

Phoebe Putney Health System, Inc.

POLICY TITLE: RESEARCH REVISIONS AND AMENDMENTS

ENTITY: PPMH

Approved by: IRB CHAIR

Effective Date: 10-26-2016

Review Period: 3 Years

Review Date: 08-28-2019

Contact Information: IRB COORDINATOR

Scope: The Research Revisions and Amendments policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

Purpose: To define the Phoebe Putney Memorial Hospital (PPMH) and Institutional Review Board (IRB) requirements for investigators reporting revisions or changes to the protocol, informed consent form, recruitment materials, and/or other changes.

Definitions:

An amendment is a permanent, intentional action or process that revises / amends / modifies a previously approved research activity. Federal regulations require that all modifications in approved research, during the period for which approval has already been given, may not be initiated without prior IRB review and approval except where necessary to eliminate apparent immediate hazards to human subjects. Investigator modifications to the protocol in order to eliminate apparent immediate hazards to a subject are not subject to this policy. [See related PPMH policy, "Adverse Events and Unanticipated Risk Reporting" for applicable reporting requirements.]

Policy:

1. The IRB is responsible for oversight of all research conducted at PPMH. It is imperative that all changes to an approved research project, during the year for which approval has been granted, be submitted to the IRB for review and approval before initiation. The only exceptions to this requirement are when the change must be made to eliminate apparent immediate hazards to the subject.
2. Revisions or changes to the protocol, informed consent, recruitment materials and other study procedures:
 - a. Investigators shall submit any revisions or changes to the current protocol, recruitment materials, informed consent form and/or other study procedures for IRB review and approval prior to initiation. Revisions / changes of a procedural nature that must be reviewed by the full IRB should be submitted with the normal committee deadlines in mind in order to ensure

- review at the next IRB meeting. Revisions / changes of a minor nature, such as minor wording changes, personnel changes (with the exception of the principal investigator), and/or corrections can be reviewed through the expedited review process and can be submitted at any time, but should be submitted in a timely manner.
- b. With the exception of minor changes, new recruitment materials or changes to previously approved recruiting materials must be reviewed by the full IRB. Examples of minor changes include, but are not limited to, changes in the medium only (e.g., print versus radio advertisements) and changes in contact information.
 - c. In order to simply this procedure, the IRB Amendment-Modification form must be completed. The proposed change(s) must be clearly described. The current procedure should be described together with the proposed change and the rationale(s) for each change. Revisions to the current protocol and/or informed consent form must be highlighted and clearly summarized. Revisions to the sponsor's protocol must also be made in the investigator's summary. Revisions without adequate explanation and/or highlighting will be returned to the investigator for proper completion prior to forwarding the materials to the IRB for review.
3. Changes to and additions of investigators.
- a. A new principal investigator (PI) or new co-investigator can be added to an existing, active, approved protocol through full IRB approval only. A new sub-investigator can be added to an existing, active approved protocol through the expedited review process. The following procedures will be followed to determine investigator eligibility to participate in an existing protocol.
 - i. The investigator applicant will make a written request for addition to a protocol, including name and address of the proposed investigator and name of the protocol, to the IRB office. Include a copy of the investigator's current curriculum vitae.
 - ii. For sponsored medical device studies, proof of investigator's acceptability to use the device is required by presentation of a certification of training in the use of the device or a letter from the sponsor accepting the investigator to join the named protocol or other proof of qualification through training and experience.
 - iii. The name(s) of the PPMH facility(ies) the investigator will use for the protocol.
 - iv. A commitment by the investigator that he/she:
 1. Is familiar with and will comply with all rules and regulations from the IRB, FDA, OHRP and other regulatory requirements for the conduct of clinical research.
 2. Will personally conduct or supervise the clinical investigation as described in the protocol.
 3. Will obtain informed consent from all potential subjects as required by the IRB and federal regulations.
 4. Will report to the sponsor and the IRB in a prompt and timely manner any adverse events that occur in the course of the investigation.
 5. Has read and understands the information provided by the sponsor of the study relating to the drug or device to be studied, such as the protocol, investigator's brochure and other documents, including the potential risks and side effects of the drug or device.

6. Will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
 7. Will comply with all IRB requirements and directives, including prompt filing of continuing review documents when requested, notification of adverse events and protocol deviations, and proper approval by the IRB of any changes in the protocol or informed consent prior to enrolling new subjects, except when such changes are necessary to eliminate apparent immediate hazards to the human research subjects.
 8. Will complete a financial disclosure form and assure the IRB that no conflict of interest exists or provide a written description of any conflict for evaluation by the IRB during review of the request for addition to a study protocol.
- v. Upon receipt of all required documents, as outlined above, the full board will review the co-investigator or new PI request and determine if the investigator can be added to the protocol. Upon receipt of all required documents, as outlined above, the IRB Chair or a designated IRB member will review the sub-investigator request and determine if the investigator can be added to the protocol. A letter notifying the applicant of the decision will be issued.
 - vi. A new investigator from a new site can be added to an existing, active, approved protocol through full IRB approval only. In addition to providing the documents listed above in section 3.a.iv., the protocol and informed consent must be submitted for the board's review. Upon receipt of these required documents, the full board will review the new PI request and determine if the investigator can be added to the protocol. A letter notifying the applicant of the decision will be issued.

4. Study Termination / Closure:

The decision by the investigator(s) to terminate a study for any reason (including completion) must be communicated in writing to the IRB as soon as practical. Investigators should not wait until the time of next continuing review. [See PPMH policy "Closure of Studies"]

5. Effect on period for continuing review: Revisions / changes to a currently approved protocol may alter the initial or previous risk-benefit determination. Consistent with an increased risk determination, the IRB may elect to set a shorter interval for continuing review than was originally assigned to the project at the time of initial review or last continuing review. However, the interval may not be extended by setting a date greater than one year from the date of the initial review or last continuing review.
6. Effect on subjects already enrolled: The investigator shall recommend whether he/she feels subjects should be re-consented. However, the IRB shall make the final determination as to whether subjects already enrolled need to be apprised of revisions / changes to the study and the manner in which subjects shall be apprised, including, but not limited to, requiring all subjects to be re-consented.
7. The investigator will be notified in writing of any action taken by the IRB for the referenced submission(s), including the time period for continuing review if changed from the date set at the initial review or last continuing review.

Procedure:

1. Investigators shall complete and submit the IRB Amendment-Modification form for all changes / revisions not implemented to eliminate apparent immediate hazards to subjects in accordance with the instructions in the form.
2. Investigators shall complete and submit the proper IRB form when a study is either completed or discontinued. [See PPMH policy, "Closure of Studies" for details.]
3. The IRB Coordinator will review all submission and determine whether an expedited review process is appropriate in accordance with policy, PPMH "Expedited Review." If appropriate, the IRB Coordinator will forward the applications to the IRB Administrator and IRB Chair for review and approval of the submission. Changes approved through the expedited review process will be reported to the full IRB at the next scheduled meeting.
4. It is the IRB Administrator/Coordinator's responsibility to notify the investigator in accordance with the requirements of section 7, above.

References:

- 45 CFR part 46.103(b)(4)(iii)
- 21 CFR part 56.108(a)(4)

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	10-26-2016
0	Reviewed – No Changes	IRB Committee	08-28-2019