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: IRB Composition and Membership Appointments

PURPOSE:

To describe the process for the appointment of the Institutional Review Board (IRB) Chair, IRB members, and IRB alternates and the procedure for maintaining the Office for Human Research Protections (OHRP) membership roster.

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:

The structure and composition of the IRB is appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws.

IRB Chair

The Chair shall be appointed by the Institutional Official (IO). Selection is based on the person's professional experience and knowledge of the regulations and ethical considerations relevant to the protection of the rights and welfare of research subjects. Generally, the Chair has had significant experience as an IRB member. There is no term limitation on length of service. The Chair has direct access to the IO and serves at the direction of the IO.

IRB Members

The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

No IRB member shall participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

If the IRB ***regularly reviews*** research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

The IRB shall include:

- At least one member whose primary concerns are in scientific areas;
- At least one member whose primary concerns are in non-scientific areas;
- At least one member who is not otherwise affiliated with HPHC/I and who is not part of the immediate family of a person who is affiliated with the institution;
- At least one member who is a physician (required for review of FDA regulated products including drugs, biologics and devices);
- At least one member who represents experience of research subjects, such as a former or current research subject or a research subjects advocate;
- The IRB shall not consist entirely of members of one profession;
- one member may fulfill multiple roles.

The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

IRB Alternate Members

Alternate members may be appointed to the IRB by the IO and shall have similar qualifications and experience to the primary IRB member with whom they alternate. Alternate members are provided with and review the same material as the primary members. Alternates may vote in place of an absent or excused regularly appointed member. If alternates are appointed, they may attend all meetings; however, their votes are counted only in the absence of the regularly appointed member. Meeting minutes must indicate when an alternate member replaces the appointed member.

Prisoner Representatives

In the event the IRB reviews research involving prisoners, the IO, upon request of the Chair or the Chair's delegate (the Director, Research Integrity & Compliance Officer (DRICO)), shall be responsible for appointing a qualified prisoner representative as a member of the IRB or rely on an external IRB with a prisoner representative pursuant to an IAA.

PROCEDURES:

1. Appointment of the IRB Chair

The IRB Chair shall be appointed by the IO or designee in consultation with the DRICO. Generally, the Chair has had significant experience as an IRB member. The term of appointment is at least one-year with the option to serve additional terms. There is no term limitation on length of service.

The IRB Chair will have knowledge to enforce consistent application of the ethical principles of the Belmont Report, applicable federal and state regulations, and HPHC/I policies and procedures governing human subjects research. The Chair will have the same standard voting privileges as members of the IRB. Whenever the Chair is not available to conduct IRB business, the Chair may designate an experienced IRB member as Acting Chair during the period of their absence. The DRICO or designee shall serve as the meeting facilitator if requested by the Chair.

2. Appointment of IRB Members, Alternates and Ex Officio Members
   a. The IO or designee, in collaboration with the IRB Chair appoints, evaluates, and removes IRB members, including alternate IRB members when applicable.
   b. *Ex Officio* IRB members are included on the IRB by virtue of position but shall not be counted toward the quorum and do not have voting privileges.
   c. Recommendations for appointees may be made by the IRB Chair, current IRB members, HPHC/I employees, or by self-referral.
   d. Solicitation for new members is based on need as well as expertise and knowledge required for conducting regulatory and ethical review of protocols.
   e. Individuals being considered as IRB members may not be responsible for HPHC/I business development functions (e.g. Director, Office of Sponsored Programs, etc.).

f. Individuals being considered as IRB members must submit a current resume or curriculum vitae (CV). Upon selection, new IRB members must complete new member orientation.
g. IRB members shall submit updated CVs annually to IRB staff.
h. Prior to formal appointment, the Restricted Party Screening list will be screened by the DRICO for the new member being considered.
i. Appointment letters will be sent to the member with a copy maintained in the IRB office.
j. There is no term limitation on length of service, however, members are asked to serve for a minimum of three years. Continued appointment may occur by mutual agreement of the member, Chair and IO.
k. Appointment and removal of members and Chairs are at the discretion of the IO or designee, as appropriate.
l. The IRB membership roster and CVs are maintained in the IRB office.

3. Selection of Prisoner Representatives

In the event the IRB reviews research involving prisoners:

a. The majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.
b. The IO, upon request of the Chair or DRICO, shall be responsible for appointing a qualified prisoner representative as a member of the IRB; or
c. Where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement. In this case, the HPHC IRB may rely on an external IRB with a prisoner representative pursuant to an IRB Authorization Agreement (IAA) and in accordance with the following steps:
    (1) As per the Initial Application, research staff shall contact the IRB office if prisoners are identified as potential research subjects.
    (2) The IRB office shall ask the principal investigator (PI) if they have already identified a local IRB who is able to conduct the Subpart C determination.
    (3) If the PI confirms they have a local IRB to make the determination, the following takes place after the study has secured IRB approval, after all participating sites have enrolled, and after receiving a copy of the local IRB's Subpart C determination:
        i. IRB meeting minutes are clearly documented to address Subpart C.
        ii. If the research qualifies for a request of an OHRP epidemiological waiver, the IRB staff will prepare all the materials for this request and then send to the IRB Chair, and then DRICO for review. The materials include:
            - a draft letter to OHRP outlining the request
            - original determinations
            - justification for request, and
            - a list of attachments.
        iii. The attachments to the letter include:
            - initial and continuing review applications
            - grant application (where necessary)

- current approved protocol (providing a list of amendment modifications if any in the letter)
- list of sites that have relied on HPHC IRB (as applicable), and
- additional materials as needed.

d. After approval by the Chair and DRICO, the waiver request is sent to OHRP via email. A copy of all materials sent is recorded in IRBNet.
e. The IRB office or DRICO shall respond to OHRP's request for additional information as applicable.
f. OHRPs final response shall be documented in IRBNet by the IRB office and notification sent to the PI.
g. If the PI indicates they do not have a local IRB to make the Subpart C determination, the IRB office shall consult with Harvard Catalyst who offers this type of service on an as needed basis and follow the prescribed steps.

REVISION HISTORY:

Department: Office of Research Integrity & Compliance	**Title**: IRB Composition and Membership Appointments
Effective Date: 03/08/24	**Owner:** Director, Research Integrity & Compliance Officer
Replaces P/P Dated: IRB SOP (02/08/17); P/P (07/17/18, 12/16/18, 03/22/19, 03/28/23)	
Related Documents: Policy and Procedure on IRB Use of Consultants; IRB Member Roster	
References: 45 CFR 46.107; 45 CFR 46.304; OHRP Guidance on Written Institutional Review Board Procedures; 21 CFR 56.107; FDA Information Sheets: Non-Local IRB Review, IRB Membership; ICH-GCP: 3.2.1, 3.3.1; AAHRPP Element II.1.B; AAHRPP Tip Sheets 18 and 22	