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| **DEPARTMENT:**  **Phoebe Putney Memorial Hospital Institution Review Board** | **POLICY DESCRIPTION:**  **Closure of Studies** |
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| **APPROVED BY:**  **Suresh Lakhanpal, MD, IRB Chair** | **RETIRED:** |
| **EFFECTIVE DATE:**  **September 25, 2013** | **NUMBER:** |

## BACKGROUND

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.

## SCOPE

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

1. 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.

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* 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.

1. 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:
      1. The level of risk,
      2. Possible benefit,
      3. Funding source,
      4. Value of the knowledge to be gained,
      5. Possibility of remedy
2. 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.

## PROCEDURES

1. **When a Study may be Closed by the Investigator**
   1. Reasons for study closure may include but are not limited to:

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* + 1. Completion of research and data analysis;
    2. Inadequate enrollment;
    3. Loss of funding;
    4. PI transfer
  1. Investigator‐initiated protocols may be closed when individually‐identifiable follow‐up data are no longer being collected or analyzed on subjects.
  2. 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.

## 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:
     1. Submit a PPMH IRB Application for Final Study Closure form (attachment #1); or
     2. 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.)

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* 1. 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)

## Attachments

IRB Application for Final Study Closure IRB Request to Re‐Open a Closed Study IRB Enrollment Closure Form

## IRB Application for Final Study Closure

### Closure of a study means that no further research, follow up, or data analyses will be performed. If any subjects are ongoing, the study may not be closed. A study is not closed simply because no additional subjects will be enrolled.

Principal Investigator:

Address:

Contact Number:

Study Number:

Study Title:

Date of this request:

## Reason for Closure

Data collection has ceased and there is no ongoing data analysis/or follow−up of subjects

The FDA, the IRB, the Sponsor or other regulatory agency has terminated the study. You must attach all relevant documentation from the termination party.

The study is being withdrawn; the study has not been initiated, no subjects have been enrolled and study will not be conducted at this site.

Explain:

The study is being terminated due to lack of subject enrollment (subject recruitment was unsuccessful and no subjects have been enrolled).

Explain:

## Subjects

Number of subjects anticipated: Number of subjects enrolled:

Number of subjects completed: Number of subjects withdrawn: Reason(s) for withdrawals:

## Adverse Events / Withdrawal from Study

* 1. Since your last IRB review, has any subject suffered any serious adverse event or unanticipated problems involving risk to subjects or others?

Yes No

If **YES**, specify the number of events and describe briefly their nature and significance:

Were these reported to the IRB, to a sponsor, to the FDA or to anyone else?

Yes No

* 1. Summarize all adverse drug reactions in which a relationship to your study’s drug cannot be ruled out:
  2. Was the frequency of serious but expected side effects different from what you anticipated?

Yes No

If **YES**, explain:

* 1. How many of the recruited subjects at this site complained about any aspect of the study since the initiation of this project?
  2. Did you remove any subject from the study due to adverse reactions, noncompliance or other reasons?

Yes No

If **YES**, provide a description of the medical problem or other circumstances for each subject who was terminated involuntarily:

* 1. Did any subject voluntarily withdraw from the study for medical or non−medical reasons?

Yes No

If **YES**, provide a description of any know reasons for such subject who withdrew:

## Study Results

* 1. Summarize the final findings of your study. Attach copies of relevant publications.

## Signature

P.I.’s Name: Date:

Electronic Signature:

NO FURTHER RESEARCH, FOLLOW−UP ANALYSIS OR SUBJECT TREATMENT ASSOCIATED WITH THIS STUDY WILL CONTINUE PAST THE DATE ENTERED ABOVE. MY STUDY RESULTS ARE AN ACCURATE SUMMARIZATION OF THIS STUDY’S RESULTS.

# Submit Form



Please save a copy of the form for your records and submit the final form electronically by clicking the “Submit Form” to the left or at top of page.

|  |  |  |  |  |  |  |
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| **IRB Office Only**  **Date of Receipt:**  **Is the Application for Final Study Closure Complete? Report returned to Investigator (indicate reason):** | | | | **Yes** | **No** |  |
|  |  | | | | |  |
| **Full Board Review (date):** | |  |  | | | |

## IRB Request to Re-Open a Closed Study

*On occasion, researchers seek to temporarily re−open a study after study closure has occurred. This is typically related to a request from the sponsor or the FDA for clarification of existing data or for follow− up communication to subjects. This form provides the IRB with the basic information to consider the request.*

## Re-opening of a closed study will require the same level of review as the original study. If the PI or protocol has changed, an Amendment/Modification Form must accompany this request. If the IRB determines the study to be significantly different from the original, with a substantially different endpoint or outcome, a new application will be required.

