Harvard Pilgrim Health Care Institute

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 Use of Consultants

PURPOSE:

To describe the process used by the Institutional Review Board (IRB) requiring research protocols or plans to be reviewed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge as required to review the research protocol or plan.

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, including the IRB.

POLICY:

In order to effectively protect the rights and welfare of human subjects, the IRB shall have the appropriate competence and knowledge to review the research. When there is no IRB member with such expertise, the protocol review shall be deferred until a consultant with the requisite expertise is retained to assess the protocol and present findings, in writing or orally, to the IRB. If the consultant attends an IRB meeting, the consultant is not counted toward the quorum and must leave the meeting during the final discussion and vote on the protocol.

PROCEDURE:

1. When, before or during an IRB meeting, the IRB Chair determines that there is not at least one IRB member with appropriate scientific or scholarly expertise or other knowledge necessary

to review a particular protocol, the IRB Chair shall defer review of that protocol until such expertise can be obtained through IRB membership or consultation.

2. The IRB Chair with the assistance of the IRB staff shall identify a consultant with the appropriate expertise to review the protocol. Consultants may be recommended by the Chair, IRB members or HPHC/I employees.

3. The consultant's services will be retained via a consulting services agreement negotiated by the Director, Research Integrity & Compliance Officer (DRICO) and signed by the Director of the Office of Sponsored Programs.

4. The consultant will be given the relevant and necessary review materials and may be invited to attend an IRB meeting(s), either in person or by electronic means, to make a presentation to the IRB, and/or provide a written report to the IRB.

5. If the consultant attends the IRB meeting, the presence of the consultant shall not be counted toward quorum. The consultant must leave the meeting prior to the final discussion, and shall not vote on the protocol.

6. The minutes of the relevant meeting(s) shall reflect that the consultant attended as a guest and/or provided a written report.

7. When necessary, IRB staff shall provide the consultant with instructions on how to register with IRBNet. Each submission record in IRBNet for which the consultant provided input shall include reference to the consultant's IRB personnel file which will contain:

a. the consultant's qualifications to serve as an expert as relevant to the protocol;
b. a copy of the contract including compensation plan, if relevant;
c. a *Confidentiality Agreement*; and
d. an HPHC/I *Conflict of Interest Statement for IRB Members and Consultants*.

REVISION HISTORY:

Department: Office of Research Integrity & Compliance	**Title**: IRB Use of Consultants
Effective Date: 10/18/24	**Owner:** Director, Research Integrity & Compliance Officer
Replaces P/P Dated: P/P (01/21/19), IRB SOP (02/17)	
Related Documents: Form: Conflict of Interest Statement for IRB Members and Consultants; Confidentiality Agreement	
References: 45 CFR 46.107; 21 CFR 56.107; 34 CFR 356.3; ICH-GCP: 3.2.6; AAHRPP Element II.1.E	