Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs and Office of Research Integrity & Compliance

Policy and Procedure

TITLE: IRB Member and Consultant Conflicts of Interest

PURPOSE:

To prevent a conflict of interest (COI) held by Institutional Review Board (IRB) members, including the IRB Chair, as well as any consultants retained by the IRB, from interfering with the IRB review process either by competing with the IRB's obligation to protect research participants or by compromising the credibility of any IRB review process (e.g. initial, continuation, amendment, noncompliance, unanticipated problem/adverse event, protocol violation) and to prevent business interests of the organization from interfering with the IRB review function.

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/I, including IRB members and expert consultants.

POLICY:

The IRB review process shall be free of COI so that the IRB's obligation to protect research participants or ensure the integrity of the review process is not compromised by competing financial, personal or professional interests. Specifically:

- IRB members, including the IRB Chair, and consultants retained to assist the IRB, are prohibited from participating in the review of research protocols or plans in which they have a COI, except to provide information requested by the IRB. Unlike financial COI (FCOI) of investigators (researchers and research staff), there is no latitude for the management of an IRB member's or consultant's COI.

- HPHC/I separates competing business interests from the IRB review function by ensuring that individuals responsible for business development shall not serve as members of the IRB and shall not carry out the day-to-day operations of the IRB review process.

DEFINITIONS

For the purposes of this policy:

Conflict of Interest (COI)
Any situation where an IRB Chair, IRB member, consultant or immediate family member of the IRB Chair, IRB member or consultant has any financial, personal, or professional interest that may interfere with the IRB review process either by competing with the individual's obligation to protect research subjects, by conflicting with the individual's ability to objectively review a protocol, or by compromising the credibility of the IRB review process in any way.

Example of FCOI: when an IRB Chair, IRB member or consultant has equity in the sponsor of the research or has or will receive compensation with value that may be affected by the outcome of the research.

Example of personal COI: personal relationships with the investigator (such as spouse, partner or relative) or strong positive or negative interactions that may be perceived as a possible conflict or a personal belief system that would preclude acceptance of any research in that area even though permitted under existing regulations or policies.

Example of professional COI: involvement in the design, conduct or reporting of research, including roles as investigator, consultant, or supervisory/mentoring role.

Consultant
An individual who is not a member of the IRB and has expertise in specific area(s), who is invited by the IRB Chair and retained by HPHC to provide expert assistance to the IRB.

Disclosure
The requirement for an IRB Chair, IRB member or consultant to disclose to IRB staff any COI related to their responsibilities to the IRB process. Disclosure reporting is required:

a. upon initial retention of IRB members and consultants to IRB review on the *Conflict of Interest Statement for IRB Members and Consultants*;
b. annually in January of each subsequent year by IRB members and consultants on the *Conflict of Interest Statement for IRB Members and Consultants;* and
c. at each IRB meeting.

Financial Interest
Anything of monetary value received or held by an IRB member or consultant 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 individual.

Investigator
Any individual who is responsible for the design, conduct, or reporting of research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator (PI), co-investigator, research staff or sub-investigator on a particular protocol, and may include other faculty, fellows, postdoctoral associates, senior scientists, graduate students, project managers and data analysts and any other individual who has a substantive role in the research. Substantive roles include those in which individuals have decision making authority or provide advice to those who have decision making authority with respect to: the design of the research, the conduct of the work, or the reporting of results. The definition may also include collaborators or consultants as appropriate.

Sponsor
The entity responsible for the award, administration, and monitoring of funded research activities. Usually, this is an institute or center at a federal or state agency such as the National Cancer Institute or the Massachusetts Department of Public Health, respectively, but it may also be a private funder such as a not-for-profit foundation or a pharmaceutical company.

