agency do not need to be reported. However, paid and unpaid relationships and positions with foreign governments and agencies must be reported; or
- travel reimbursed by a United States government agency, an institution of higher education in the United States, or an academic teaching hospital, medical center, or research institute affiliated with an institution of higher education located in the United States. You also do not need to report travel if you receive less than $5000 in aggregate from the entity (including travel). This means that you only have to report travel if a reasonable estimate for that travel exceeds $5000, you earn more than $5000 from the entity or the combination of the two exceed $5000.

When following FDA regulations: financial interests of the researcher or research staff, or their immediate family member(s) means:

- Ownership interest, stock options, or other financial interest related to the research unless it meets four tests:
  - Does not exceed $50,000 when aggregated for the immediate family.

    - Publicly traded on a stock exchange.
    - No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.
    - Does not exceed 5% interest in any one single entity when aggregated for the immediate family.
- Compensation related to the research unless it meets two tests:
    - Does not exceed $25,000 in the past year when aggregated for the immediate family.
    - No arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.

Small Business Innovation Research (SBIR) Program: means the extramural research program for small businesses that is established by the Awarding Components of the PHS and certain other federal agencies under Public Law 97-219; the Small Business Innovation Development Act, as amended. For purposes of this policy, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

PROCEDURE:

1. Responsibilities of Researchers and Research Staff

Researchers and research staff including any Investigator or any other person regardless of title or role, responsible for the design, conduct or reporting of research are required to report their external commitments and financial interests annually, and on an event-required basis for themselves and their immediate family member(s). Event-based reporting is required:

a. when external commitments and financial interests materially change;
b. prior to submission of new application for federal funding;
c. when submitting an application for grant renewal or IRB approval;
d. prior to expenditure of funds under federal award or initial IRB approval;
e. upon appointment or employment;
f. when newly assigned to a research personnel role;
g. when initiating licensing activity; and
h. when otherwise required.

2. Annual Disclosure Reporting

Researchers and research staff are required to disclose external commitments and financial interests annually. HPHCI's Financial Disclosure form can be found in Cayuse at: https://harvardpilgrim.app.cayuse.com/. Guidance information can be found at: https://www.hphcinstituteosp.org/. Annual reports must be submitted even where researchers and research staff do not have any SFI to disclose. Researchers who have HMS faculty appointments through the Department of Population Medicine are also required to disclose financial interests to HMS in accordance with HMS policy.

3. Event-Based Reporting

a. *External funding:* researchers and research staff seeking external funding for a research project must submit their initial financial disclosure form or annual update no later than the time of application for funding.

b. *Non-exempt research with human subjects*: researchers and research staff intending to conduct non-exempt research with human subjects must submit their initial disclosure form or annual update prior to final IRB approval of the project.
c. *Changes:* Any changes to SFI for researchers, research staff or immediate family member(s) must be reported within 30 days of discovering or acquiring a new SFI.
d. *Travel:* researchers and research staff must disclose reimbursed or sponsored travel related to their institutional responsibilities. Disclosures must include, at a minimum:
   - purpose of the trip;
   - identity of the sponsor or organizer;
   - destination;
   - duration; and
   - if known, the monetary value.

   The COIMC or its designee(s) will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a FCOI with the investigator's research.
e. Documentation of completed disclosures will be maintained in Cayuse by the COI administrator for a minimum of three years.

4. Training

All researchers and research staff must complete training related to the contents of this policy and federal regulations about objectivity in research at least once every four years and more frequently if there are significant changes to this policy or related regulations that affect the responsibilities of researchers or research staff, or as determined by HPHCI. Training will be required more frequently for those who do not comply with this policy or as part of a FCOI management plan.

HPHCI uses an online FCOI training program provided by the Collaborative Institutional Training Initiative (CITI). The CITI training program can be found at: www.citiprogram.org (See, *Policy and Procedure on Training*).

