

Phoebe Putney Health System, Inc.

**POLICY TITLE:           ADVERSE EVENTS AND UNANTICIPATED RISK REPORTING**

**ENTITY:                   PPMH**

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<b>Approved by:</b> IRB CHAIR	<b>Effective Date:</b> 12-01-2012
<b>Review Period:</b> 3 Years	<b>Review Date:</b> 01-22-2020
<b>Contact Information:</b> IRB COORDINATOR	

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**Scope:**           The Adverse Events and Unanticipated Problems Reporting Policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

**Purpose:**           The researcher shall submit reports of Adverse Events or other Unanticipated Problems involving risks to subjects or others as outlined below.

**1.) Definitions:**

**a) Adverse Event.**

Any experience or abnormal finding that has taken place during the course of a research project and was harmful to the subject participating in the research, or increased the risks of harm from the research, or had an unfavorable impact on the risk/benefit ratio, that was temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Note that the Food and Drug Administration (FDA) also includes in its definition abnormal preclinical or laboratory findings which may not yet have resulted in direct harm to subjects (e.g. a bacteria is identified in a culture from the same batch of cells used to produce a vaccine which has been administered, even if no cases of infection have been reported).

The FDA characterizes Adverse Events resulting from devices as adverse device effects. Only unanticipated adverse device effects that are serious need to be reported promptly. The PPMH IRB policy encompasses this regulatory requirement.

**b) PPMH Site.**

Any site at which the research is conducted under the direction of or supervision of a Phoebe Putney Memorial Hospital investigator and which is noted on the Phoebe Putney Memorial Hospital Federalwide Assurance (PPMH FWA) as under the PPMH IRB's jurisdiction.

**c) External.**

Occurring in a study or site for which a Phoebe Putney Memorial Hospital investigator is not responsible for the conduct of the study.

**d) Internal.**

Occurring in a study approved by the PPMH IRB at a site for which a Phoebe Putney Memorial Hospital investigator is responsible for the conduct of the study.

**e) Serious Adverse Event (SAE).**

Any experience occurring that results in any of the following outcomes: death; life-threatening experience; requires in-patient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse experience when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of these outcomes.

**f) Unanticipated Problems.**

Include any incident, experience, or outcome that meets **all** of the following criteria:

- i. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- ii. Related **or** possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- iii. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Examples include, but are not limited to, breach of confidentiality, protocol violations and deviations, and complaints about the research procedures or treatments by key personnel on the research team.

**g) Unanticipated Adverse Event.**

Any Adverse Event occurring in one or more subjects participating in a research protocol, the nature, severity, or frequency of which is **not** consistent with either:

- i. The known or foreseeable risk of Adverse Events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
- ii. The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the Adverse Event.

Note that the FDA characterizes Adverse Events resulting from devices as adverse device effects. Only unanticipated adverse device effects that are serious need to be reported promptly. The PPMH IRB policy encompasses this regulatory requirement.

2.) Summary.

a) Adverse Events.

i. INTERNAL: The following Adverse Events shall be reported to the PPMH IRB within **48 hours** of the event or the investigator being notified of the event:

- Adverse Events that meet all of the following criteria:
  - Serious and Unanticipated; *and*
  - Occurred at a site under the purview of a PPMH IRB (i.e., internal).

ii. EXTERNAL: The following Adverse Events shall be reported to the PPMH IRB within **5 business days** of the event or the investigator being notified of the event:

- Adverse Events that meet all of the following criteria:
  - Serious and Unanticipated; *and*
  - Possibly related to study procedures; *and*
  - Occurred at a site that is **not under the purview of a PPMH IRB (i.e., external)**; *and*
  - We have patients enrolled at our site and/or study is open to enrollment.

Events that do not meet the above criteria shall ONLY be reported in summary form at the time of continuing review. If reported as they occur, the reports will be returned to the researcher without IRB review.

b) Unanticipated Problems.

Unanticipated Problems (other than Adverse Events) involving risks to subjects or others, occurring at any site, shall be reported to the PPMH IRB within 5 business days using the IRB Adverse Event / Unanticipated Problem Report Form(Attachment A).

c) **If an Adverse Event/Unanticipated Problem Report is required:** The Investigator shall submit for IRB review a detailed Adverse Event/Unanticipated Problem Report in the time frame indicated above. In filing the report, the investigator must make the preliminary determination whether revision(s) to the protocol and/or consent document(s) is/are necessary. If a change is required, a modification must be submitted promptly.

d) **If a report in Summary Format is indicated:** The Investigator shall submit for IRB review a summary report with the submission of the scheduled continuing review request.

Adverse Events		
	Not Serious	Serious
Anticipated	Report in summary at time of continuing review	Report in summary at time of continuing review
Unanticipated	Report in summary at time of continuing review	Report promptly in accordance with terms of this policy

Unanticipated Problems	
Nature	Action
Involves risk to subjects or others	Report promptly in accordance with terms of this policy
Does not involve risk to subjects or others	No report required

### 3.) Policy/Procedure:

#### a) Internal Adverse Events.

The Investigator shall report all internal Adverse Events that are determined to be serious and unanticipated to the IRB within 48 hours of the event, or notification of its occurrence, by electronically submitting the Adverse Event /Unanticipated Problem Report.

The IRB Chair or designee will review reports of Adverse Events. Reports of all internal Adverse Events that are serious and unanticipated will also be reviewed by the full Board.

