

Phoebe Putney Health System, Inc.

POLICY TITLE: ALLEGATIONS OF NON-COMPLIANCE, CONCERNS OR COMPLAINTS

ENTITY: PPMH

Approved by: IRB CHAIR

Effective Date: 1-25-2017

Review Period: 3 Years

Review Date: 12-18-2019

Contact Information: IRB COORDINATOR

Scope: The Allegations of Non-Compliance, Concerns or Complaints policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

Purpose: To provide a mechanism for anyone inside or outside Phoebe Putney Memorial Hospital (PPMH) to report any serious or continuing noncompliance with applicable regulatory requirements or with the determinations of the PPMH Institutional Review Board (IRB) and/or to report any concerns with research involving risks to human subjects or others.

This policy does not apply to reporting of adverse events, protocol deviations or unanticipated problems involving risks to subjects or others.

Definitions: N/A

Policy:

1. It is the policy of this institution to provide the highest level of protection to its human subject research participants. Reports of noncompliance will be directed to the IRB for investigation and corrective action. Federal regulations 21 CFR 56.113 and 45 CFR 46.113 provide the IRB with the authority to suspend or terminate approval of research that is not conducted in accordance with IRB requirements, or wherever there is evidence of serious or continuing noncompliance with FDA and DHHS regulations.
 - a. Where the IRB Chair determines that such action is necessary to protect the rights and welfare of subjects the Chair may require an immediate, temporary suspension of enrollment of new subjects or of continued participation of previously enrolled subjects, pending investigation and review of the situation by the convened IRB.
 - b. After review and deliberation, the IRB may vote to suspend or terminate approval of the research. The principal investigator will be notified of such actions in writing, which will include a statement of the reasons for the suspension or termination of approval. The investigator will be provided with an opportunity to respond.

2. All investigators conducting research at PPMH or as employees or agents of PPMH are required to notify the IRB promptly of any serious or continuing noncompliance with applicable regulatory requirements or with the determinations of the IRB. In addition, all non-investigator employees and agents of PPMH are required to notify the IRB promptly if they become aware of any serious or continuing noncompliance.

Procedure:

1. Reports of noncompliance may be provided to the IRB Chair, IRB members, or IRB staff from anyone inside or outside of the institution community who has reason to believe that noncompliance with IRB policies and procedures has occurred. These complaints will be accepted verbally or in writing. Upon receipt of an allegation of noncompliance or discovery/admission of noncompliance, the person receiving the information will immediately notify the IRB Administrator or IRB Coordinator. The IRB Administrator or the IRB Coordinator will notify the IRB Chair that the information has been received.
2. The IRB Administrator or IRB Coordinator, unless it is believed that notification will jeopardize the investigation, will notify the Respondent that an allegation has been received and provide an opportunity to respond. The IRB will be notified that an allegation was received and an investigation is being conducted.
3. The Compliance Officer or designee will conduct an investigation into the matter. Upon completion of the investigation, the IRB will be provided, in writing, a report of the findings of the investigation and other relevant information. The IRB will review the information and make a determination to close the investigation or initiate corrective action.
4. All appropriate parties will be notified of the allegation and the outcome.

References:

- 21 CFR 56.113
- 45 CFR 46.113

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 | 1-25-2017 |
| N/A | Policy Review. No changes. This policy replaces all other versions. | IRB Committee | 12-18-2019 |
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