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

Policy and Procedure

TITLE: Training

PERSONS AFFECTED
This policy applies to all Harvard Pilgrim Health Care, Inc. ("HPHC") and Harvard Pilgrim Health Care Institute, LLC ("HPHCI"), (collectively, "HPHC/I") personnel who are engaged in or support education and research activities in support of the charitable and educational mission of HPHC, Inc.

PURPOSE
To describe the policy and procedure on training requirements for all HPHC/I personnel who are engaged in or support education and research activities.

POLICY
The Research Integrity & Compliance (RIC) Office within the Office of Sponsored Programs (OSP) shall conduct mandatory and supplemental training programs at HPHCI to ensure that HPHC/I personnel who are engaged in or support education and research activities have the appropriate knowledge, qualifications, and skills for protecting the rights and welfare of human research subjects and appropriate stewardship of sponsored research.

DEFINITIONS & COURSE NAMES
Collaborative Institute Training Initiative (CITI): Mandatory web-based training required of all HPHC/I personnel as set forth in the OSP/Compliance Training Matrix, based on the level/function of involvement in human research activities.

HPHC/I personnel: HPHC/I employees (including the Institutional Official (IO), faculty, staff, fellows), contingent workers, students, and volunteers (including Institutional Review Board ("IRB") members).

OSP/Compliance Seminars – Optional workshops or informational sessions at which OSP and/or Compliance staff present programs or targeted in-person training sessions on subjects related to sponsored programs at HPHCI. Topics may include, but are not limited to: research compliance, conflicts of interest ("COI") (including Cayuse COI disclosure submission system), grants submission process, and grants submission budget creation.

OSP Training Matrix – The description of OSP Learner Groups and required CITI training based on position and function for HPHC/I personnel.

PROCEDURE

1. Supervisors and hiring managers are responsible for assigning each new HPHC/I personnel a Training Learner Group based on duties as assigned. This information should be supplied on the Institute New Hire IT/Network Checklist submitted to the Operations Manager, Research Compliance QA/QI Specialist (QA/QI Specialist), and the Associate Facilities Coordinator.

2. Learner Groups are set forth in the OSP Training Matrix. Training categories include but are not limited to: onboarding orientation/s, grants management, IRB activities, and research compliance. Training may be provided on-line, in-person, annually, or span multiple years, depending on the topic.

3. Supervisors are responsible for ensuring that the individuals they lead or supervise complete mandatory onboarding and refresher training.
   - Full-time HPHC/I personnel (over 20 hours) are required to complete mandatory onboarding training within the first five business days of their start date. Part-time staff (20 hours or less) must complete mandatory onboarding training within the first ten business days of their start date. New hires will be assigned applicable onboarding training via email on their start date.
   - Individuals who have taken CITI training within the past three years at another institution must affiliate with "Harvard Pilgrim Health Care" on the CITI website and determine if there are additional training modules that are required to meet HPHC/I training requirements.
   - All HPHC/I personnel must complete refresher training within five business days of the required expiration date.
   - Any individual who does not complete onboarding training within the required number of business days or refresher training within three business days of the expiration date will receive a notice of non-compliance by email from the QA/QI Specialist, with a copy (cc) to their direct supervisor and grants manager, if applicable.
   - For personnel involved in the conduct of research, supervisors must send an email to the QA/QI Specialist certifying that the individual will not participate in research until the completion of the required training.
   - If the individual does not complete the training within the next three business days, that individual will receive a notice of non-compliance from the Executive Director and Chair of the Department of Population Medicine with a cc to their direct supervisor and grants manager, if applicable.
   - That individual will then have 48 hours to either complete the training or provide a supervisor-approved corrective action plan to the QA/QI Specialist .
   - If the training is not completed and no supervisor-approved corrective action plan is submitted within 48 hours, the matter will be escalated to human resources.

Anyone who does not complete mandatory training within the required time frames will not be allowed to participate in research.
- Onboarding Orientation: New faculty and project/program managers are required to attend an onboarding orientation that includes specific OSP/Compliance training based on position and function with their designated grants manager and other relevant personnel within ten days of their start date.

4. All supervisors are expected to be familiar with required trainings and must allow personnel time to complete the trainings. Supervisors and employees who need assistance in identifying the required trainings should consult the QA/QI Specialist .

5. Grants managers will work in conjunction with the QA/QI Specialist to ensure personnel listed on project budgets have completed the mandatory trainings and any additional supplemental trainings applicable to particular research projects.
   a. The QA/QI Specialist will notify Grants managers when study personnel are not in compliance with mandatory trainings.
   b. Grants managers will communicate with the Project Manager and/or Principal Investigator and will request removal of non-compliant personnel from projects.

6. Additional training requirements for IRB members:
   a. An orientation shall be provided to new members prior to participating as a voting member on the IRB. This training will be provided by the Research Integrity & Compliance Officer (RICO) or designee. The orientation session is designed to provide education on the following topics:
      - responsibilities and obligations of IRB members;
      - interaction between the IRB staff and the IRB;
      - statutes, regulations and policies (FDA, OHRP, NIH, HPHC, etc.);
      - meeting basics (quorum, voting procedures, acceptable templates, etc.); and
      - vulnerable populations.
   b. Reference materials provided to new IRB Members include:
      - The Belmont Report;
      - The "2018 Common Rule" 45 CFR 46;
      - FDA 21 CFR 50, 56;
      - Glossary of Terms;

      - IRB Member Roster;
      - Investigator's Handbook;
      - On-line access to HPHC/I Policies and Procedures; and
      - HIPAA Privacy Rule

   New members are encouraged to attend and observe an IRB meeting prior to beginning their appointment and may attend several meetings before assignment as a Primary Reviewer.
   c. All IRB members are required to receive continuing education on the protection of human research subjects at least every three years. The approved course for continuing education is the CITI Human Subject Research course. In addition, IRB

members are encouraged to participate in at least six (6) hours of continuing education annually on the protection of human research subjects. Engaging in any of the following is considered evidence of continuing education:

- educational presentations as part of regularly scheduled IRB meetings, including changes in statutes, regulations, IRB processes, or forms;
- books, periodicals, or handouts provided as assigned reading to IRB members;
- HPHC training seminars on relevant topics; and
- regional or national seminars or conferences.

REVISION HISTORY

Department: OSP – Research Integrity & Compliance	**Title**: Policy and Procedure on Training
Effective Date: 03/07/23	**Owner**: Research Integrity & Compliance Officer
Replaces P/P Dated: Policy and Procedure on Mandatory Training (10/15/2020), (7/27/2020), (2/13/2020), (1/2017), P/P (4/26/21, 1/21/2019, 3/6/2019, 12/10/2019)	
Related Documents: OSP Training Matrix	
References: AAHRPP Element I.1.E	