Phoebe Putney Health System, Inc.

POLICY TITLE: EXPIRATION OF IRB APPROVAL AND SUBSEQUENT NOTICE TO CEASE STUDY ACTIVITY

ENTITY: PPMH

Approved by: IRB CHAIR
Effective Date: 8-21-2013
Review Period: 3 Years
Review Date: 01-22-2020
Contact Information: IRB COORDINATOR

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

Purpose: N/A

Definitions:

Research: As defined by the Department of Health and Human Services ("DHHS") any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Under the Food and Drug Administration ("FDA") regulations activities are "research" when they involve:

a. Use of a drug other than the use of an approved drug in the course of medical practice (21 CFR 312.3(b)).
b. Use of a medical device other than the use of an approved (means approved by the FDA for marketing) medical device in the course of medical practice (Food, Drug and Cosmetic Act 530(g) (3) (a) (i)).
c. Gathered data that will be submitted to or held for inspection by FDA in support of a FDA marketing permit for a food, including a dietary supplement that bears a nutrient content claim or a health claim, an infant formula, a food or color additive, a drug for human use, a medical device for human use, a biological product for human use, or an electronic product. (21 CFR 50.1(a) or 21 CFR 56.101(a)).

Human Subject (or Participant): As defined by DHHS: a human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46.102(f)). If the research involves a medical device, individuals are considered "subjects" when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control (21 CFR 812.3(p)).

As defined by FDA: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient 21 CFR 56.102(e). If the research involves a medical device, individuals are considered "subjects" when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control (21 CFR 812.3(p)).
A cadaver is not considered to be a human subject.

Research Activities Involving Human Subjects: Activities that either (1) meet the DHHS definition of "research" and involve "human subjects" as defined by DHHS OR (2) meet the FDA definition of "research" and involve "human subjects" as defined by FDA. The definition of research and human subjects must consistently reference the *same set of regulations* (i.e., DHHS or FDA) and cannot reference the definition of research from one set of regulations, and the definition of a human subject from the other. Anyone who plans to engage in an activity that qualifies as "research involving human subjects" requires Institutional Review Board (IRB) review and approval prior to commencement of the research.

Institutional Review Board (IRB) is an administrative body established by a local institution to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution.

Interaction: Includes communication or interpersonal contact between an Investigator or his/her research staff and the research participant or their private identifiable information.

Intervention: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subjects' environment that are performed for research purposes.

Private Information: Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order to be considered information to constitute research involving human participants.

Policy:

In compliance with the federal regulations governing research with human subjects and PPMH policy, all active research studies conducted at PPMH or by PPMH employees involving human subjects must have PPMH IRB approval. For the purpose of this policy statement, an active research study is defined as a study in which any of the following study activities is occurring:

- Preliminary activities:
    - Advertisement
    - Ascertainment for which identifiable private information is recorded for research purposes
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- Interaction or intervention with research participants or potential research participants:
    - Recruitment
    - Enrollment
    - Protocol-directed intervention or interaction
    - Participant follow-up
    - Notification of subjects concerning their randomization status or study results

- Use of identifiable private information for research purposes:
    - Data analysis
    - Data transmission
    - Preparation of a study publication
    - Internal or external audit
    - Any other activity involving the use of identifiable private information for research purposes.

The expiration date for an IRB protocol is the first date that the protocol is no longer approved. When a protocol is nearing its expiration date, the Principle Investigator must submit an application for continuing review. If the IRB has not approved the protocol by 12:00 AM (midnight) on the expiration date cited on the most recent Notice of IRB Approval, IRB approval expires automatically. All study activity as described above, including recruitment of new subjects, advertisement, screening, enrollment of new subjects, conducting the consent process, interventions and/or interactions with existing subjects, the collection of identifiable private information from existing subjects, and the analysis of existing identifiable private information, must cease.

When all study activities are complete, the PI must submit and receive IRB approval without modification of a Final Study Closure report. If the PI is no longer affiliated with PPMH, the PI's site-based research group medical director or the lead coordinator may submit the Final Study Closure report.

Expiration Reminder Notices

At 60 days prior to the expiration date, the first email reminder of approaching protocol expiration will be sent (see Attachment 1). At 30 days prior to expiration, the second reminder (see Attachment 1) will be sent. Upon receiving the 30 day notice, the PI must promptly submit either a Continuing Review form or Final Study Closure form (if not already submitted) to permit the IRB to have sufficient time to perform a complete review before the study's expiration.

Expiration Action Notices

At 14 days prior to expiration, if IRB approval of the Continuing Review is not complete, and action notice will be sent (Attachment 2). If the Continuing Review form or Final Study Closure form has been submitted to the IRB, the PI must contact the IRB to resolve any outstanding issues and ensure that IRB final approval is received before expiration. If neither report has been submitted, and the PI believes that continued research participation during this lapse in approval would be in the best interests of individual subjects (such as to avoid creating an overriding safety concern or ethical issues), the PI must request this in writing to the IRB Administrator or the IRB Chair. The correspondence must contain the following:

1. A brief (2-4 sentences) description of the study;
2. A description of the study activity that the PI wishes to continue until the IRB approval has been

reinstated, with a justification for why its continuation would be in the individual subject's best interest;
3. A listing by study number of each current subject for whom continued research participation would be in the person's best interest;
4. A description of the effect of the activities described in #2 above on risks and benefits to subjects; and
5. An explanation for why the PI failed to complete the timely renewal of the protocol, and the plan to prevent such a recurrence.

The IRB may require either re-consent of affected subjects for continued study participation, or documentation of written permission from the affected subjects for use of any research data collected during the period of approval lapse, as solely determined by the IRB.

If the IRB final approval for closure or renewal has not been issued by the expiration date, after 12:00 AM (midnight) on the expiration date a Research Protocol Expiration Notice (see Attachment 3) is issued via email. The PI is also contacted by the IRB Chair or designee using other means (telephone call or page) during the day the expiration occurs and instructed to stop all research related to the protocol. Under no circumstances can participants be enrolled into expired research unless the activity meets the criteria for emergency use of test article in a life threatening situation without prior IRB review.

This expiration of IRB approval is not reported to OHRP or FDA as a suspension or termination of IRB approval under the DHHS or FDA regulation. If no written reply is received from the PI to email #3 within 60 days post-termination date, a Notification of Study Termination (see Attachment #4) email is issued to the Key Personnel and PPMH Research Office. The study is then permanently closed; it may not be re-opened.

Procedure: N/A

References: NOTED IN "DEFINITIONS"

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	8-21-2013
N/A	Policy Review. No Changes. This policy replaces all previous versions.	IRB Committee	2-22-2017
N/A	Policy Review. No Changes. This policy replaces all previous versions.	IRB Committee	01-22-2020