

Phoebe Putney Health System, Inc.

POLICY TITLE: INSTITUTIONAL REVIEW BOARD (IRB) MEMBERSHIP

ENTITY: PPMH

Approved by: IRB CHAIR

Effective Date: 1-28-2015

Review Period: 3 Years

Review Date: 10-28-2020

Contact Information: IRB COORDINATOR

Scope: Phoebe Putney Memorial Hospital, Inc. (PPMH) has established an Institutional Review Board (IRB), independent of all other departments of those entities, which is responsible for initial and continuing review and oversight of all research involving human subjects conducted on the premises of, or supported by PPMH (hereinafter referred to as the "Institution").

Purpose: To establish an Institutional Review Board (IRB) with oversight responsibility for the protection of human subjects participating in research studies conducted on the premises of, or supported by PPMH, PPHS, or any of their affiliated organizations (hereinafter collectively referred to as the "Institution"). This policy describes the requirements for membership and composition of the IRB.

Definitions: N/A

Policy:

1. Composition:

- a. The IRB shall have at least five (5) voting members with varying backgrounds to promote a complete review of research activities commonly conducted at PPMH.
- b. Members will be sufficiently qualified through their experience and expertise as well as through their diversity of race, gender, cultural backgrounds and sensitivity to such issues as community attitudes, so as to promote respect for IRB advice and counsel in safeguarding the rights and welfare of human subjects.
- c. Of the permanent members selected for IRB membership:
 - i. At least one must be from a scientific area of interest,
 - ii. At least one must be from an area of interest that is primarily non-scientific (lawyer, clergy, ethicist), and
 - iii. At least one must be independent of PPMH and not part of the immediate family of a person who is affiliated with PPMH (community member).
 - iv. NOTE: One member may fulfill the requirements of both ii and iii.
- d. Alternates shall be formally appointed and listed in the membership roster. Alternate members shall receive and review the same material that the primary members receive. Alternate

members are subject to all IRB policies governing voting members (e.g., qualifications, term, etc.)

2. Institutional Support:

- a. PPMH will provide the IRB with resources and professional and support staff sufficient to carry out their responsibilities under PPMH's Federal wide Assurance (FWA) effectively.
- b. Educational training and oversight mechanisms will be established to ensure IRB members and staff maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal regulations, OHRP and FDA guidance, other applicable guidance, state and local laws, and IRB policies for the protection of human subjects.

3. Selection, Term, and Removal of IRB Members

- a. Members of the IRB shall be selected in accordance with the criteria set forth in these policies by the Chief Executive Officer of PPMH, or his/her designee, in consultation with the Chief Medical Officer, Chief Nursing Officer, IRB Administrator, and General Counsel. The CEO or his/her designee shall designate one such member to serve as Chair of the Board and one member to serve as Vice Chair of the Board.
- b. The members of the IRB shall serve two (2) year terms coinciding with the fiscal year employed by PPMH. Members may serve for unlimited successive terms. Members appointed to fill vacancies on the IRB due to death, removal, or resignation of a member shall hold office for the unexpired portion of that member's term.
- c. Excessive absences may result in the removal of a member from service on the IRB. In addition, a member may be removed for any one of the following:
 - i. Lack of participation in IRB meetings, including frequent abstention from voting activities;
 - ii. Ineffectiveness (as determined by the IRB Chair) due to a consistent lack of preparation or follow-up as necessary to ensure the objectives of the IRB are being met;
 - iii. Failure to attend training sessions as offered by PPMH;
 - iv. Except under emergency circumstances, failure to notify the IRB Coordinator or IRB Chair in advance of an absence; and,
 - v. Frequent early departures from the meeting resulting in loss of quorum.

4. Membership Roster

- a. A list of the current voting members, both primary and alternate, will be maintained. The list will identify members by name, earned degrees, representative capacity, indications of experience (e.g., board certifications and licenses) sufficient to describe each member's primary anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the institution.
- b. Any changes in IRB membership or other authorized institutional officials listed on PPMH's most recent Assurance on file with DHHS must be timely reported to the Office of Human Research Protections (OHRP).

5. Compensation

- a. Community Members, PPG Physicians, and Physician Community Members will be compensated in the amount of One Hundred Dollars (\$100.00) per month for review of the

materials, preparation, and attendance at the IRB meeting. These IRB members will only receive compensation if they attend the meeting and are prepared and only per the letter of written agreement with PPMH, as identified below. In the event they cannot attend a meeting, they will not be compensated for that month.

6. Consultants may be engaged to assist the IRB however, they will be non-voting members. Consultants must be independent of the investigator and/or sponsor of the proposed research and cannot be counted towards quorum.

Procedure:

1. Membership Process

- a. IRB members will be presented with a Letter of Agreement, which must be signed and returned to IRB Coordinator.
- b. IRB Members should submit the following to the IRB Coordinator:
 - i. Current curricula vitae (CV) or resume that is signed and dated;
 - ii. Contact information; and
 - iii. Current photograph
- c. Each new member of the IRB will be required to complete the web-based modules on human subject protections provided by NIH and provide written verification of training completion to the IRB Coordinator. If a new member has previously completed a human subject training module comparable to those listed above at PPMH or elsewhere, evidence of this training should be provided to the IRB Coordinator for the records of the IRB.

These trainings are located at the following web addresses:

<http://ohsr.od.nih.gov/IRBcbt/intro.php>

<http://cme.nci.nih.gov>

2. The IRB Coordinator will be responsible for maintaining:
 - a. Member files including current CVs or resumes, training certificates and other relevant documentation; and
 - b. Membership rosters in accordance with policy provision 4.a., above.
3. The IRB Coordinator will be responsible for keeping the filing current and up-to-date with OHRP, including reporting any changes in IRB membership or other authorized institutional officials on PPMH's most recent Assurance on file with DHHS.

References:

- 21 CFR50
- 21 CFR 56
- 45 CFR46

REVISION HISTORY

| Revision Number | Description of Changes | Approvals | Date |
|-----------------|---|---------------|-----------|
| N/A | Initial release of Policy for PPHS Policy Management System (Compliance 360 Program). This policy replaces all previous versions. | IRB Committee | 1-28-2015 |
| N/A | Reviewed – No Changes | IRB Committee | 10-28-20 |
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