

REQUIREMENTS – Check each box indicating you have read, understood, and will submit as required:

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:

Study Title:

PI Address:

PI Telephone / Email:

Date of Submission:

Closure Status

Closed to Enrollment – Permanent

Closing Cohort:

Closed to Enrollment – Temporary

Closing Phase:

Closing Arm:

Closure Assessment

Initial Accrual Goal:

Total number of subjects accrued or samples obtained on or before closure effective date:

Total number of subjects who completed participation or samples analyzed on or before closure effective date:

Are there any patients in long-term follow-up? Yes No

Closure Summary

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

Principal Investigator 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 PPMH IRB, and that all activities must be performed in accordance with state and federal regulations and those of the PPMH IRB.

P.I.'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" to the left or at top of page.

**IRB Review of Enrollment Closure Form
(Completed by IRB Office Only)**

Date of Receipt: _____

Is the Form Complete with Required Documents? Yes

No

Report returned to Investigator (indicate reason):

Full Board Approval Date: _____