



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 all Harvard Pilgrim Health Care, Inc. ("HPHC") and Harvard Pilgrim Health Care Institute, LLC ("HPHCI") (collectively, "HPHC/I") personnel engaged in research, teaching or research administration activities in support of the charitable and educational mission of HPHC, specifically including senior administrative leaders at HPHCI and on 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 of human subjects research carried out at HPHCI or by individuals whose HPHCI appointments, or whose access to HPHC/I resources are under their direct oversight.

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):

Human Subjects Research

Any research that requires review and approval by the HPHC IRB.

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 HPHC Foundation on behalf of or for use with/for HPHC/I research activities;
- HPHC/I or HPHC Foundation 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:

- Board of Managers;
- Executive Director HPHCI/Chair, Department of Population Medicine;

- Vice Chair, Department of Population Medicine;
- Director, Institute Administration;
- Director of Research;
- Director, Office of Sponsored Programs;
- HPHC VP Controller; and
- HPHC VP Corporate Compliance/Institutional Official.

Disclosure

The requirement for a Key Leader to disclose any OFCOI related to their responsibilities as a Key Leader. Disclosure reporting is required: 1) upon initial appointment as a Key Leader; 2) annually in January of each subsequent year; and 3) as any new potential OFCOI arises by submitting the *Conflict of Interest Statement for Key Leaders*.

Financial Conflict of Interest Management committee (“FCOIMC”)

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

Financial Interest

Anything of monetary value received or held by a Key Leader or any of their immediate family members, whether or not the value is readily ascertainable, including, but not limited to: compensation or other payments for management, advisory, or consulting roles or services (e.g., salary, consulting fees, honoraria, gifts or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, dividends, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, copyrights, and licensing agreements), upon receipt of royalties or other income related to such intellectual property rights and interests.

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:

Responsibilities of Key Leaders: It is the responsibility of each Key Leader to disclose any OFCOI and to excuse themselves from deliberations and voting regarding that matter in accordance with any OFCOI management plan:

1. Institutional Conflict of Interest Identification for Key Leaders:

- a. Upon Appointment/hire and then annually thereafter, the Key Leader shall complete the *Conflict of Interest Statement for Key Leaders (“COI Statement”)* as provided by the RICO.
- b. Each Key Leader shall return the completed and signed COI Statement to the RICO whereupon it shall be maintained securely in RICO files.
- c. The RICO shall review the COI Statement for indication of any OFCOI.
- d. If an OFCOI is identified, the RICO shall contact the Key Leader for additional information as needed.
- e. Any potential OFCOI shall be submitted by the RICO to the FCOIMC for review and discussion. The RICO shall convene the FCOIMC as needed.
- f. The FCOIMC shall work with the Key Leader to develop an OFCOI management plan.

2. *OFCOIs Arising from the Financial Holdings or Investments of HPHC/I:* All gifts to HPHC/I through the HPHC Foundation, HPHC or any other means shall be managed by HPHC 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.

REVISION HISTORY:

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