Initial training must be completed prior to the submission of any new application for PHS funding. Researchers and research staff are responsible for ensuring that research personnel on their project complete initial training. Failure to complete initial training may result in suspension of access to grant funds until training has been completed. Additional training will be required immediately whenever this Policy and procedure is revised in a manner that changes the requirements. Newly hired researchers and research stuff must comply with training timelines according to the *Policy and Procedure on Training*.

COIMC members will also complete the FCOI training program provided by CITI. The Director, Research Integrity and Compliance Officer (DRICO, or designee) will assist in this process.

5. Supervisor Responsibilities

Supervisors are responsible for ensuring that those individuals they lead or supervise are aware of the importance and requirements of this policy and procedure. In the event that the DRICO (or

designee) becomes aware that an investigator has acquired a new FI that has not yet been reported, the following steps will take place:

- The DRICO or designee will contact the investigator to remind them of the reporting requirements according to this policy.
- If the OAR has not been updated within 30 calendar days, the DRICO or designee will send a notice of non-compliance to the investigator by email with a copy (cc) to her/his direct supervisor.
- For personnel involved in the conduct of research, supervisors must send an email to the DRICO or designee certifying that the delinquent investigator will not participate in research until the OAR has been updated.
- If the investigator does not complete the updated OAR within the next 15 calendar days, a notice of non-compliance will be sent to the investigator from the Executive Director and Chair of the Department of Population Medicine with a cc to their direct supervisor and grants manager, if applicable.
- The investigator will then have 48 hours to either complete the updated OAR.
- If the OAR is not completed, the non-compliance will be escalated to the COIMC to make them aware of the events that have occurred and to determine appropriate next steps. If it is determined that the newly acquired FI is a SFI, the DRICO or designee will move forward according to the steps under 6.d.

6. Institutional Responsibilities

a. Training

The DRICO (or designee) is responsible for implementing FCOI training to inform researchers and research staff of (1) HPHCI's FCOI Policy and (2) the disclosure reporting obligations as set forth herein.

b. Disclosure Review and Conflict Management

Disclosures of financial interests will initially be reviewed by the DRICO within 14 days of submission. SFIs related to research activities will be referred to and reviewed by the COIMC for a FCOI determination. If a FCOI exists, the COIMC will take action to eliminate, reduce, or manage the conflict, as appropriate.

A FCOI will exist when the COIMC or designee reasonably determines that a SFI could directly and significantly affect the design, conduct, or reporting of research. If the COIMC determines that there is a FCOI that can be managed, the COIMC must approve a written management plan before the expenditure of PHS funds or enrollment of research subjects.

The COIMC will work with the investigator to develop an appropriate conflict management plan. The COIMC may employ a number of resources in order to assist in the determination of FCOI and development of management plans. This includes the utilization of professionals and other experts. The COIMC has final authority regarding the acceptability of a conflict management plan for the purposes of compliance with the PHS regulation, if applicable. Every precaution will be made to assure the objectivity and confidentiality of the proceedings.

At its discretion, the COIMC may consider requests for reconsideration from researchers and research staff. The DRICO will respond to the request ordinarily within three (3) weeks after receiving the request. A single such request will be allowed for any case.

The COIMC may designate oversight committees or individuals to periodically review the ongoing research activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan. HPHCI's Board of Managers may also request interim compliance audits of the monitoring plans be conducted by the DRICO. These audits may be requested either for cause or on a routine basis.