If the investigator believes a change in the protocol or consent documentation is warranted, he/she should submit an IRB Amendment/Modification Request Form (Attachment B). The Chair or designee will forward the modification, when received, for appropriate review (i.e., expedited review if the change(s) is/are minor or full Board review if the change(s) is/are substantive).

If the investigator has indicated that no change is required and the Board disagrees, the investigator will be asked to submit a modification.

Reports of internal Adverse Events that are not serious and unanticipated will be returned without review if they are submitted as they occur. These should only be reported in summary form at the time of continuing review.

#### b) External Adverse Events.

All external Adverse Events that are determined by the Principal Investigator to be serious, unanticipated, and possibly related must be reported to the IRB within 5 business days of notification. A detailed Adverse Event/Unanticipated Problem Report must be submitted within 5 business days of the event or notification. The IRB Chair or designee will review the report of Adverse Events or Unanticipated Problems.

Reports of all external Adverse Events that are Serious, Unanticipated, and possibly related to the study will also be reviewed by the full Board.

In filing the report, the investigator must make the preliminary determination whether revision(s) to the protocol and/or consent document(s) is/are necessary. If a change is required, a Report of Amendment must be submitted.

The Chair or designee will forward the amendment, when received, for appropriate review (i.e., expedited review if the change(s) is/are minor or full Board review if the change(s) is/are substantive).

If the investigator has indicated that no change is required and the Board disagrees, the investigator will be asked to submit a modification.

Reports of external Adverse Events that are not serious, unanticipated and possibly related to the study will be returned without review. These should only be reported in summary form at the time of continuing review.

**c) Unanticipated Problems (Internal or External) Involving Risks to Subjects or Others.**

All Unanticipated Problems involving risks to subjects or others must be reported promptly to the IRB via submission of an Adverse Event/ Unanticipated Problem Report.

A detailed Adverse Event/Unanticipated Problem Report must be submitted electronically within 5 business days of the event or notification, whether the problem was internal or external. The IRB Chair or designee will review all reports of Unanticipated Problems, and make a determination of whether additional review, by the full IRB Board, is required.

In filing the report, the investigator must make the preliminary determination whether a revision(s) to the protocol and/or consent document(s) is/are necessary. If a change is required, a Report of Amendment must be submitted promptly.

The IRB Chair or designee will forward the modification, when received, for appropriate review (i.e., expedited review if the change(s) is/are minor or full Board review if the change(s) is/are substantive).

Reports of Unanticipated Problems that do not involve risks to subjects or others will be returned without review. These should only be reported in summary form at the time of continuing review.

**d) Other Adverse Events/Unanticipated Problems.**

A summary of Adverse Events and Unanticipated Problems that occur during the approved study period must be submitted with other required materials at the time of continuing review. The summary for each type of adverse event should include, at a minimum:

- Number of subjects who experienced the event;
- Investigator's determination of whether or not the event is serious;
- Investigator's determination of the event's relationship to the study procedures (e.g., definitely, probably, possibly, probably not, definitely not related)

**e) Data Safety and Monitoring Board (DSMD) Reports.**

All DSMD reports that the investigator receives should be promptly reported to the IRB and submitted as a modification to the protocol.

**f) Report to Institutional Officials.**

All Unanticipated Problems involving risks to subjects or others must be reported promptly to the IRB via submission of an Adverse Event/ Unanticipated Problem Report Form. When such reports are made regarding external Unanticipated Problems, the PPMH institutional officials who shall review such reports are the IRB Chair and IRB Staff.

When such reports are made regarding internal Unanticipated Problems, the IRB Staff shall promptly provide a copy of the Adverse Event/Unanticipated Problem Report to the Executive Vice President / Chief Operating Officer for Phoebe Putney Memorial Hospital.

**g) Report to Office for Human Research Protections (OHRP).**

Unanticipated Problems occurring in research covered by a Federalwide Assurance must be reported by the institution to the supporting HHS agency head (if applicable) and OHRP. Phoebe Putney Memorial Hospital, through its Federalwide Assurance, has adopted the Common Rule for all human subject research conducted at a PPMH Site.

This requirement applies only to internal Unanticipated Problems. The IRB Chair and IRB Staff will evaluate all reported internal Unanticipated Problems for possible reporting to OHRP, and the IRB Staff shall be responsible for making such reports in accordance with OHRP rules and regulations.

**References:**

- 45 CFR part 46
- 21 CFR part 50
- 21 CFR part 56
- 21 CFR part 312
- 21 CFR part 812
- Office for Human Research Protections, "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events," January 15, 2007
- Food and Drug Administration, "Guidance for Clinical Investigators, Sponsors and IRBs – Adverse Event Reporting to IRBs – Improving Human Subject Protection," January 2009

**REVISION HISTORY**

Revision Number	Description of Changes	Approvals	Date
0	Initial release of Policy for PPMH Adverse Events and Unanticipated Risk Reporting. This policy replaces all previous versions.	IRB Committee	12-1-2012
N/A	Initial release of Policy for PPHS Policy Management System (Compliance 360 Program). This policy replaces all previous versions.	IRB Committee	6-21-2013
N/A	Policy Review. No Changes. This policy replaces all previous versions.	IRB Committee	2-22-2017
1	Policy Review. Format Changes Only. This policy replaces all previous versions.	IRB Committee	01-22-2020