

Phoebe Putney Health System, Inc.

POLICY TITLE: INSTITUTIONAL REVIEW BOARD (IRB) JURISDICTION AND AUTHORITY

ENTITY: PPMH

Approved by: IRB CHAIR

Effective Date: 1-28-2015

Review Period: 3 Years

Review Date: 2-26-2021

Contact Information: IRB COORDINATOR

Scope: Phoebe Putney Memorial Hospital, Inc. (PPMH) has established an Institutional Review Board (IRB), 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.

Purpose: The purpose of these policies and procedures is to ensure compliance by PPMH with requirements of 45 CFR 46, 21 CFR 56 and 21 CFR 50. This policy grants the IRB jurisdiction and authority to the fullest extent needed in order to conduct its reviews and other activities in such a manner as to provide adequate protection to human research subjects.

Definitions:

Policy:

1. The jurisdiction of the IRB extends to all "research" as defined in regulations promulgated by the Office of Human Research Protection (OHRP) and the Food and Drug Administration (FDA).
 - a. "Research" is defined in OHRP regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." "Human subjects" are defined as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."
 - b. "Research" is defined in FDA regulations as "any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit."
2. The IRB may agree to review clinical investigations from investigators who are affiliated or unaffiliated with a PPMH facility. If an investigator is unaffiliated, he/she must include a member of the PPMH medical staff or an allied health care professional as part of his/her investigative team for the IRB to agree to review the study.
3. All research under the jurisdiction of the IRB shall be reviewed and approved by the IRB prior to enrolling subjects unless the IRB has (1) specifically exempted the research study from review or (2)

has deferred full IRB review based on prior review and approval by a non-local IRB. [See related PPMH policies, "Exempt Review" and "Non-local IRB Review"]

4. The IRB shall have the authority and responsibility to:
 - a. Approve, require modifications in, or disapprove all research activities that fall within its jurisdiction. If a protocol is disapproved, the applicant has the right to appeal the decision to the IRB for reconsideration. Administrative approval may not be given for research that has been disapproved by the IRB.
 - b. Suspend or terminate research that is not being conducted in accordance with applicable laws and IRB or PPMH policies, or that has been associated with unexpected serious harm to subjects.
 - c. Provide ongoing oversight of approved research studies, which may include, but is not limited to: conducting audits, investigating complaints, reviewing reported protocol deviations and/or reports of scientific misconduct, and requiring third-party verification.
 - d. Ensure prompt reporting to the FDA and other authorities, as appropriate, of: (1) any unanticipated problems involving risks to subjects or others; or (2) any instance of serious or continuing noncompliance by an investigator; or (3) any suspension or termination of IRB approval. [See related PPMH policy, "External Reporting"]
 - e. Request any documentation and information it deems necessary beyond the protocol and sample informed consent form, such as budgets and grant applications. The IRB will notify all investigators via email or other method of the requested documentation.
5. The IRB Chair or other member(s) designated by the IRB Chair to conduct expedited review or make determinations of exemption shall have all the authority of the IRB in 4.a., except that reviewers may not disapprove a study under expedited review procedures.
6. Research that has been approved by the IRB shall still be subject to other reviews and approvals required by PPMH (e.g., legal, nursing, facility and/or finance reviews). PPMH may not, however, approve research that has been disapproved by the IRB.
7. PPMH's Chief Operating Officer serves as the Institutional Official for all purposes under the federal research regulations. As Institutional Official, this individual is specifically responsible for ensuring PPMH's compliance with applicable laws, regulations, and PPMH policies governing human subject research and ensuring PPMH has the resources and support necessary to achieve this compliance. The Institutional Officer is legally authorized to represent PPMH with respect to matters of research compliance, is the signatory of the Federalwide Assurance (FWA), and ensures PPMH meets the obligations of the FWA. The Institutional Official also holds ultimate responsibility for ensuring and supporting the authority and independence of the IRB.

Procedure: N/A

References:

- 45 CFR 46.111
- 45 CFR 46.113
- 21 CFR 50.1
- 21 CFR 56.102
- 21 CFR 56.108

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	12-20-17
1	Changes – General cleanup of policy for grammar and formatting purposes.	IRB Committee	2-24-2021
		PPMH CEO	2-26-2021