PROCEDURE:

1. Responsibilities of IRB members

It is the responsibility of each IRB member to disclose any COI when conducting a review and to excuse themselves from deliberations and voting:

a. During annual COI identification for IRB members:
   (1) In January of each year, IRB staff shall provide the *Conflict of Interest Statement for IRB Members and Consultants* to all IRB members, including the IRB Chair.
   (2) Within 14 days, each IRB member and IRB Chair shall complete and return the signed statement to IRB staff where it shall be reviewed and maintained in IRB Office files. If an IRB member is unable to return the statement within 14 days, the IRB member shall request an extension with IRB staff. If the IRB member is unresponsive to IRB staff's request to return the statement, IRB staff will contact the IRB Chair for assistance.
   (3) If a COI is identified, IRB staff shall notify the IRB member that they shall not be involved in the review of any research related to that COI. If they have questions, IRB

staff shall seek guidance from the IRB Chair and the Director, Research Integrity & Compliance Officer for next steps as necessary.

b. Upon reviewer assignment:
   (1) Members shall identify a COI on the Reviewer's sheet in IRBNet upon designation as a Primary or Secondary reviewer.
   (2) If a COI is identified, the review will be re-assigned to another member without a COI.

c. At the beginning of each convened IRB meeting:
   (1) At the beginning of each convened IRB meeting, the Chair, or the Chair's designee, shall ask IRB members to disclose any COI with agenda items scheduled for review.
   (2) Any IRB member with a COI shall identify and disclose the nature of the conflict.
   (3) The IRB member with a COI shall be allowed to remain in the room (which is either a physical meeting room or virtual room or phone if remote) to provide information requested by the IRB.
   (4) The IRB member, including the IRB Chair, with the COI will be asked to leave the room before any discussion and voting on the protocol or plan with which the IRB member has a COI.
   (5) While they are out of the room, they are not counted towards the quorum.
   (6) IRB members with a COI are documented in the minutes as being absent for the time period they are out of the room, with an indication that a COI was the reason for the absence.
   (7) In any circumstance where an IRB member COI is identified, the review will be re-assigned to another member without a COI.

2. <u>Responsibilities of consultants retained by the IRB</u>

Consultants may not participate in the review of any research at any stage in which the consultant has a COI.

a. Prior to entering into an agreement with any consultant for the provision of services:
   (1) IRB staff shall provide the *Conflict of Interest Statement for IRB Members and Consultants* to any potential IRB consultants.
   (2) Each potential consultant shall complete and return the *Conflict of Interest Statement for IRB Members and Consultants* which shall be reviewed and maintained in the IRB Office files.
   (3) Any COI shall be brought to the attention of the IRB Chair who will determine if retaining the individual's services are warranted, taking into consideration factors such as area of expertise, availability of other consultants with the same expertise, etc.
   (4) The IRB Chair, or their designee, shall document the circumstances under which a consultant with a COI is allowed to provide information to the IRB.

b. Annual COI identification for IRB consultants:
   (1) In January of each year, IRB staff shall provide the *Conflict of Interest Statement for IRB Members and Consultants* to all IRB consultants whose term of service extends into the subsequent year following the year of contracted services.
   (2) Each consultant shall complete and return the signed statement to IRB staff where it shall be reviewed and maintained in IRB Office files.

(3) Any COI shall be brought to the attention of the IRB Chair who will determine if retaining the consultant is warranted, taking into consideration factors such as area of expertise, availability of other consultants with the same expertise, etc.
(4) The IRB Chair or designee shall document the circumstances under which a consultant with a COI is allowed to provide information to the IRB.

REVISION HISTORY:

Department: Office of Research Integrity & Compliance	**Title**: IRB Member and Consultant Conflicts of Interest
Effective Date: 06/27/24	**Owner:** Director, Research Integrity & Compliance
Replaces P/P Dated: P/P (01/21/19, 06/23/20, 11/19/20); IRB SOP (02/08/17)	
Related Documents: Form: Conflict of Interest Statement for IRB Members and Consultants; Reviewer Sheets: Amendment; Continuing Review; Initial Review; Reportable Event; Exemption Determination; Not Human Subjects Determination	
References: 45 CFR 46.107(e); 21 CFR 56.107(e); ICH-GCP: 3.2.1, 3.2.4, 3.2.5, 3.2.6; AAHRPP Element II.1.C and II.1.D; AAHRPP Tip Sheet 13	