IRB APPLICATION FOR STUDY FINAL CLOSURE

1. STUDY INFORMATION

IRB #:

Study Title:

2. CONTACT INFORMATION

Principal Investigator(s):

Co-Investigator(s):

3. CURRENT RESEARCH STUDY STATUS (Please check one that best describes the current state of this research study)

☐ Study completed. Data collection has ceased and there is no ongoing data analysis/or follow-up of subjects **(Please forward final study report, any progress report, multi-center trial reports, and publications as available).**

☐ The study is being withdrawn; the study has not been initiated, no subjects have been enrolled and study will not be conducted at this site.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

Explain:

_____

_____

☐ Study Terminated (If terminated, please provide reasons or relevant documentation from the termination party (IRB, sponsor, FDA). (Explain, sign last page and submit).

Explain:

_____

_____

4. STUDY IND/IDE INFORMATION

Does the study involve the use of an investigational *drug* or an approved drug for an unapproved indication? ☐ Yes ☐ No If yes,

Drug Name: ___ IND #: ___

Does the study involve the use of investigational *device*? ☐ Yes ☐ No If yes,

Device Name: ___ IDE #: ___

5. STUDY PROGRESS SUMMARY

Duration of the Study:

Number of participants anticipated:

Number of participants (local site) enrolled:

Number of participants completed (local site):

Number of participants' withdrawn (local site):

Reason(s) for withdrawals:

Explain:

Did any participants studied at local site experience any adverse events, unanticipated problems during this reporting period? ☐ Yes ☐ No
If yes, attach copies of safety report(s) that have not been forwarded to IRB. For multi-center studies, provide detailed report of external safety issues if not yet reported prior to this review.

Have there been any participant complaints regarding the research? ☐ Yes ☐ No

Reported to the IRB? ☐ Yes ☐ No ☐ NA (if yes, no further documentation n required).

If no, attach a brief description summarizing the complaints.

Since the most recent IRB approval have there been relevant literature, abstracts, and/or publications? ☐ Yes ☐ No

Reported to the IRB? ☐ Yes ☐ No ☐ NA (if yes, no further documentation n required).

If no, list or attach copy.

Since the most recent IRB approval have there been any interim findings, progress reports or multi-center trial reports? ☐Yes ☐ No

Reported to the IRB? ☐ Yes ☐ No ☐ NA (if yes, no further documentation n required).

If no, attach copies and brief description.

Since the most recent IRB approval has there been any other information relevant to this research discovered, especially information about the risk and benefits associated with this research? ☐ Yes ☐ No

Reported to the IRB? ☐ Yes ☐ No ☐ NA (if yes, no further documentation n required).

If no, please list and/or attach copies of the information.

Since the most recent IRB approval have there been any protocol violation and/or deviation? ☐ Yes ☐ No

Reported to the IRB? ☐ Yes ☐ No (if yes, no further documentation n required).

If no, attach report.

Have there been any changes to the study (amendments or modifications)? ☐ Yes ☐ No

Reported to the IRB? ☐ Yes ☐ No ☐ NA (if yes, no further documentation n required).

If no, please summarize all the amendments. Use separate sheet if needed.

Since the most recent IRB approval has any of the study personnel changed (added or removed)? ☐ Yes ☐ No

Reported to the IRB? ☐ Yes ☐ No ☐ NA (if yes, no further documentation n required).

Did the IRB require the use of written informed consent document, written assent for this study? ☐ Yes ☐ No

Are copies of the informed consents being appropriately filed? ☐ Yes ☐ No ☐ NA

If yes, the patient must receive a copy, the investigator must maintain a copy, and the original must be placed in the patient's health [or study] record).

IF No, explain why ___ (e.g., IRB waived documentation for informed consent).

Explain:

_____

_____

Are adequate measures in place to prevent unauthorized access to patient identifiers? ☐ Yes ☐ No

If no, attach report of protocol violation.

Has the research site or records been audited? ☐Yes ☐ No (IRB, Sponsor, other)

Reported to the IRB? ☐ Yes ☐ No ☐ NA (if yes, no further documentation n required).

If no, please complete the following and provide audit report as available.

Who conducted the audit?

_____

Date(s) of Audit:

_____

6. STUDY FUNDING, FEES

Is the study funded? ☐ Yes ☐ No

Provide source of funding:

If this is a company sponsored study are IRB dues paid? ☐ Yes ☐ No (If No, explain)

Explain:

_____

7. INVESTIGATOR'S CONFLICT OF INTEREST STATEMENT

Has a new conflict of interest developed since the most recent IRB approval that could affect or appear to affect the design, conduct, or reporting of the research as more specifically described in IRB Conflict of Interest Policy? ☐ Yes ☐ No
If yes, please complete the Conflict of Interest and Disclosure form.

PRINCIPAL INVESTIGATOR'S ASSURANCE STATEMENT

By signing this form, I certify that all relevant information including adverse events or other issues that might affect the risk/benefit ratio of this study has been disclosed to the IRB.

_____ _____

Signature over Printed Name of Principal Investigator | Date