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: Responsibilities of the Institutional Official

PURPOSE:

To describe the responsibilities of the Institutional Official (IO).

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:

Point32Health's Vice President, Chief Compliance Officer serves as the HPHC IO.

DEFINITIONS:

Institutional Official (IO)
The individual who is legally authorized to act for HPHC/I and, on behalf of HPHC/I, obligates HPHC/I to the Terms of the Federalwide Assurance (FWA). The IO is responsible for implementation, maintenance and oversight of the HPHC/I human research protection program (HRPP) and ensures that the HRPP functions effectively and that HPHC/I provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. Except for those duties that cannot be delegated, the IO shall delegate certain duties to, and be assisted by, the Research Integrity & Compliance Officer (RICO) in the performance of duties.

PROCEDURE:

1. IO Training

The IO shall complete HPHCI mandatory training to ensure understanding of relevant statutes, regulations, P/Ps and guidance that govern human subjects research and shall be involved directly or indirectly via the RICO in the allocation of resources to the HRPP and its day-to-day operations.

2. Responsibilities

The IO's responsibilities include, but are not limited to:

- ensuring that human research subjects are protected;
- ensuring that investigators comply with applicable statutes and regulations and HPHC/I policies protecting human research subjects;
- selecting and appointing a qualified Institutional Review Board (IRB) Chair;
- selecting and appointing qualified IRB members in accordance with HPHC/I policy and Office for Human Research Protections (OHRP) guidance;
- assuring that IRB staff demonstrate appropriate knowledge and experience for their roles;
- assuring adequate resources for the IRB administration;
- assuring adequate compensation/recognition of the IRB Chair, members and staff;
- ensuring that the actions of the IRB are independent, and that the IRB members do not have conflicts of interest (COI) that prevent them from protecting human research subjects;
- conducting investigations of complaints about undue influence of IRB members and instituting corrective action when needed;
- providing appropriate educational opportunities to the IRB Chair, members and staff;
- assuring access for the IRB to legal counsel with expertise in human subjects protection issues;
- providing guidance with complex issues, e.g., investigator non-compliance with applicable statutes and regulations or serious adverse events/unanticipated problems, privacy, confidentiality, emergency issues involving research subjects;
- on behalf of HPHC obligating HPHC to the Terms of the Federal Wide Assurance; and
- approving and signing IRB Authorization Agreements.

With regard to research compliance matters, the IO shall receive from the IRB Chair and/or RICO, pertinent information necessary to facilitate compliance with applicable statutes and regulations and HPHC/I policy including:

- any unanticipated problem involving risks to human subjects or others arising from research;
- any serious or continuing noncompliance with regulations or IRB policies, procedures, and determinations;
- any suspension/ termination of IRB approval of research; and
- having signatory authority for reporting to external organizations and/or governmental agencies as required under the FWA and HPHC policy.

3. General Administrative Obligations of the IO:

- designating one or more IRBs that will review research covered by the institution's FWA;
- providing sufficient resources, space, and staff to support the IRB's review and record keeping duties;

- providing training and educational opportunities for the IRB and investigators;
- "Setting the tone" by promoting an institutional culture of respect and conscience, so that the ethical conduct of human subjects research is supported at the highest levels of the organization;
- ensuring effective institution-wide communication and guidance on human subjects research;
- ensuring that investigators fulfill their responsibilities;
- encouraging that all staff engaged in the conduct or oversight of human subjects research participate in education activities;
- serving as a knowledgeable point of contact for OHRP and other federal and state agencies, or delegating this responsibility to another appropriate individual;
- depending on the organizational structure at a given institution, other administrative arrangements may be appropriate.

4. Actions the IO or RICO Cannot Do:
    - approve research that has been disapproved (or not yet approved) by the IRB.

5. Responsibilities that may be delegated by the IO to the RICO

The IO may delegate the performance of certain oversight and operational duties to the RICO. Any delegation of duty must be in writing, either in the RICO's job description or delegation letter. Upon designation of a new IO, all delegations must be reviewed and renewed by the new IO if the new IO chooses to maintain delegation:

- appointing IRB members. Suspending or terminating the IRB membership of any individual for whom it has been determined that he/she is not fulfilling membership responsibilities and or obligations;
- appointing the IRB Chair. Suspending or terminating the appointment of any Chair who is fulfilling his/her responsibilities and or obligations;
- performing periodic evaluation of the performance of the IRB Chair and administrative staff;
- managing and administering funds. Ensuring that adequate personnel, space and other resources are allocated to the HRPP;
- reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements);
- being the point of contact for correspondence addressing human subjects research with the OHRP, FDA and other agencies as applicable, including reports to federal and state agencies;
- ensuring that IRB members and investigators are knowledgeable to perform their duties in accordance with ethical standards and all applicable regulations;
- developing and implementing an educational plan for IRB members, staff and investigators;
- ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;

- performing periodic evaluation of the performance of the IRB members and administrative staff;
- recruiting qualified members to include expert, non-scientific and unaffiliated representation on the IRB;
- reviewing and approving P/Ps for the IRB and HRPP;
- overseeing daily operations of the IRB and HRPP in accordance with HPHC/I P/Ps.

6. Responsibilities that should not be delegated by the IO to the RICO:
   - signatory authority for the FWA;
   - completing mandatory training for the IO;
   - ensuring that the IRB functions independently and that its Chair and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB; and
   - ensuring that adequate resources, including funds, space, and personnel are provided to support the operation of the HRPP.

REVISION HISTORY:

Department: Research Integrity & Compliance	**Title**: Responsibilities of the Institutional Official
Effective Date: 10/27/23	**Owner:** Research Integrity & Compliance Officer
Replaces P/P Dated: IRB SOP (02/17); P/P (01/21/19)	
Related Documents: HPHC IRB Authority Statement; Research Compliance Committee Charter	
References: 45 CFR 46.103(c); AAHRPP Element I.1.B.	