c. Institutional Reporting for PHS Funded Research
    i. *Initial Report:* prior to the expenditure of any funds under a PHS-funded research project, the Office of Sponsored Programs (OSP) will provide to the PHS Awarding Component a FCOI Report regarding any investigator with a SFI which has been determined by the COIMC to constitute a FCOI and which requires the creation of a FCOI Management Plan. If the management of the FCOI involves elimination of the conflict, no such report is required.
    ii. *Report Contents:* FCOI reports to the PHS Awarding Component will include sufficient information to enable PHS to understand the nature and extent of the FCOI, and to assess the appropriateness of the FCOI management plan. Elements of the report shall include:
        - project number;
        - grant/contract number;
        - project title;
        - period of performance;
        - name of principal investigator;
        - name of the investigator with the FCOI;
        - name of the entity with which the investigator has a FCOI;
        - nature of the FCOI;
        - value of the FCOI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
        - description of how the FCOI relates to the PHS-funded research and the basis for the determination that the financial interest conflicts with such research; and
        - description of the management plan itself, to include:
            - role and principal duties of the conflicted investigator on the research project;
            - conditions of the FCOI management plan;
            - how the FCOI management plan is designed to safeguard objectivity in the research project;
            - confirmation of the investigator's agreement to the FCOI management plan;
            - how the FCOI management plan will be monitored to ensure compliance; and

- other information as needed.

iii. *Frequency of Reports:* FCOI reports will be updated on at least an annual basis for the duration of the PHS-funded research project (including extensions with or without funds). The annual report will specify whether the FCOI is still being managed, changes have been made to the FCOI management plan, or that the FCOI no longer exists.

iv. *Reporting New Information:* new FCOIs that are identified after the initial expenditure of funds shall be reported to the PHS Awarding Component within 60 days of the identification of the conflict. The FCOI report should provide an assurance that HPHCI has implemented an appropriate FCOI management plan for the newly identified conflict.

v. *Reporting Noncompliance:* policy breaches, defined below, which result in a retrospective review determination finding that any portion of the research was biased in design, conduct, or reporting, shall be reported to the PHS Awarding Component in accordance with the time frame established in this policy and by PHS regulation. A mitigation report will also be required in this case.

d. Noncompliance

i. *Breach:* a breach of this policy by an investigator may include, but is not limited to:

- SFIs that were not disclosed in a timely manner;
- disclosing inaccurate, erroneous or misleading information;
- failure to provide additional information to the COIMC regarding a disclosure; or
- violation of the terms of an approved FCOI management plan.

A breach of the policy might also include the failure of the COIMC to provide a timely review of a properly disclosed SFI.

ii. *Action Upon Breach:* if an alleged or actual policy breach occurs, the convened COIMC shall, within 60 days, review the SFI; determine whether it is related to the research project; determine whether an FCOI exists; and, if so, shall implement, on at least an interim basis, a FCOI management plan that shall specify the actions that have been, and will be taken to manage such FCOI going forward. The COIMC may suspend all relevant activities or take other action until the matter is resolved or other action deemed appropriate by the COIMC is implemented.

iii. *Retrospective Review:* if a policy breach is found to be an unreported FCOI, the COIMC shall, within 120 days of being made aware of the breach, complete a retrospective review of the investigator's activities and the research project to determine whether any of the research conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of the research. This retrospective review must be documented and contain, at a minimum, the following elements:

- project number;
- project title;
- name of principal investigator;
- name of investigator with the FCOI;
- name of the entity with which the investigator has the FCOI;
- reason(s) for the retrospective review;
- detailed methodology used for the retrospective review; and

- findings and conclusions of the review.

The results of the retrospective review shall be reported to the sponsor or funding agency as required by 42 CFR 50.605(a)(3)(iii). The Director of OSP will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, a mitigation report will be submitted and include a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias. In addition to the above, investigators who have an FCOI that was not reported or managed will be required to do the following:

- disclose the FCOI in each public presentation of the results of their research; and
- amend previously published presentations to include the disclosure of the FCOI

iv. *Additional Training:* any policy breach by a researcher or research staff will result in immediate additional training regarding the policy and the federal regulations.

vi. *Intentional Noncompliance:* If the COIMC determines that the breach was part of an intentional plan to deceive the COIMC or regarding one's financial interests, the COIMC may recommend additional sanctions to HPHCI's Board of Managers. These sanctions may include, but are not limited to:

- a letter of reprimand to the investigator with a copy to the investigator's Chair, Director of Research and personnel file;
- temporary or permanent suspension of the investigator's ability to submit new applications for external funding and/or research involving human subjects;
- temporary or permanent suspension of research privileges;
- non-renewal of appointment or dismissal in accordance with HPHCI's policies and Code of Conduct.

6. Sub-Recipient Monitoring by Grants Managers

In cases where HPHCI carries out research through a sub-recipient institution, HPHCI Grants Managers will take reasonable steps to ensure that any sub-recipient investigator is adhering to the regulations concerning COI in research in 42 CFR 50.604(c).

As part of the agreement with sub-recipient institutions, HPHC's OSP will obtain a certification from the sub-recipient institution indicating whether the policies of HPHCI or the sub-recipient institution will apply to the sub-recipient researchers and research staff.

a. Following Sub-Recipient Institution's Policies

If the sub-recipient institution's policies are followed, the Grant Manager for that project will verify that certification must include a statement that the sub-recipient institution's conflicts of interest in research policies comply with 42 CFR 50. The certification must also indicate a time frame by which any sub-recipient's FCOI will be reported to HPHCI, preferably within 30 days. If such a certification cannot be provided, then HPHCI's policies will apply to all sub-recipient researchers and research staff for disclosing SFI that are directly related to the sub recipient's work for HPHCI.

b. Following HPHCI's Policies

If HPHCI's policy applies, the agreement must specify a deadline for the sub-recipient to submit disclosures of their researchers' SFI to HPHCI. The disclosures must be provided in a timely manner in order to allow review and any actions required by the COIMC prior to the expenditure of funds.

c. Institute Reporting Responsibility

For PHS-funded grants awarded to HPHC, the Director of OSP is responsible for providing FCOI reports to the PHS Awarding Component prior to the expenditure of funds, and within 60 days of any subsequently identified FCOI.

7. Public Accessibility

As required by 42 CFR Part 50, information regarding SFIs for PHS-funded research for which FCOI management plans have been developed will be made available to requestors within five (5) business days after HPHCI receives the request. Submit inquiries to: research_admin@hphci.harvard.edu.

In order for HPHCI to disclose the information, the following criteria must be met:

- The SFI must have been disclosed to HPHCI and is still held by the senior key personnel;
- The SFI is related to the PHS-funded research; and
- The SFI has been determined to be a FCOI.

The information to be shared with requestors shall be consistent with the requirements of the PHS regulations and will include the following:

- name of researcher or research staff;
- title and role with respect to the research project;
- name of entity in which the SFI is held;
- nature of the interest;
- approximate dollar range of the SFI (or a statement that the value cannot be readily determined).

This Financial Conflicts of Interest of Researchers and Research Staff policy can be found at: https://www.hphcinstituteosp.org/fcoi.

8. Records Retention

HPHCI will retain all disclosure forms, FCOI management plans, and related documents in accordance with HPHCI's *Research Records Retention and Destruction* policy.

9. Confidentiality

As far as is practicable and consistent with legal obligations, HPHCI protects the confidentiality of FCOI information. Information and written materials provided to HPHCI are shared to the most limited degree possible with those COIMC members and staff who are involved in the processing and review of reported information and the creation and implementation of FCOI management plans and compliance reports. In certain instances, HPHCI may make such information available to external entities, including but not limited to, an agency funding research of the investigator; a requestor of information concerning FCOI related to PHS funding; HMS; or to the primary entity who made the funding available to the Institution, if requested or required. If HPHCI is requested to provide disclosure forms, FCOI management plans, and related information to an outside entity, the investigator will be informed of this disclosure.

Administrative Functions

Disclosure Submissions Process in Cayuse

1. A research-based disclosure submission is submitted by a researcher or research staff via Cayuse for either a new Research Certification Request or if the investigator updates his/her Outside Activity Report due to changes and/or new reports of travel.

2. COI Administrator(s) are alerted to research-based disclosure submissions by receipt of an email or by accessing the inbox account for Outside Interests in Cayuse.

3. The COI Administrator will review the disclosure. The COI Administrator will confirm the required COI CITI training has been completed for the investigator and that all questions on the form have been answered completely. Documentation of CITI training is maintained by the RIC Compliance Specialist. If the training is incomplete or has expired, the COI Administrator will click the Return to Disclosee link and will send the certification back to the investigator with instructions to complete the training and submit changes once completed.

4. When COI CITI training has been confirmed, the COI Administrator will move forward with the review and add comments that the CITI training is complete and assign the review to the DRICO as applicable. Automatic notification will be sent to the DRICO that the form is ready for review.

5. The DRICO or designee will review the actual disclosure.

6. If the Outside Activity Report (OAR) requires any clarification, or if parts of the form were left blank, the OAR will be returned to the investigator for correction by clicking the Return to Disclosee link. The DRICO or designee may consult with the investigator, and/or the Director of the Office of Sponsored Programs, and/or the HPHCI Vice President, Administration & Finance on sections requiring correction or clarification. The investigator will be automatically notified via Cayuse when corrections or clarifications are required. After the investigator completes the corrections, the form is re-submitted for review by the DRICO or designee.

7. If the Outside Activity Report (OAR) does not identify any financial disclosures, the DRICO or designee will:
   a. click the 'Review disclosure and confirm your review' link and add any comments relevant to the review
   b. click 'confirm review'
   c. click 'resolve' for the Administrative Determination
   d. check 'No COI determined'

8. If the OAR identifies a financial disclosure, the DRICO or designee will evaluate to determine if the disclosure is a SFI related to the research.
   a. If a SFI related to the research is not identified, and all disclosed entities have been previously reviewed, the DRICO or designee will:

i. 'Review disclosure and confirm your review' link and add any comments relevant to the review and add that there is no SFI related to the research identified.
ii. click 'confirm review'.

b. If the DRICO confirms there is not an actual SFI related to research, the COI Administrator will complete the steps as cited in 7a.

c. If the DRICO confirms there is an apparent SFI related to research, the COI Administrator will:

i. click to confirm the review add comments that the disclosure has been sent to the COIMC for review;
ii. Update the excel spreadsheet documenting the COIMC reviews (documented here: J:\rashare\COI\Agendas & Minutes).
iii. Send an email to the COIMC which contains a summary of the disclosure, a pdf attachment of the Disclosure, and a request for determination of FCOI (as described in the Institutional Responsibilities section above). All committee reviews take place outside of the Cayuse system.
iv. Once the review is complete, the DRICO (or designee) will update the COIMC reviews excel spreadsheet. In Cayuse, the COI Administrator will click the Resolve link and update the Disclosure Resolution.
v. If the COIMC issues a management plan, the DRICO (or designee) will have the IRBNet record tagged as applicable.
vi. If an IRBNet record does not yet exist, the DRICO (or designee) will notify the applicable Grants Manager (GM) and the Director of OSP that a management plan is place. The GM will track that a management plan exists and will alert IRB staff at the time of IRBNet submission.

9. Once the Disclosure Resolution has been updated, a notice will be sent to the Disclosee.

Process for Public Accessibility of any FCOI

1. The COI Administrator is alerted to a request for public accessibility via the email inbox; COI_Administrator@hphci.harvard.edu.

2. The COI Administrator HPHCI shall provide a written response to the requestor within 5 business days and use time stamps throughout the process.

3. The COI Administrator will send the request to the DRICO for review.

4. If the information requested meets the appropriate criteria, the DRICO will send a response to the requestor within 5 business days that provides the requested information:

a. researcher/staff name;
b. researcher/staff title and role with respect to the research project;
c. name of entity in which the FCOI is held;
d. nature of the FCOI; and
e. approximate dollar range of the FCOI (or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value).

The response shall also note that the information is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of HPHCI's identification of a new FCOI, which should be requested subsequently by the requestor.

