**\* Note: Annual (Interval) Renewal Forms must be submitted as required in the REB Approval Notice. This form must be submitted 30 days prior to the REB approval expiry date. Refer to Policy REB-405 for more information.**

|  |
| --- |
| **General Information:** |
| Holland Bloorview REB#: |
| Project Title: |
| Local Principal Investigator (LPI): |
| Type of Study:  FDA Regulated  Clinical Trial  Database  Other |
| Today’s Date: |
| Study Approval Expiry Date: |
| Projected Date of Study Completion: |

# *Study Status*

(Check all that apply)

Not started Reason:

On hold Reason:

Premature termination of the study by investigator or sponsor

Date of termination:

Please describe the reason(s) for premature termination:

Number of participants enrolled from Holland Bloorview:

Please describe how the participants were notified:

Actively enrolling participants

Actively collecting data through health records or research repositories

Actively collecting biological samples

Participant enrolment closed, but follow-up with participant(s) continues

Participant enrolment closed and no further contact with participant(s) planned.

Data analysis continues

Manuscript/publication/dissemination of knowledge in progress

***Participant Status:***

|  |  |
| --- | --- |
| No enrollment to date. *Reason*: | |
| Target number of participant charts or biological samples approved by the Holland Bloorview REB to be reviewed: |  |
| Number of participant charts reviewed or biological samples utilized: |  |
|  |  |
| Target number of participants approved at this site by the Holland Bloorview REB: |  |
| Number of participants consented at Holland Bloorview: |  |
| Number of participants who dropped out/were withdrawn at Holland Bloorview**:** |  |
| Number of participants currently receiving study intervention, participating in data collection, or being followed at Holland Bloorview: |  |
|  |  |
| Target number of participants approved at all other sites by the Holland Bloorview REB**:** |  |
| Total number of participants consented at all other sites: |  |
| Total number of participants who dropped out/were withdrawn at all other sites**:** |  |
| Number of participants currently receiving study intervention, participating in data collection, or being followed at other sites**:** |  |

# *Study Summary*

1. Protocol version date:
2. Summary of Consent Documents

Please list **all** Information Letter and Consent/Assent Form(s) **currently** in use. N/A

|  |  |
| --- | --- |
| Name of Document | Version Date (dd-mmm-yyyy) |
|  |  |
|  |  |
|  |  |

1. Is there any new information in the literature or as a result of other ongoing studies that would change the rationale, procedures, study design, vulnerability of participants, or risks/benefit ratio for this study?

Yes  No

If yes, please describe:

1. Is there any new information that could affect the willingness of people to participate or continue to participate in the study?

Yes  No

If yes, please describe:

1. Have participants or others raised any ethical concerns about the research study?

Yes  No

If yes, please describe:

1. Have any difficulties occurred during the conduct of the study since it was initially approved including study design, recruitment or data management?

Yes  No

If yes, please describe:

1. If any participants dropped out and/or were withdrawn from the study **SINCE LAST RENEWAL**, please provide details below. N/A

|  |  |  |
| --- | --- | --- |
| Date of Drop-out/Withdrawal | Reason for Drop-out/Withdrawal | Action taken to mitigate risk of harm (physical, psychological, economic or social) of participants or others (if relevant) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. Provide a summary and update on the status of all local unanticipated problems **SINCE LAST RENEWAL**. N/A

|  |  |  |  |
| --- | --- | --- | --- |
| Date of Onset | Description of Unanticipated Problem | Date reported to REB | Describe the current status of participant outcome resulting from the response or action. |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. Provide a summary of all amendment requests submitted **SINCE LAST RENEWAL**.

N/A

|  |  |  |
| --- | --- | --- |
| Date submitted to REB | Summary of Amendment Areas | Date Approved by REB |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. Have there been any secondary protocol deviations **SINCE LAST RENEWAL**?

(**Please refer to Policy REB-406 for more information**)

Yes  No

If yes, please attach Annual Secondary Protocol Deviation Log. Attached

1. Have there been any changes to the investigators’ affiliations or qualifications since the last REB approval?

Yes  No

If yes, please describe:

1. Describe any changes to previously disclosed or new conflicts of interest **since the initial REB approval**.

Yes  No

If yes, please describe:

1. Have there been any funding agency changes? Yes  No

If yes, please describe:

1. (*For regulated clinical trials*) Attach a copy of your most recent Information Letter and Consent Form and Assent Form to this Annual (Interval) Renewal. Attached  N/A

***Local Principal Investigator Statement***

As Local Principal Investigator, I will continue to assume responsibility for the scientific and ethical conduct of this study. I agree to conduct this study in compliance with the 2nd Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and, where required, in accordance with Health Canada regulations, Good Clinical Practices, and regulations in other jurisdictions.

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Signature Date

**For REB Use Only**

Annual (Interval) Renewal approved as submitted.

Study suspended pending further review.

Rationale:

Annual (Interval) Renewal denied:

Rationale:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of REB Chair (or Designate)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date