

<b>PARKVIEW HEALTH</b>	<b>INSTITUTIONAL REVIEW BOARD MANUAL</b>
Policy & Procedure Title: IRB Authority, Membership and Board Positions Category: IRB Review Process	

## I. Policy Statement

PH IRB is a group formally designated to review research involving human subjects and has the authority to approve, require modifications of, and disapprove research protocols based on consideration of human subject protection.

## II. Definition of Terms

PH Institutional Official: A high-level PH official, who has the authority to act for PH, as well as all the institutional components listed in the Federalwide Assurance (FWA), and on behalf of PH, obligates PH to the terms of the FWA. The PH Institutional Official cannot be the chair or member of any IRB designated under the FWA.

PH IRB Chairperson (Chair): A Member of the PH IRB, appointed by the PH Institutional Official or designee, and who directs the proceedings of the PH IRB.

Primary PH IRB Member (Primary): An individual appointed by the PH Institutional Official or designee to serve on the PH IRB.

Alternate PH IRB Member (Alternate): A Member of the PH IRB appointed by the PH Institutional Official or designee who may serve on the PH IRB and may vote when the Primary Member for whom that Member is a designated alternate is absent from the Meeting.

Quorum – A number of voting Members equal to or greater than the majority of the number of Primary PH IRB Members currently on the PH IRB and including at least one voting Member whose primary expertise is in a nonscientific area.

## III. Procedure

### A. Composition.

- PH IRB shall have at least five Members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the Institution. PH IRB shall be sufficiently qualified through the experience and expertise of its Members, and the diversity of the Members, including consideration of race, gender, 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.
- PH IRB shall include at least one Primary Member whose primary concerns are in scientific areas (examples: physicians, nurses, pharmacists, veterinarians, dentists, PhD. Scientists); and at least one Primary Member whose primary concerns are in nonscientific areas (examples: lawyers, clergy, administration, ethicists).

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3. PH IRB shall include at least one Primary Member who is not otherwise affiliated with PH and who is not part of the immediate family of a person who is affiliated with PH (sometimes called a community member).
4. All PH IRB Members, including the Chair and Alternates, must be approved by the PH Institutional Official or designee.
5. Primary and Alternate Members may serve on the PH IRB indefinitely. (See PH IRB Membership Roster)
6. The employment or other relationship between each Member and PH, e.g., full-time employee, part-time employee, member of governing panel or board, paid consultant, or unpaid consultant, shall be described in the PH IRB records.
7. No Member of the PH IRB shall participate in a voting capacity in the PH IRB's review or monitoring of an initial or continuing review of any protocol if the Member has a conflicting interest or if the Member is in any way involved in the protocol, except to provide information requested by the PH IRB.
8. No Investigator shall participate in the selection of Members for the PH IRB, which will review his/her Protocol, except to provide information requested by PH IRB.
9. Individuals with experience and competence in special areas may be invited to assist in the review of complex issues which require expertise beyond or in addition to that available on the PH IRB. These individuals may not vote with the PH IRB.

**B. Appointment of PH IRB Members (Members)**

1. New Members may be sought through the following means:
  - a. Recommendations from current Members, staff, or other professionals;
  - b. Other means as determined by the PH IRB or PH IRB Office.
2. All candidates will be evaluated for potential membership (Primary or Alternate) based on the following:
  - a. Evidence of education and training, as documented in their CV
  - b. Specific needs of the PH IRB
  - c. Willingness and time to serve
  - d. Other criteria as decided upon by the PH IRB or PH IRB Office.

**C. PH IRB Members (Members)**

1. Prospective Members will provide a current CV or resume and copy of any professional license (if applicable).
2. Prospective Members will complete New PH IRB Member Orientation.
3. All Members will sign a Confidentiality Agreement, Conflict of Interest Agreement, and Financial Conflict of Interest Agreement which will be maintained on file at the PH IRB Office.
4. A Member may resign from the PH IRB by submitting a letter of resignation to the Chair.

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- D. **PH IRB Chairperson (Chair).** The Chair is a Member of the PH IRB and may serve indefinitely. Removal of the Chair may be done by resignation in writing or by the PH.
1. The Chair may perform functions including, but not limited to the following:
    - a. Direct the proceedings of the PH IRB Meetings;
    - b. Direct compliance with the establishment and enforcement of PH IRB policies, standards, and all applicable state, federal rules, regulations and statutes concerning human subject protection;
    - c. Conduct expedited reviews. This task may be shared with other Members of PH IRB who are designated by PH IRB.
    - d. Interact with Investigators, Coordinators, Sponsors, Institutional Officials, subjects, and auditors regarding ethical questions, questions of PH IRB policy / oversight and human subject protection information.
- E. **Alternate PH IRB Members (Alternates).**
1. The PH IRB may appoint and use Alternates for Primary Members in accordance with Federal regulations.
  2. PH IRB's quorum requirement is unaffected by the appointment of Alternates. The quorum requirement is still based on the number of Primary Members.
  3. Alternates may serve as an Alternate for more than one Primary if the Alternate's qualifications are comparable to the Primary whom the Alternate would replace.
  4. Alternates may attend any PH IRB Meetings, and may vote and are counted toward quorum at the Meeting only if the designated Primary for whom that Member is an Alternate is absent from the Meeting.
  5. An Alternate may substitute for the Primary for an entire Meeting or at any time during a Meeting.
  6. The minutes of the PH IRB Meeting shall indicate clearly that the Alternate has replaced the designated Primary, and if this occurs during a Meeting, the reason for the substitution shall be documented.
- F. **Attendance:**
1. Members are encouraged to attend all scheduled PH IRB Meetings.
  2. The Chair or designee may contact Members who miss consecutive PH IRB Meetings to determine the action to be taken, including resignation of the Member(s) as deemed necessary.

#### IV. References

- A. [21 CFR Parts 50 and 56](#)
- B. [45 CFR 46](#)
- C. [ICH Guidelines relating to Good Clinical Practice](#)
- D. [Belmont Report](#)
- E. [Declaration of Helsinki 2008](#)
- F. [OHRP IRB Registration Frequently Asked Questions](#)
- G. [FDA Frequently Asked Questions: IRB Membership](#)

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