DRISCOLL CHILDREN'S HOSPITAL (DCH)
INSTITUTIONAL REVIEW BOARD

CONTINUING REVIEW APPLICATION FORM

1. STUDY INFORMATION

IRB #:

Study Title:

2. CONTACT INFORMATION

Principal Investigator:

Sub-Investigator(s):

Study Contact:

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

☐ Active (recruitment and/or enrollment of new participants or review of records/specimen continue).

☐ Closed to enrollment but participants are still engaged in research activities.

☐ Closed to enrollment but study remains active for long term follow-up.

☐ Study enrollment permanently closed, participants have completed all research activities and long term follow-up has been completed. The remaining research activities are limited only to data analysis that may require contact with records or specimens.

☐ Completed (please forward final study report, any progress report, multi-center trial reports, and publications as available.

☐ No participants (DCH) have been enrolled to date.

☐ Never Initiated/ Terminated (please provide reasons). Sign last page and submit.

_____

_____

4. STUDY INFORMATION

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

Drug Name ___ IND #: ____

Does the study involve the use of investigational device? ☐ Yes ☐ No ☐ N/A If yes,

Device Name ___ IDE #: ____

5. STUDY PROGRESS SUMMARY

How many participants/charts (local site) were enrolled/reviewed since this study was initiated? ___

How many participants/charts (local site) were enrolled/reviewed since the last continuing review? ___

How many participants withdrawn? (if not applicable, mark N/A) ___

Please provide detailed information. Use a separate sheet of paper if needed.

Did any participants studied at local site experience any adverse events, unanticipated problems during this reporting period? ☐ Yes ☐ No ☐ N/A (Non therapeutic study)
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
If yes, attach a brief description summarizing the complaints.

Since the most recent IRB approval have there been relevant literature, abstracts, and/or publications? ☐ Yes ☐ No If yes, 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 If yes, attach copies and brief description. If a CIRB facilitated study attach CIRB approval letters and related correspondence.

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 If yes, 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 If yes, attach report.

Have there been any changes to the study (amendments or modifications)? ☐ Yes ☐ No If yes, 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 If yes, complete request form to add or remove investigator and/or study staff.

Did the IRB require the use of written informed consent document, written assent for this study? ☐ Yes ☐ No If yes and the study are continuing to enroll participants, submit a copy of the currently approved informed consent, a clean copy of an identical consent and electronic copy for expiration date assignment.

Are copies of the informed consents being appropriately filed? ☐ Yes ☐ No ☐ N/A

Record Retention: All study related documents are to be retained for three (3) years after termination of research study/clinical investigation (or longer as justified in the study). These records shall be accessible for inspection and copying by the DCH IRB and/or regulatory agencies involved in overseeing research.

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

Has the research site or records been audited? ☐Yes ☐ No

If yes, 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 ☐ N/A

If No, 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

In addition to the above responses, I understand I cannot initiate any changes in my approved protocol before I received IRB approval and/or complied with the contingencies/stipulations with regards to that approval. By signing this form, I also certify that all relevant information concerning 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