5. If the requested information does not meet the appropriate criteria, the COI Administrator will respond to the requestor with the following template letter:

Hello,

The information you have requested is not publicly accessible. In order for HPHCI to make the requested information publicly accessible, the following criteria must be met:

a. The FCOI was disclosed to HPHCI and is still held by the researcher or research staff; and

b. The FCOI is related to the PHS-funded research.

6. All inquiries and correspondence shall be saved in the COI Administrators "FCOI Inquiry Records" folder in Outlook and shall remain available for at least three years from the date that the information was most recently updated.

Annual Certification Disclosure Process

1. An Annual Certification submission is submitted by a researcher or research staff via Cayuse as part of the annual reporting requirement.

2. COI Administrator(s) are alerted to annual certification submissions by accessing the inbox account of the COI Administrator.

3. The COI Administrator will click the link to review the disclosure within 14 days of submission.

4. The COI Administrator will review the actual certification to ensure the disclosee checked that they have read/understood requirements box and that the rest of the form is complete and to review any new disclosures that may have been made.

5. If the Annual Certification does not identify any new financial disclosures, the COI Administrator will click the Resolve link updating the appropriate fields.

6. If the Annual Certification identifies a new financial disclosure, the DRICO (or designee) will evaluate to determine if the disclosure is a SFI related to current research.

a. If a SFI related to current research is not identified, and all disclosed entities have been previously reviewed, the DRICO will:

- click the 'Review disclosure and confirm your review' link and add comments that there is no SFI related to current research identified
- click 'confirm review'
- click 'resolve' for the Administrative Determination updating the appropriate fields.

b. If the DRICO confirms there is an apparent SFI related to current research, the COI Administrator will:

i. add comments that the Annual Certification has been sent to the COIMC for review.

ii. update the excel spreadsheet documenting the COIMC reviews (documented here: J:\rashare\COI\Agendas & Minutes).
iii. send an email to the COIMC which contains a summary of the disclosure, a pdf attachment of the Cayuse Disclosure, and a request for determination of FCOI (as described in the Institutional Responsibilities section above). All committee reviews take place outside of the Cayuse system.
iv. Once the review is complete, the COI Administrator will update the COIMC reviews excel spreadsheet. In Cayuse, the COI Administrator will click the 'Review disclosure and confirm your review' link and update the appropriate fields.

iv. If the COIMC issues a management plan, the COI Administrator will have the IRBNet record tagged as applicable.
v. The investigator will attach the COI management plan to the IRB initial application or amendment (if study already in process).
vi. If an IRBNet record does not yet exist, the COI Administrator will notify the applicable Grants Manager (GM) that a management plan is place. The GM will track that a management plan exists and will alert IRB staff at the time of IRBNet submission.

7. Once the Resolve link has been updated a notice will automatically be sent to the Disclosee.

8. Reports of the results shall be provided to the Chief Compliance Officer as requested.

9. The Office of Research Integrity & Compliance maintains documentation for a period of the of 11 years or as long as the Cayuse system can retain the documentation if less than 11 years.

REVISION HISTORY:

Department: Office of Research Integrity and Compliance	**Title**: Financial Conflicts of Interest of Researchers and Research Staff
Effective Date: 09/20/24	**Owner:** Director, Research Integrity & Compliance Officer
Replaces P/P Dated: HPHCI FCOI In Research Policy (12/16/14); P/P (07/10/18); P/P (12/26/18, 03/22/19, 03/16/20, 09/23/20, 03/31/21, 04/27/21, 05/13/21, 08/01/22, 03/08/24)	
Related Documents: Investigators Handbook; Frequently Asked Questions: Financial Conflict of Interest; Initial Application; Form: Continuing Review	
References: 42 CFR 50; 45 CFR 94; 45 CFR 690; 45 CFR 74.53(b); 45 CFR 92.42(b); 21 CFR 54.2(a)-(d); 21 CFR 54.2(f); 21 CFR 54.4(a)(3); 21 CFR 54.4(b); 21 CFR 812.110(d); AAHRPP Elements I.6.B and III.1.B; AAHRPP Tip Sheet 10.	