

Phoebe Putney Health System, Inc.

POLICY TITLE: CONTINUING REVIEW

ENTITY: PPMH

Approved by: IRB CHAIR

Effective Date: 3-25-2015

Review Period: 3 Years

Review Date: 2-26-2021

Contact Information: IRB COORDINATOR

Scope: The Continuing Review policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

Purpose: To provide for continuing review of research activities conducted within Phoebe Putney Memorial Hospital (PPMH) in accordance with the human subjects protections regulations. This policy outlines the procedures to be used for determining the period for and conducting continuing reviews of research activities falling under the jurisdiction of the Institutional Review Board (IRB).

Definitions: N/A

Policy:

1. Time Period for Continuing Review
 - a. The IRB is responsible for determining the period for conducting continuing review of all research within its jurisdiction to ensure that the rights and welfare of human subjects are protected. Such reviews will occur as provided in this policy, but not less than annually.
 - b. The IRB will determine the frequency of continuing review for each study during initial review and approval of the research. [See related PPMH policy "Initial Review"] The determination shall include identifying projects that require continuing review more often than annually. Such determination may change at the time of continuing review due to new information, changes to the protocol, etc. The factors to consider when making these determinations include, but are not limited to:
 - i. The nature of the study;
 - ii. The degree of risk involved; and
 - iii. The vulnerability of the subject population.
 - c. Continuing IRB review is required as long as the research remains active for long-term follow-up of subjects or where the remaining research activities are limited to data analysis. However, continuing review may be conducted using an expedited review process under certain circumstances. [See related PPMH policy "Expedited Review"]

2. Extensions of Approval Period
 - a. The continuation of research after expiration of IRB approval is a violation of federal regulations. Extensions beyond the expiration date will not be granted.
 - b. If the IRB has not reviewed and re-approved a research study by the study's current expiration date, IRB approval has expired and research activities, including subject accrual, must cease. Continuation of research interventions or interactions with subjects already enrolled should only continue when the IRB finds that it is in the best interest of the subjects to do so.

3. Criteria for Approval
 - a. Continuing review must be substantive and meaningful. Review by the full board is required unless the research is otherwise appropriate for expedited review. Ordinarily, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review. It is also possible that research activities that previously qualified for expedited review have changed or will change such that full board review is now required.
 - b. When considering whether or not to approve a study, the IRB revisits the same criteria used to grant initial approval. Therefore, the IRB must determine that:
 - i. The risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits;
 - ii. The selection of subjects continues to be equitable;
 - iii. Informed consent continues to be documented appropriately;
 - iv. Adequate provisions for monitoring the data;
 - v. Adequate provisions to protect the privacy of subjects and confidentiality of the data; and
 - vi. Appropriate additional safeguards for vulnerable populations.

4. Additional Criteria
 - a. Research studies may require verification from sources other than the investigator that no material changes have occurred since previous IRB review. To determine when further verification is needed, the IRB will consider:
 - i. The probability and magnitude of anticipated risks to subjects;
 - ii. The likely medical condition of the proposed subjects;
 - iii. Prior experience with the principal investigator and research team;
 - iv. The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed; and
 - v. Any other factors the IRB deems relevant.
 - b. In making determinations about independent verification, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period, or may retrospectively require such verification at the time of continuing review.

5. IRB Review System
 - a. IRB members will receive a copy of the complete protocol (which includes all modifications previously approved by the IRB), current informed consent document, status report on the progress of the research and findings obtained thus far (including the number of subjects enrolled to date), and a summary of any relevant recent literature, amendments or modifications to the research since the last review and any relevant multi-center reports.

- b. For multi-center trials, the IRB may rely on a current statement from the Data and Safety Monitoring Board (DSMB), other similar body, or the sponsor indicating that it has reviewed study-wide adverse events, interim findings, and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB. The IRB must still receive and review reports of local, on-site adverse events and unanticipated problems involving risks to subjects or others and any other information reported during the prior approval period to ensure that its continuing review is substantive and meaningful.
 - c. Complete documentation will be available to all IRB members upon request.
 - d. The IRB may require the principal investigator or his/her alternate to attend IRB meetings during which their protocols are reviewed.
6. Notice of Decision
- a. The IRB may approve, approve with minor modifications, or disapprove any study under consideration. All IRB decisions will be documented in the meeting in accordance with the IRB Recordkeeping policy.
 - b. The IRB shall notify the principal investigator, in writing, of its decision to approve, require modifications in, or disapprove a study.
 - c. If the IRB approves a study for continuing review with minor modifications/clarifications, the notification letter will contain such requests. The IRB Chair or designee may provide final approval once the modifications have been made or reviewed. The investigator will be informed of the date the revisions must be received.
 - d. If the IRB disapproves a study, the letter shall include the reason(s) for the decision, and give the investigator an opportunity to respond.

Procedure:

1. Investigators must submit an IRB Continuation form and shall include the number of subjects enrolled to date and summarize the progress of the research and findings obtained thus far; and any relevant recent literature, amendments or modifications to the research since the last review to the IRB Coordinator.
2. It is the IRB Coordinator's responsibility to provide all applicable documentation listed in section 5 above to IRB members. The documentation must be forwarded significantly in advance of the meeting to allow for adequate review.
3. The IRB Coordinator will document all IRB decisions and deliberations in the meeting minutes in accordance with the IRB Recordkeeping policy.

References:

- 45 CFR 46.111
- 21 CFR 56.108, 56.111

REVISION HISTORY

Revision Number	Description of Changes	Approvals	Date
0	Initial release of Policy for PPMH Continuing Review. This policy replaces all previous versions.	IRB Committee	3-25-2015
N/A	Reviewed – No Changes	IRB Committee	2-28-2018
N/A	Reviewed – No Changes	IRB Committee	2-24-2021
		PPMH CEO	2-26-2021