**Federal regulations (45CFR46.109(e)) require that all human subjects research be reviewed at least annually. If the study in question was closed and at least 12 months since the last IRB approval have passed, a Request for Continuation From must accompany this submission.**

### \*\*This form should not be used if the researcher is seeking to re-open due to a lapse in continuing review.

Principal Investigator:

Address:

Contact Number:

Study Number:

Study Title:

Date of this request:

## Indicate the Reason for Re-opening this Study at this Time:

Audit Site Visit

Query for data clarification/data existing at the time of study closure Query for new data related to events occurring since study closure To Notify Subjects of their Randomization and the Study Results

Other (please explain why this was closed and must now be reopened):

If Audit: provide the anticipated date of the audit:

Who is conducting the audit (regulatory agency, sponsor, other institution for which we were a sub−site, etc.)?

Attach the audit notification and any other relevant communications.

## Have there been any study-related unanticipated problems or serious adverse events since the study was closed?

No

Yes. Include copies of these reports with this submission. N/A

## If subjects will be notified of their randomization and study results, describe how subjects will be notified and attach any documents that will be sent to subjects for IRB review.

* 1. Who will coordinate the notification process?

Name: Role in Study: Phone:

* 1. Who will sign the letters to the subjects? (\*\*should be the PI)

Name: Role in Study: Phone:

## Signatures

**PRINCIPAL INVESTIGATOR’s Name:**

Date:

Electronic Signature:

**Submit Form**

Please save a copy of the form for your records and submit the final form electronically by clicking the “Submit Form” to the left or at top of page.

**Approved**

**Not Approved. Reason(s):**

**No**

**Yes**

**IRB Office Only**

**Date of Receipt:**

**Is the Request to Re-Open a Closed Study Form Complete?**

## IRB Enrollment Closure Form

**REQUIREMENTS – Check each box indicating you have read, understood and will submit the following**

This form is used for ENROLLMENT closures only.

Closed studies that will remain active for treatment or long−term follow−up and/or data analysis are still required to undergo a continuing review each year, up until the time of completion.

This form may NOT be used for a complete/final closure notification of a study. Investigators must submit an Application for Final Study Closure.

If your study involves an outside sponsor, attach correspondence as appropriate.

If your study has been temporarily closed to enrollment, you MUST notify the PPMH IRB BEFORE being re−opened to accrual.

Principal Investigator:

Address:

Contact Number:

Study Number:

Study Title:

Date of this request:

## Closure Details

* 1. Closure Status

Closed to Enrollment – Permanent Closing Cohort:

Closed to Enrollment – Temporary Closing Phase: Closing Arm:

* 1. Closure Assessment
     1. Initial accrual goal:
     2. Total number of subjects accrued or samples obtained on or before closure effective date:
     3. Total number of subject who completed participation or samples analyzed on or before closure effective date:
     4. Are there any patients in long−term follow−up: Yes No
  2. Closure Summary

Provide a summary for the reason the protocol noted above has been closed to enrollment:

## Designee

The Primary Investigator has designated the following individual to complete this form:

Designee’s Name:

Occupational Title:

## Assurance / Authentication

The undersigned assures that the information provided in this “Enrollment Closure” form is complete and accurate, and that it is consistent with proposal(s) submitted to external funding agencies. The undersigned assures that modifications to the approved project will not take place without prior review and approval by the Phoebe Putney Memorial Hospital Institutional Review Board (PPMH IRB), and that all activities will be performed in accordance with state and federal regulations and those of the PPMH IRB.

P.I.’s Name: Date:

Electronic Signature:

# Submit Form



Please save a copy of the form for your records and submit the final form electronically by clicking the “Submit Form” to the left or at top of page.

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| --- | --- | --- | --- | --- | --- |
|  | **IRB Office Only**  **Date of Receipt:**  **Is the Enrollment Closure Form Complete? Yes Report returned to Investigator (indicate reason):** | | | **No** |  |
|  |  | | | |  |
| **Full Board Review (date):** | |  |  | | |