

Phoebe Putney Health System, Inc.

POLICY TITLE: INSTITUTIONAL REVIEW BOARD (IRB) USE OF NON-LOCAL IRBs

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 IRB Use of Non-Local IRBs policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

Purpose: To authorize the Phoebe Putney Memorial Hospital (PPMH) Institutional Review Board (IRB) to accept IRB review and approval from another site's IRB or a central IRB in lieu of full board review of multi-site studies by the PPMH IRB.

Definitions: N/A

Policy:

1. Federal regulations do not prohibit a local IRB from delegating responsibility for initial and continuing review to a non-local IRB, provided that: (a) the non-local IRB is competent to understand the local context of the research, and (b) has entered into a written agreement with PPMH's IRB delineating the roles and responsibilities of the respective IRBs. If the research is regulated by the Department of Health and Human Services' (DHHS) Office of Human Research Protections (OHRP), PPMH must also amend its Federal-wide Assurance listing the non-local IRB as an IRB authorized to review and approve research taking place within PPMH.
2. The PPMH IRB Chair or his/her designee must review and approve each request to use a non-local IRB on an individual basis. Principal investigators shall not be allowed to engage in research with a non-local IRB until the PPMH IRB Chair has signed a waiver of jurisdiction for the study. The PPMH IRB reserves the right to suspend and/or terminate, with or without cause, any research study approved by a non-local IRB in violation of this policy. Suspensions and/or terminations of research for violation of this policy will be reported in accordance with PPMH policy, "External Reporting."
3. Investigators shall submit a copy of the study protocol to the Office of Clinical Research. Investigators shall submit a letter to the PPMH IRB Chair requesting use of a non-local IRB. The following information should be provided:

- a. How the research will utilize any property, facilities, equipment, services or employees or agents of PPMH.
 - b. If the protocol requires access, use or disclosure of protected health information from human subjects that is held by PPMH.
 - c. Contact information for the non-local IRB.
 - d. The non-local IRB's waiver form, signed by the investigator.
4. Prior to submitting an application for initial review to a non-local IRB, the IRB Chair will ensure a written agreement is in place between the non-local IRB and the PPMH IRB delineating the specific roles and responsibilities of the respective IRBs and/or, in the case of research under the jurisdiction of OHRP, the PPMH FWA has been amended.
 5. Investigators will be notified of the decision to accept or reject the non-local IRB review.
 6. Once the non-local IRB is approved, the following information should be made available to the PPMH IRB for review by the IRB Chair or his/her designee:
 - a. Continuing Reviews (Renewals)
 - b. Unanticipated Problems (including Serious Adverse Events (SAEs))
 - c. Modifications (Amendments / Updates / Revisions)
 - d. Study Closure
 7. All research studies accepted from non-local IRBs will be reported to the convened PPMH IRB through local agendas and meeting minutes.

Procedure:

This section has been intentionally left blank. Please refer to related policies for applicable procedures.

References:

- 45 CFR 46.114
- 21 CFR 56.114

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