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The study is being withdrawn; the study has not been initiated, no subjects have been enrolled and study will not be conducted at this site.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| Number of subjects completed: |  | Number of subjects withdrawn: |  |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

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**

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.l.’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: |