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: Ethical and Legal Standards and Practices for Human Subjects Research

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PURPOSE:

To describe the legal and ethical standards and practices for involvement in human subjects research.

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/I.

POLICY:

HPHC/I personnel engaged in human subjects research activities are obligated to conduct the research in a manner that minimizes any risks of harm to human research subjects. The Institutional Review Board (IRB) review and approval process is in place to ensure that all research with human subjects adheres to this mandate.

DEFINITIONS:

HPHC/I Personnel
HPHC/I employees, including the Institutional Official (IO), faculty, staff, fellows, contingent workers, students, and volunteers (including IRB members).

PROCEDURE:

1. The HPHC IRB was established by HPHC for the review and oversight of all research activities involving human subjects at HPHC/I (IRB registration # 00000882). The IRB is constituted as an independent committee and also serves as the research privacy board.

2. HPHC holds a Federalwide Assurance (FWA) with the United States Department of Health and Human Services (DHHS) (FWA # 00000100). HPHCI is listed as a component under HPHC's FWA.

3. The FWA is HPHC's assurance of compliance that all research involving human subjects will be conducted in accordance with the ethical principles of the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research,* U.S. Department of Health and Human Services regulations at 45 CFR 46 (the "2018 Revised Common Rule") including all of Subparts B (Additional Protections for Pregnant Women, Human Fetuses and Neonates involved in Research), C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects), and D (Additional Protections for Children Involved as Subjects in Research).

4. 45 CFR 46 provide the practical basis for the review and approval of all research at HPHC regardless of funding.

5. Any research involving a drug, biologic, or a medical device subject to applicable regulations of the Food and Drug Administration (FDA) will be conducted in accordance with those regulations (21 CFR Parts 50, 56, 312, 612 and 812).

6. The IRB is guided by the basic ethical principles set forth in the Belmont Report:
   - Respect for Persons: informed consent, comprehension, voluntariness, privacy and confidentiality as well as added protections for vulnerable populations;
   - Beneficence: a systematic assessment of risks and benefits for determination as to whether the proposed research is properly designed and whether the risks that will be presented to subjects are justified; and
   - Justice: equitable selection of subjects which ensures a fair distribution of risks and benefits to different groups within society.

7. The International Conference on Harmonization – Good Clinical Practice (*ICH-GCP*) an ethical and scientific quality guidance document that is used internationally in the conduct of clinical trials shall be considered by the IRB when applicable.

8. All staff involved in human subjects research shall receive training on ethical and legal standards and responsibilities through online Collaborative Institutional Training Initiative (CITI) training and Office of Sponsored Programs (OSP) seminars (See the *Policy and Procedure on Training*).

9. HPHCI policies and procedures regarding the Human Research Protection Program (HRPP) are available for viewing in IRBNet and on the HPHCI OSP website (https://www.hphcinstituteosp.org/osp-policies).

REVISION HISTORY:

Department: Office of Research Integrity & Compliance	**Title**: Ethical and Legal Standards and Practices for Human Subjects Research

Effective Date: 05/17/24	**Owner:** Director, Research Integrity & Compliance Officer
Replaces P/P Dated: IRB SOP (02/08/17); P/P (07/17/18, 01/21/19, 04/27/21, 05/26/22)	
Related Documents: Investigators Handbook; Policy and Procedure on Researcher Qualifications	
References: 45 CFR 46.103; 21 CFR 56.108(a), 21 CFR 56.108(b); ICH-GCP: 2.1, 2.3, 2.6, 2.13, 3.3.6, 4.5.1; AAHRPP Element I.1.D; AAHRPP Tip Sheet 11.	