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

Policy and Procedure

TITLE: Concerns, Complaints, and Questions about the Human Research Protection Program

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PURPOSE:

To describe the process for communicating suggestions, questions, concerns and complaints regarding human subjects research activities.

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) personnel engaged in research, teaching or research administration activities in support of the charitable and educational mission of HPHC.

POLICY:

HPHC/I provides several mechanisms for current, prospective and past research participants, their designees, researchers and research staff to address concerns, complaints, and requests for information regarding the human research protection program, including the ethics review process.

PROCEDURE:

1. Contact Information
   a. The telephone number for the Institutional Review Board (IRB) hotline and the contact information for the Research Integrity & Compliance Officer (RICO) and the Research Compliance Program Manager (RCPM) are available to the public on HPHC's website: https://www.hphcinstituteosp.org/
   b. The research hotline number is: 1-800-807-6812.

2. Research Participant Concerns
   a. Research participants and their designees are encouraged to share their suggestions, questions, concerns and complaints regarding research activities with the researcher or research staff.
   b. Researchers must include their contact information on the consent form and inform participants during the consent process of their options to contact the designated research staff or an informed unaffiliated individual with any inquiries, concerns or complaints.
   c. Prior to IRB approval, the IRB shall confirm that the informed consent form provides contact information for research participants/designee who wish to reach out to researchers as well as an informed individual who is unaffiliated with the specific research protocol or plan.
   d. Research participants and their designees may also report their concerns to the HPHC IRB. The IRB is dedicated to protecting the rights, welfare and safety of research participants.
   e. IRB staff is responsible for answering and responding to IRB hotline calls. When IRB staff is not available to answer the call, the system automatically transfers the voice message to the voice mail boxes of the IRB staff and the RICO and sends them a notification email.
   f. All hotline calls, in-person inquiries, and written correspondence are tracked by IRB staff. The following information is recorded:
      (1) caller's name and contact information (anonymous complaints are accepted);
      (2) date of the call;
      (3) reason for call; and
      (4) action/resolution.
   g. Depending on the nature of the call, IRB staff will either respond to the caller directly or forward the information to the appropriate person.
   h. Suggestions, questions, concerns and complaints are also accepted by IRB staff in writing (including email), in person, or by telephone.

3. Research Misconduct Concerns
   a. Anyone suspecting research misconduct (fabrication, falsification and plagiarism) in research activities should contact the RICO at 1-617-867-4817.
   b. Concerns involving allegations of research misconduct are handled in accordance with the *HPHCI Policy and Procedure for Responding to Allegations of Research Misconduct*.

4. Concerns about the IRB Ethical Review Process
   Researchers and anyone else concerned about the IRB ethical review process may bring their concerns to the IRB Chair, the IRB staff, the RICO or the Institutional Official.

5. Questions about Financial Conflicts of Interest Disclosures and IRB Submissions - contact the IRB staff.

6. Questions about Export Controls, Intellectual Property, Regulatory Compliance, QA/QI – contact the RICO.

7. Questions about Sponsored Program Funding – contact the Grants Manager.

REVISION HISTORY:

Department: OSP – Research Integrity & Compliance	**Title** Concerns, Complaints, and Questions about the Human Research Protection Program
Effective Date: 03/15/22	**Owner:** Research Integrity & Compliance Officer
Replaces P/P Dated: P/P (1/21/19), IRB SOP (2/2017)	
Related Documents: Consent and Authorization Template; Consent and Authorization Checklist and Guidance; HPHCI Policy and Procedure: Responding to Allegations of Research Misconduct	
References: 45 CFR 46.116(a)(6)-(7); 21 CFR 50.25(a)(6)-(7); AAHRPP Elements I.4.A, I.5.C, and III.1.G.	