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

Policy and Procedure

TITLE: Researcher Qualifications

PURPOSE:

To ensure that researchers and research staff who are conducting human subjects research are qualified for their designated roles and adhere to all applicable laws, policies and procedures regarding 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.

POLICY:

All researchers and research staff:

- are qualified by training and experience for their roles and responsibilities in conducting research so that they follow the protocol and abide by HPHCI's policies and procedures;
- have the knowledge to follow laws, regulations, codes and guidance such as those concerning IRB review, consent requirements, reporting requirements, maintenance and retention of records, and supervision of research conduct; and
- understand and apply relevant professional standards that are applicable to their research.

DEFINITIONS:

Researchers
Research Staff
Principle Investigator (PI)
Risk

PROCEDURE:

1. Prior to engaging in research activities, researchers and research staff must:

a. certify that they are qualified by training and experience for their roles and responsibilities in conducting research;
b. complete all required training as per the *Policy and Procedure on Mandatory Training*;
c. know which laws govern their research and which requirements pertain to specific research studies;
d. know the Institute's policies and procedures; and
e. follow other requirements, as needed.

2. When engaging in research activities, researchers and staff must:
   a. protect the rights, safety, and well-being of subjects of human research;
   b. weigh the foreseeable risks against the anticipated benefits for the human subject involved in a particular study and initiate research only if the anticipated benefits justify the risks;
   c. know which laws govern their research and which requirements pertain to specific research studies;
   d. know HPHCI's policies and procedures;
   e. adhere to the requirements and determinations of the IRB;
   f. follow the requirements of the research protocol; and
   g. follow other requirements, as needed.

3. In addition to the requirements above, researchers with the assigned role as principle investigator (PI) must:
   a. oversee all aspects of the study, including but not limited to recruitment, the consent process, protocol procedures, privacy and data security;
   b. ensure that research personnel on their project complete initial training; failure to complete training may result in suspension of participation in research until training has been completed or a suspension of research by the IRB;
   c. provide for adequate resources, including staff and facilities, to ensure the safety of subjects;
   d. hire qualified staff;
   e. delegate responsibility to others commensurate with their training and qualifications;
   f. certify that scientific review had been conducted and approved prior to submission of application to the IRB;
   g. be available to research staff when needed; and
   h. perform other required functions, as needed.

4. Researchers and research staff must follow reporting requirements for research studies, by reporting:
   a. adverse events and unanticipated problems (actual or possible) involving risks to subjects or others;
   b. non-compliance;
   c. suspension or termination of research;
   d. complaints;
   e. protocol deviations and violations;
   f. data and safety reports;
   g. research misconduct (fabrication, falsification and plagiarism); and

h. other required information.

5. Researchers from other institutions, who are collaborating on HPHC/I research must:
   a. confirm that they are qualified by training and experience for their research roles and responsibilities in compliance with all applicable laws, HPHC/I policies and procedures, and IRB determinations; and
   b. when applicable, submit a conflict of interest (COI) disclosure to their institution or the HPHC/I Cayuse COI disclosure process.

REVISION HISTORY:

Department: OSP - Research Integrity & Compliance	**Title**: Policy and Procedure on Researcher Qualifications
Effective Date: 10/28/22	**Owner:** Research Integrity & Compliance Officer
Replaces P/P Dated: P/P (01/21/19)	
Related Documents: Investigators Handbook; Policy and Procedures: *Ethical and Legal Standards for Human Subjects Research*; *Financial Conflicts of Interest of Researchers and Research Staff*; *Reporting and Review of Adverse Events, Protocol Deviations, Protocol Violations, and Unanticipated Problems*; *Data and Safety Monitoring Plans*; *IRB Review of Risks and Benefits*; *Suspending or Terminating IRB Approval*; *Human Research Protection Program Oversight*; *Scientific or Scholarly Validity of Proposed Research*; *Financial Conflicts of Interest of Researchers and Research Staff*; *Informed Consent.*	
References: Belmont Report; 45 CFR 46; 21 CFR 56; 21 CFR 50; 21 CFR 312; FDA – Good Clinical Practice; ICH-GCP; AAHRPP Tip Sheets: 14, 15, 18, 23; AAHRPP Elements III.2.A-D.	