Phoebe Putney Health System, Inc.

POLICY TITLE: CLOSURE OF STUDIES

ENTITY: PPMH

Approved by: IRB CHAIR
Effective Date:9-25-2013
Review Period: 3 Years
Review Date: 12-18-2019
Contact Information: IRB COORDINATOR

Scope: The Closure of Studies policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

Purpose: This policy describes when and how a study may be closed by the Principle Investigator (PI) or the PPMH IRB.

Definitions:

Closed to Enrollment: this action is either permanent or temporary:

Temporary Closure to Enrollment: A study may be temporarily closed to enrollment when there is a pause in the conduct of research or recruitment. This often happens when conducting an interim analysis.

Permanent Closure to Enrollment: A study is closed permanently to enrollment when no further enrollment will occur and participants may remain active for treatment or long-term follow-up and/or data analysis.

Final Study Closure: No further research, follow-up, or data analysis will be performed. A study may be terminated when it no longer constitutes human subject research, such as de-identifying the data. The IRB may also terminate a study for cause, therefore halting further research.

Policy:

Just as proposed modifications to study procedures require prior IRB approval, so does study closure. Continuing PPMH IRB review and approval is required as long as study activity is ongoing, including intervention or interaction with subjects, continued use of a drug or device, and/or data analysis. Only when ALL study activity has ceased should an investigator close a research study.

A. A study should be finally closed by the PI when no further contact with human subjects or their individually identifiable information is planned; no subjects are or will be treated or followed; all data are gathered and analyzed; and any final reports or publications are complete.

1. The completion or final closure of a previously approved research protocol or project constitutes a change in activity that must be reported to the PPMH IRB.
2. Subsequent use of any data from a finally closed project will require a new IRB submission.
3. Study final closure is not a withdrawal. It does not refer to an investigator's or IRB's withdrawal of a submission from the IRB review process prior to IRB approval.
4. Investigators should not finally close research which is "closed to enrollment", as this means only that no additional subjects will be enrolled in the study.

B. The PPMH IRB may finally close or suspend projects without PI approval in the following circumstances:
    1. If it is determined that the investigator is no longer affiliated with PPMH;
    2. In response to unanticipated problems involving risk to subjects or others, serious or continuing non-compliance, findings presented during an IRB review, or problems identified in a monitoring process;
    3. If the investigator has not responded to the IRB's requests for revisions and/or clarifications within a timeframe which is determined on a case-by-case basis, based upon the vulnerability of the subject population and the risk of research; OR
    4. If a study is not accruing participants. When deciding if a study should be finally closed, the IRB considers, among other things:
        a. The level of risk,
        b. Possible benefit,
        c. Funding source,
        d. Value of the knowledge to be gained,
        e. Possibility of remedy

C. Final Closure or suspension of IRB-approved studies is reportable to institutional officials and to the appropriate regulatory authorities. Final Closure of an expired study is not termination of approval of research per 45 CFR 46.113 and is not reportable.

Procedure:

A. When a Study may be Closed by the Investigator

1. Reasons for study closure may include but are not limited to:
    a. Completion of research and data analysis;
    b. Inadequate enrollment;
    c. Loss of funding;
    d. PI transfer
2. Investigator-initiated protocols may be closed when individually-identifiable follow-up data are no longer being collected or analyzed on subjects.
3. Multi-sites may be closed when the sponsor has completed all data queries on the PPMH study records, has "locked" the PPMH data and remaining data analysis will not be completed by PPMH.

B. Investigator Responsibilities

1. PIs should submit a PPMH IRB Application for Final Study Closure form (attachment #1) to the IRB office within 90 days of completion or termination of all research activity. This must be submitted even if the current approval period has expired.
2. Investigators need not wait for the end of the study approval period to submit an Application for Final Study Closure.
3. Investigators must store the research records for a minimum of three (3) years, in accordance with federal regulations and any additional requirements stipulated by research sponsors and/or investigators' professional associations.
4. Subsequent use of data from closed research, whether by the original investigator or other investigators, may constitute human subjects research requiring IRB approval or an exemption from IRB review and will require Investigators to submit a PPMH IRB Request to Re-Open a Closed Study form (attachment #2).
5. Investigators are expected to continue to honor confidentiality protections for data.
6. Commitments made, such as the communication of research results or compensation to subjects, should be honored even if the study is closed. These can be done for a closed study with permission of the IRB Chair.
7. When a principle investigator terminates employment or other association with PPMH, he or she is obligated to either:
    a. Submit a PPMH IRB Application for Final Study Closure form (attachment #1); or
    b. Transfer the study to another PPMH PI (Note: change of key personnel in federally funded or FDA-regulated research requires prior approval of the funding agency and/or FDA.)
8. Data and/or specimens from a study that is being terminated may be transferred to a research repository upon termination.

Enrollment Closures: The PI may request an Enrollment Closure, either temporary or permanent, by submitting an IRB Enrollment Closure Form (attachment #3). Studies closed to enrollment are still required to undergo a continuing review each year, up until the time of completion. If the study is temporarily closed to enrollment, the PI must notify the IRB before re-opening study to accrual.

IRB Records: The records required by this policy shall be retained for at least three (3) years, and records relating to research which is conducted shall be retained for at least three (3) years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

References:

- 45 CFR §46.113
- 45 CFR §46.115(b)

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	9-25-2013
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	12-18-2019