

## Phoebe Putney Health System, Inc.

**POLICY TITLE:** INITIAL REVIEW & PRIMARY REVIEWER SYSTEM

**ENTITY:** PPMH

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**Approved by:** IRB CHAIR  
**Review Period:** 3 Years  
**Contact Information:** IRB COORDINATOR

**Effective Date:** 6-25-2014  
**Review Date:** 2-26-2021

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**Scope:** The Initial Review and Primary Reviewer System Policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

**Purpose:** To describe the Phoebe Putney Memorial Hospital (PPMH) Institutional Review Board's (IRB) initial review process and define minimum criteria that must be met before research can be approved. To authorize the use of a "Primary Reviewer System." The primary reviewer system is generally relied upon for efficiency of review during the committee meetings.

### **Definitions:**

#### **Definitions and Determinations of Risks**

##### **1. Definition**

- a. Significant Risk in an investigational study is defined as one that presents a potential for serious harm to the health, safety or welfare of the subject.
- b. Non-Significant Risk is defined as one that does not pose significant risk for serious harm to the health, safety or welfare of the subject.
- c. Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(j)]
- d. Minor Modifications: Any change(s) to the study materials and/or clarifications requested by the IRB that do not affect the IRB's assessment of risks and benefits to subjects. Changes or clarifications that would assist the IRB in its initial assessment of risks and benefits to subjects are not considered minor.
- e. Medical Device
  - i. A medical device is defined as a diagnostic or therapeutic article that does not achieve its principal intended purpose through a chemical action or by being metabolized.
  - ii. A Significant Risk device is defined as an investigational medical device which presents a potential for serious harm to the health, safety or welfare of the subject, and

(a) is intended as an implant used in supporting or sustaining human life, or (b) is of substantial importance in diagnosing, curing, mitigating or treating disease, or (c) otherwise presents a potential for serious harm to the health, safety or welfare of the subject.

iii. A Non-Significant Risk medical device is defined as a device that does not pose significant risk for serious harm to the health, safety or welfare of the subject.

## 2. Determination of Risk

- a. The sponsor initially assesses the risk level of a device or drug study. The sponsor will provide the IRB an explanation of its determination with supporting documentation, and any other information that may assist the IRB in evaluating the risk of the study.
- b. If an investigator proposes the initiation of a claimed Non-Significant Risk investigation to the IRB, and if the IRB agrees that the study is NSR and approves the study, the investigation may begin at the institution immediately.
- c. If the IRB determines that an investigation for the use of a claimed Non-Significant Risk study is of significant risk, it will notify the investigator and, where appropriate, the sponsor.

## Policy:

1. The IRB will conduct a full board review of all research involving more than minimal risk to human subjects. Specifically, this will include all research not described in the categories for exempt or expedited review [See related PPMH policies, "Expedited Review" and "Exempt Review"]

## 2. Minimal Criteria for Approval of Research

- a. In order for a research project to be approved, the IRB shall determine all of the following requirements are satisfied:
  - i. Risks to subjects are minimized. (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
  - ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
  - iii. Selection of subjects is equitable, taking into account the purposes of the research study and the setting in which it will be conducted and being particularly cognizant of the special problems of research studies involving vulnerable populations.
  - iv. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by appropriate state and federal regulations. [See related PPMH policy "Informed Consent"]
  - v. Informed consent will be appropriately documented as required by state and federal guidelines.

- vi. Where appropriate, the research study makes adequate provision for monitoring the data collected to ensure the safety of subjects.
  - vii. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
  - viii. Appropriate additional safeguards have been included to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence).
3. Research Involving Prisoners, Pregnant Women, Human Fetuses and Neonates
- a. The institution does not currently conduct or support studies involving prisoners, pregnant women, human fetuses or neonates. Before consideration of such a study, there should be a desire to pursue such activities in the future, the IRB and the PPMH and PPHS Boards of Directors must adopt and approve special policies and procedures applicable to such studies in compliance with the Federal Regulations governing research involving these special populations.
4. Primary Reviewer System
- a. Under this system, studies will be assigned in advance to two IRB members who shall conduct a full review of all materials using the provided IRB Reviewer Checklist.
  - b. Any issues that may be identified prior to the meeting by the Primary Reviewers should be conveyed to the Principal Investigator or referred to the Director of Clinical Research to be communicated to the PI.
  - c. Role of Primary Reviewers at the IRB Meeting
    - i. During the meeting, primary reviewers take the lead for the overview and discussion of the study. There are two primary reviewers for new studies; a scientific reviewer and a community reviewer. If any reviewer is lacking the needed expertise or has a conflict with the study, they should notify the IRB Administrator or IRB Coordinator. If there is no member on the IRB with the expertise to perform the review, the IRB Chair will seek the assistance from a consultant who does have the expertise to assist with the review.
    - ii. The role of the scientific reviewer is to focus on the science, on the study design, and on the safety of the proposed research but will also review the consent form. The role of the community reviewer is to focus on the research from the point of view of a participant. The community member reviews the protocol, but will have a very detailed review of the consent form to assure it addresses all of the required elements and that it conveys the information in a way that a person with no clinical background can understand the information.
    - iii. The primary reviewers will present their questions and issues to both the committee and the principal investigator. The discussion will be opened up to the entire committee with a recommendation for the vote ending the discussion.
    - iv. In cases where the primary reviewer is unable to attend the meeting on short notice, the IRB Chair will call upon other members to lead the review. If no other member feels comfortable leading the review, the new study is deferred until the next meeting.
    - v. In cases where the IRB Chair determines that more than two reviewers are required, the IRB Chair will designate additional reviewers.

5. Research investigators wishing to perform clinical investigations of drugs or devices, or wishing to perform behavioral research within PPMH must submit an initial application (See *IRB Application for Approval of Research Involving Human Participants* form) to the IRB along with the following supplementary material:
  - a. The name of the principal investigator and current curricula vitae (CV).
  - b. A list of all proposed co-investigators and their CVs.
  - c. A copy of the investigative protocol complete with background information on any human studies demonstrating safety and efficacy of the product, the proposed investigation, attendant laboratory, radiologic and other diagnostic procedures involved in the use of the investigative drug or device, and any known adverse reactions or side effects to the use of the device or product or from participation in the behavioral research.
  - d. A copy of the proposed Informed Consent document.
  - e. Any relevant grant application(s).
  - f. Investigator Brochure (if available) or Instructions for Use (if one exists).
  - g. Any recruitment materials, including advertisements and websites intended to be seen or heard by potential subjects.
6. Research investigators must be trained in human subject protections. Certificate or other evidence of completion of training must be submitted before final approval of IRB. The following websites are potential resources to fulfill this requirement:

OHRP (Office of Human Research Protection):

<http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>

NIH (National Institute of Health)

<http://cancer.gov/clinicaltrials/learning/page2> (click on "Protecting Human Research Participants")

The Collaborative Institutional Training Initiative website:

<https://www.citiprogram.org/>

Principal investigators who are considering conducting NIH research must review the following presentation and complete the module tests with test results forwarded to the PPMH Office of Clinical Research:

NIH Training: [http://www.nihtraining.com/crtpub\\_508/index.html](http://www.nihtraining.com/crtpub_508/index.html)

Updated, signed and dated CVs will be required every two (2) years in tandem with required good clinical practice retraining.

7. The primary investigator (or his/her physician alternate) is required to be present at the meeting to discuss the protocol and answer committee members' questions.
8. The IRB Coordinator will assemble, in electronic form, all requests for review and distribute same to IRB members via the IRB SharePoint site at least seven (7) days prior to the meeting at which the request will be considered. It is the responsibility of each IRB member to review the materials and be prepared to listen thoughtfully to the study presentation, to ask questions and to identify any concerns with the proposed study or the documentation.

9. Notice of Decision. The IRB may take any of the following actions:
  - a. Approve
  - b. Approve with Minor Modifications
  - c. Table
  - d. Disapprove
10. All IRB decisions will be documented in the meeting minutes in accordance with the IRB Recordkeeping policy. The PPMH signatory official will be provided with minutes of all IRB meetings.
11. The IRB may not approve a research study for more than one year. However, at the time of initial review or during any continuing review period the IRB can set a more frequent review interval for any study that it determines warrants more frequent review. Such determinations may be based on the initial risk and benefit factors, the investigator's experience, and new findings, knowledge or adverse effects that come to light during the course of the study.

#### Procedure:

1. Investigators must submit a completed *IRB Application for Approval of Research Involving Human Participants* form along with the protocol, the informed consent document and any other documents requested, to the IRB Coordinator or to the Director of Clinical Research at PPMH for submission to the IRB.
2. It is the IRB Coordinator's responsibility to provide all applicable documentation to IRB members in accordance with section 8, above. The documentation must be forwarded significantly in advance of the meeting to allow for adequate review.
3. The IRB Chair assigns primary reviewers as necessary. The reviewers and other IRB members are notified of the review assignments by the IRB Coordinator. An IRB Review Checklist and the Initial Review Power Point Template are sent with each request by the IRB Coordinator. The checklist is completed by the reviewers and is submitted to the IRB Coordinator prior to the meeting.
4. The IRB Coordinator will document all IRB decisions and deliberations in the meeting minutes in accordance with the PPMH Recordkeeping policy and forward a copy to the signatory official of PPMH.

#### References:

- 45 CFR 46.111
- 21 CFR 56.108, 56.111

## 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	6-25-2014
1	Section 3.a. – “children” removed as IRB now accepts studies involving children (see policy regarding Research Involving Children)	IRB Committee	5/28/2015
N/A	Reviewed – No Changes	IRB Committee	04-25-2018
1	<ul style="list-style-type: none"> <li>▪ There were changes to the Federal Law regarding the Initial Review and Primary Reviewer System. The policy was revised to comply with the changes in Federal Law.</li> <li>i. In addition, on page 3, under vii, the reference to studies on “children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantages persons” was removed. Phoebe does not conduct research on children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantages persons</li> </ul>	IRB Committee PPMH CEO	2-24-2021 2-26-2021