SCOPE

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

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

- **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
expiration of IRB approval and subsequent notice to cease study activity

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.
Protocol Expiration Reminder

May 30, 2013

To:
Cc:

Name of Study Protocol

This is a reminder that IRB approval for the above-referenced human-subjects research project will have expired on [date of expiration]. Please note that the expiration date is the first date that your protocol will no longer be approved.

Before approval expires you must submit to the IRB and receive IRB approval without modification of either a continuing review application or a final study closure report. So please respond promptly.

On the expiration date all research and fund expenditures must stop.

Stopping the research means there can be no intervention, interaction or follow-up with enrolled research participants. There can also be no advertising, recruitment, enrollment or continued collection of data or specimens, analysis of data or specimens that have already been collected, or use of the data. Stopping fund expenditures means that no obligations may be made against Federal funds for research involving human subjects at PPMH sites engaged in such research for any period not covered by IRB approval.

If you intend to renew this protocol, please submit a request for Continuing Review form (attached). If you do not plan to renew this study, you must submit a Final Study Closure form (attached).

Please feel free to contact me if you have any questions.

Felicia Lewis
IRB Coordinator
312-0372
Protocol Expiration Action Notice

May 30, 2013

To: 
Cc: 

Name of Study Protocol

This is a notice that your immediate action is required. IRB approval for the above-referenced human-subjects research project will have expired on [date of expiration]. Please note that the expiration date is the first date that your protocol will no longer be approved.

At that time, you must stop all research and fund expenditures.

Stopping the research means there can be no intervention, interaction or follow-up with enrolled research participants. There can also be no advertising, recruitment, enrollment or continued collection of data or specimens, analysis of data or specimens that have already been collected, or use of the data. Stopping fund expenditures means that no obligations may be made against Federal funds for research involving human subjects at PPMH sites engaged in such research for any period not covered by IRB approval.

If you have submitted to the IRB a Continuing Review form or a Final Study Closure form, you must immediately contact the IRB to assist you to resolve any outstanding issues and receive final IRB approval without modification before the expiration date.

If you have not submitted either form or you know you will not receive final IRB approval before study expiration, you must immediately decide if continued research participation during this lapse in IRB approval would be in the best interest of some or all of your research participants. You must send this request to Dr. Suresh Lakhanpal, IRB Chair at slakhanp@ppmh.org with a copy to the IRB Coordinator, Felicia Lewis, at flewis@ppmh.org. The correspondence must contain the following:

1. A brief (2-4 sentences) description of the study;
2. A description of the study activity that you wish to continue until 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 of why you failed to complete the timely renewal of your protocol, and your plan to prevent such a recurrence.

Please feel free to contact me if you have any questions.

Felicia Lewis  
IRB Coordinator  
312-0372
RESEARCH PROTOCOL EXPIRATION NOTICE

May 30, 2013

To:
Cc:

Name of Study Protocol

1) IRB approval for the above-referenced human-subjects research project expired at 12:00 AM on [date of expiration].

Stopping the research means there can be no intervention, interaction or follow-up with enrolled research participants. There can also be no advertising, recruitment, enrollment or continued collection of data or specimens, analysis of data or specimens that have already been collected, or use of the data. If you believe that it is in the best interest of individual subjects to continue participating in research interventions or interactions you must immediately contact the IRB Chair (Dr. Suresh Lakhanpal at 229-312-1301) or the IRB Administrator (Audrey Pike at 229-312-4146) if you have not already done so.

Stopping fund expenditures means that no obligations may be made against Federal funds for research involving human subjects at PPMH sites engaged in such research for any period not covered by IRB approval.

2) To comply with federal regulations and Phoebe Putney Memorial Hospital IRB policy,
   • You must send a “Final Closure Study Form” to the IRB office.
   OR
   • If you plan to reinstate this study, you must notify the IRB immediately.
   • If you do not submit to the IRB your continuing review application within 60 days of today, your research protocol will be permanently terminated. At that time, if you want to continue this research, you will need to submit an entire new IRB protocol and application.

Please feel free to contact me if you have any questions.

Felicia Lewis
IRB Coordinator
312-0372
NOTICE OF STUDY TERMINATION

May 30, 2013

To:
Cc:

The Phoebe Putney Memorial Hospital Institutional Review Board (PPMH IRB) is notifying you that the study entitled:

Name of Study Protocol

has been formally terminated. Because no response to the previous e-mail expiration notice, dated (insert date from Reminder #3 email date), was received by the PPMH IRB, this study is considered terminated as of 12:00 AM (midnight) on the original expiration date. Any study activity, including but not limited to, enrollment, drug/device intervention, follow-up, data analysis or any other use of study data, is strictly prohibited under PPMH IRB policy and the federal regulations governing research involving human-subjects. Resumption of any study activities is not allowed without first submitting a new IRB protocol and receiving specific written approval from the PPMH IRB.

To comply with federal regulations and Phoebe Putney Memorial Hospital IRB policy,

- You must send a “Final Closure Study Form” (attached) to the IRB office.

OR

- If you plan to reinstate this study, you must notify the IRB immediately and submit an entire new IRB protocol and application.

If you wish to discuss this Notice of Study Termination, please contact the PPMH IRB Administrator, Audrey Pike at 229-312-4146.