PHOEBE PUTNEY MEMORIAL HOSPITAL

IRB Continuation Request Form

Continuing Review: All continuing, nonexempt research must be re-reviewed and re-approved on an annual basis, unless the initial IRB review stipulated that IRB review is required more frequently. So that the appropriate level of review can be completed before the project's approval expires, this form must be submitted at least 30 days prior to the deadline indicated in the IRB Office notification. Human Participants research may not continue beyond a project's approval expiration date.

1 General Information

Study Title:

Study Number:

Principal Investigator:

Address:

Telephone:

Date Research Ethics Training Completed:

If Request is being submitted by a student, please complete the following:

- Type of Student Research: ☐ Thesis ☐ Dissertation ☐ N/A
- Name of School/College:
- Department:
- Faculty Advisor:

Study Funding: (select from drop down box)

Name of funding source:

2 Renewal Questions

1. Current state of this research

- ☐ Study is open to enrollment and no participants have been enrolled to date.
- ☐ Study is open to enrollment and participants have been enrolled to date.
  Total Number of Subjects Enrolled: ☐
- ☐ Study is closed to enrollment but participants are still on the protocol regimen.
- ☐ Study is closed to enrollment but follow-up of participants continues.
  Total Number of Subjects in Follow-up: ☐
- ☐ Study is closed to enrollment but analysis of identifiable/coded data continues.
- ☐ Study is closed to enrollment but awaiting close-out visit by Sponsor.
- ☐ Enrollment, data collection, and analysis of identifiable/coded data have finished or have been terminated. Provide date of termination: ☐
  CONTINUE TO SECTION 3.

2. Are there any changes in the original approved protocol/methodology that relate to the research conducted and/or human participants utilized in your research?

- ☐ Yes – **YOU MUST COMPLETE AND ATTACH A MODIFICATION REQUEST FORM**
- ☐ No

3. Have there been any adverse events or unanticipated problem(s) that relate to the research conducted and/or human participants utilized in your research?

- ☐ Yes – **YOU MUST COMPLETE AND ATTACH AN ADVERSE EVENT REQUEST FORM**
- ☐ No

3 Attachments

Please attach the following:

- ☐ Informed Consent Form(s)
- ☐ Study Protocol
- ☐ Modification Request form, if applicable
- ☐ Adverse Event form, if applicable

3 **Investigator's Assurance & Signature**

Please submit a signed application to the IRB office. Applications can be sent electronically by clicking the "Submit Form" button at the end of this application. If you are a student, we must receive an e-mail from your faculty advisor from his or her faculty e-mail address stating that the advisor has read and approved the contents of the submission. Student research will not be reviewed without faculty advisor approval.

The information and answers to the questions above are true and accurate to the best of my knowledge and I understand that prior IRB approval is required before initiating any changes that may affect the human participant(s) in the originally approved research protocol. I also understand that in accordance with federal regulations I am to report to the IRB or administrative designee any adverse events that may arise during the course of this research.

PRINCIPAL INVESTIGATOR: I will conduct the study identified above in the manner described on the attached narrative. If I decide to make any changes in the procedure, or if a participant is injured, or if any problems occur which involve the risk or the possibility of risk to participants or others, I will immediately report such occurrences or contemplated changes to the PPMH Institutional Review Board.

P.I.'s Name: _____ Date: _____

Electronic Signature: _____

FACULTY ADVISOR (IF THE INVESTIGATOR IS A STUDENT, A FACULTY ADVISOR MUST SIGN BELOW)**:** I have read and approved this protocol. I believe this is research as defined by the Department of Health and Human Services (i.e., a systematic investigation designed to develop or contribute to generalizable knowledge) and that the student is competent to conduct the activity as described therein.

Faculty Advisor's Name: _____ Date: _____

Electronic Signature: _____

Please save a copy of the form for your records and submit the final form electronically by clicking the "Submit Form" button.

IRB Office Only

Date of Receipt:

Is the Continuing Review Form Complete? ☐ **Yes** ☐ **No**

Does study still meet criteria for Exempt or Expedited Review (if applicable)? ☐ **Yes** ☐ **No**

Is the current Informed Consent form included? ☐ **Yes** ☐ **No**

Report returned to Investigator (indicate reason):

Continuing Review Approval Date: