



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

Policy and Procedure

TITLE: Organizational Financial Conflicts of Interest in Research

PURPOSE:

To identify, evaluate, manage and minimize or eliminate any financial interests of the organization or key organizational leaders that conflict with the organization's obligation to protect participants, preserve the integrity of the research, or maintain the credibility of the Harvard Pilgrim Health Care, Inc. human research protection program ("HRPP").

PERSONS AFFECTED:

This policy and procedure ("P/P") applies to senior administrative leaders at Harvard Pilgrim Health Care Institute, LLC ("HPHCI") and the HPHCI Board of Managers ("Key Leaders").

POLICY:

The financial interests or holdings of HPHC/I and its Key Leaders must not affect, or reasonably appear to affect, the design, conduct, reporting, review or oversight research conducted at HPHCI.

Financial conflicts of interest are identified, managed, and minimized or eliminated to maintain protection of research participants, ensure the integrity of the research, and ensure the credibility of the HRPP.

Potential conflicts of interest that may involve members of the Institutional Review Board ("IRB") or consultants retained by the IRB are regulated by the *Policy and Procedure on IRB Members and Consultant Conflicts of Interest*.

Potential conflicts of interest that may involve investigators are regulated by the *Policy and Procedure on Financial Conflicts of Interest of Researchers and Research Staff*.

DEFINITIONS (for purposes of this policy):

Organizational Financial Conflict of Interest (“OFCOI”) in research

Any situation in which the financial investments or holdings of HPHC/I or the personal financial interests or holdings of Key Leaders might affect or reasonably appear to affect processes for the design, conduct, reporting, review, or oversight of human subjects research. An OFCOI in research may arise when:

- a Key Leader with any direct or indirect business or significant financial interest in an entity is able to act on behalf of HPHC/I regarding research activities in a way that may benefit or be perceived to benefit the entity;
- HPHC/I licenses an invention to an entity and holds royalty or equity interests in the entity that may be affected by ongoing HPHC/I research or other HPHC/I activities;
- a HPHC/I vendor donates a gift to HPHC/I or to the Harvard Pilgrim Health Care Foundation, Inc. or its successor in interest, the Point32Health Foundation, Inc. (collectively, the “Foundation”) on behalf of or for use with/for HPHC/I research activities;
- HPHC/I or its affiliate holds investments in a business entity that has a research relationship with HPHC/I;
- HPHC/I enters into a commercial transaction that compromises or appears to compromise HPHC/I’s research, teaching, or outreach mission activities, or its institutional reputation; or
- HPHC/I has a business or significant financial interest in a business entity whose commercial interests may be affected by human subjects research conducted at HPHCI.

Key Leaders

Those senior administrative leaders who have direct authority over, but not limited to, faculty appointments, salaries, promotions, and/or allocation of institutional resources, such as assignment of graduate students or other trainees, and funding or space for faculty/investigators who are conducting human subjects research. Key Leaders include, but are not limited to those in the positions of:

- Officers and Members of the Board of Managers of Harvard Pilgrim Health Care Institute, LLC;
- President/Chair, Department of Population Medicine;
- Vice Chair, Department of Population Medicine;
- Executive Director;
- Research Integrity and Compliance Officer;

- Director, Office of Sponsored Programs; and
- Chief Compliance Officer/Institutional Official.

Conflict of Interest Management Committee (“COIMC”)

Consists of the Executive Director of HPHCI, an attorney from the Office of the General Counsel, and the Chief Compliance Officer who meet quarterly and on an *ad hoc* basis upon request by the Research Integrity & Compliance Officer (the “RICO”).

Financial Interest

Includes, but is not limited to: compensation or payment for employment or services, independent contractor service fees, service contract fees, consulting fees, or board stipends or fees. Compensation may be in any form, including cash, fees, stocks, bonds, options, securities and other investments, other ownership interest, honoraria, etc.

Immediate Family Member

The spouse, domestic partner and/or dependent children of the Key Leader.

Sponsor

The entity responsible for the award, administration, and monitoring of funded research activities. Usually this is an institute or center at a federal agency such as the National Cancer Institute (“NCI”), but it may also be a private organization such as a private funder, or a device or pharmaceutical company.

PROCEDURE:

On an annual basis, the Executive Director and President of HPHCI (or designee) will conduct a review of the financial investments or holdings to identify, manage, and minimize or eliminate OFCOI that could influence the conduct of the research or the integrity of the Human Research Protection Program. If the Executive Director of HPHCI is made aware of any changes to the financial investments or holdings outside of the annual review process, and if those changes could influence the conduct of the research or integrity of the HRPP, they will report the updates to the Research Integrity & Compliance Officer (RICO) who will forward the matter to the COIMC for review and discussion.

1. Organizational Conflict of Interest Identification:

- In January of each year, the RICO will forward the Organizational Conflict of Interest Statement to the Executive Director of HPHCI.
- The Executive Director shall return the completed and signed COI Statement to the RICO.
- The RICO shall review the COI Statement for indication of any OFCOI.
- Any potential OFCOI shall be submitted by the RICO to the COIMC for review and discussion. The RICO shall convene the COIMC as needed. The Executive Director of HPHCI will recuse themselves from the review as appropriate.
- The COIMC will work with the Executive Director to develop an OFCOI management plan as appropriate.

2. OFCOIs Arising from the Financial Holdings or Investments of HPHC/I: All gifts to HPHC/I made either directly or through any affiliate under common control, including the Foundation, or by any other means shall be managed by the Foundation or HPHC in accordance with HPHC/I policy in a manner which avoids any OFCOI with the research, teaching and educational activities at HPHC/I.

3. Licensing Activities: All HPHC/I product licensing, technology transfers and patents are administered under HPHC/I organizational policies and procedures in a manner which avoids any OFCOI with the research, teaching and educational activities at HPHC/I.

4. Conflict of Interest Identification for Key Leaders:
 - a. It is the responsibility of the Key Leader to disclose any OFCOI. In January of each year, the RICO will forward the Conflict of Interest Statement for Key Leaders Statement to the Key Leaders.
 - b. Each Key Leader shall return the completed and signed COI Statement to the RICO.
 - c. The RICO shall review the COI Statement for indication of any OFCOI.
 - d. Any potential OFCOI shall be submitted by the RICO to the COIMC for review and discussion. The RICO shall convene the COIMC as needed.
 - e. The COIMC will work with the Key Leader to develop an OFCOI management plan as appropriate.
 - f. The Key Leader must excuse themselves from deliberations and voting in accordance with any OFCOI management plan.

REVISION HISTORY:

Department: OSP - Research Integrity & Compliance	Title: Organizational Financial Conflicts of Interest in Research
Effective Date: 10/28/22	Owner: Research Integrity & Compliance Officer
Replaces P/P Dated: P/P (01/21/19)	
Related Documents: Policy and Procedures: <i>IRB Members and Consultant Conflicts of Interest; Financial Conflicts of Interest of Researchers and Research Staff</i> ; Forms: Organizational Conflict of Interest Statement, Conflict of Interest Statement for Key Leaders	
References: AAHRPP Elements I.6.A.	