INSTITUTIONAL REVIEW BOARD
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:

Study Title:

PI Address:

PI Telephone / Email:

Date of Submission:

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☐ The study is being withdrawn; the study has not been initiated, no subjects have been enrolled and study will not be conducted at this site.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Number of subjects withdrawn: _____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

2. Summarize all adverse drug reactions in which a relationship to your study's drug cannot be ruled out:

3. Was the frequency of serious but expected side effects different from what you anticipated?

☐ Yes

☐ No

If **YES**, explain:

4. How many of the recruited subjects at this site complained about any aspect of the study since the initiation of this project?

5. 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:

6. 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

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

Principal Investigator Acknowledgement

No further research, follow-up analysis, or subject treatment associated with this study will continue past the date entered below. My study results are an accurate summarization of this study's results. If no final findings are available at time of submission of this document, I will provide final findings to the IRB as soon as they are made available.

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.

IRB Review of Application for Final Study Closure (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: _____	