

### Received Date

REB Use Only

**Research Ethics Board**

**Annual Review / Termination Form**

**Please submit the signed and scanned application form and accompanying documents to** **reb@hrh.ca****. In the email subject line, please include the REB number and the type of submission.**

|  |  |
| --- | --- |
| **Principal Investigator (HRH):**       | **HRH REB Number:**        |
| **Expiry Date of REB Approval:**       (DD/MMM/YYYY) | **Funding Source:** [ ]  Current[ ]  Revised, if revised, please provide new funding source information:       |
| **Study Title:**       |
| **Annual Review or Termination requested:**   | [ ]  Annual Review [ ]  Termination |
| **Review type requested:** [ ]  Delegated [ ]  Full Board If Full Board is requested, please explain:              **Please note that studies funded by the US Federal Government or regulated by the US Food and Drug Administration must be reviewed by the Full Board, with some exceptions. Please see the REB ‘Guidelines on Annual Renewals’ for further information.** |
| **Name Of Person Completing Form:**       | **Contact Email &Telephone #:**       |

**STUDY ENROLLMENT STATUS**

Complete one or both of the following sections as applicable to your study. Only one status should be selected. For study closures, please fill out the form in as much detail as you would for an Annual Review. Original signatures are required for all Annual Review/Study Termination submissions.

**For Retrospective Studies:** [ ] N/A

**Please specify the current status of the study:**

|  |  |
| --- | --- |
| **[ ]  NOT STARTED AT *HRH***  | Reason:        |
| **[ ]  ONGOING AT *HRH*** | Projected Date of Enrollment Completion:       (DD/MMM/YYYY) |
| **[ ]  DATA/SAMPLE COLLECTION COMPLETE BUT STUDY IS STILL ONGOING:**  (Check all that applies below) [ ]  Data analysis ongoing [ ]  Manuscript in preparation  |
| **[ ]  STUDY COMPLETED** (i.e., no further data collection, clarification & transfer outside of HRH) |
| Date Closed:       (DD/MMM/YYYY) |
| <<< **Attach a copy of a final report, if available** >>> |

**Complete the following for HRH participants only:**

|  |  |
| --- | --- |
|        | Number of charts reviewed to determine eligibility  |
|       | Number of participants included in retrospective chart review study |
|       | Number of tissue samples utilized during the study |

**For Prospective Studies:** [ ] N/A

**Please specify the current status of the study:**

|  |  |
| --- | --- |
| **[ ]  NOT STARTED AT *HRH***  | Reason:        |
| **[ ]  ENROLLING PARTICIPANTS AT *HRH*** | Projected Date of Enrollment Completion:       (DD/MMM/YYYY) |
| For multicentre studies, have any participants been enrolled at other centres?       |
| **[ ]  ENROLLMENT COMPLETE BUT STUDY IS STILL ONGOING:**  (Check all that applies below) [ ]  Participants Receiving Study intervention [ ]  Post-Intervention Follow-Up of Participants (i.e., follow-up visits, data collection only)  [ ]  Intervention & Follow-Up Complete for All HRH Participants - Data Clarification and/or Data Transfer Outside of HRH (i.e., sponsors or coordinating centres) |
| Enrolment Termination Date:       (DD/MMM/YYYY) | Duration of Follow-Up Period:       |
| **[ ]  PREMATURE TERMINATION OF THE STUDY BY INVESTIGATOR OR SPONSOR** |
| Termination Date:       (DD/MMM/YYYY) |
| Reason for Termination:       |
| **[ ]  STUDY COMPLETED** (i.e., no further patient involvement/data collection, clarification or transfer outside of HRH) |
| Date Closed:       (DD/MMM/YYYY) |
| <<< **Attach a copy of a final report, if available** >>> |

**Complete the following for HRH participants only:**

|  |  |
| --- | --- |
|        | Total number of participants approved by the HRH REB to be enrolled |
|       | Number of charts reviewed for recruitment purposes to determine eligibility |
|       | Number of participants consented  |
|  | Note: Each participant should be entered below only once so that the sum of the numbers below should be equal to the number of participants consented. |
|  |       | Number of participants consented but did not meet inclusion criteria |
|  |       | Number of participants consented but have not yet started the study procedures |
|  |       | Number of participants who have withdrawn their consent from participation |
|  |       | Number of participants receiving study intervention (e.g. study drug, questionnaires, tests, or procedures done for study purposes) |
|  |       | Number of participants in post-intervention follow-up  |
|  |       | Number of participants that have completed the study (including completed follow up and/or withdrawn by PI) and no further contact for study purposes is planned |
|       | Number of tissue samples utilized during the study |

## STUDY SUMMARY

1. Has the REB approval lapsed?

[ ]  No (skip to question #2)

[ ]  Yes

If Yes, provide the reason for the lapse and describe all actions taken to prevent a lapse from occurring in the future.

 Was there a need to continue research activity or treatment or current study participants f or their safety and well-being? [ ]  No. [ ]  Yes

If Yes, describe what study activities or treatments occurred with a clear explanation as to why it was necessary to continue treatment during the lapse in approval.

1. Please provide a brief summary of the progress of the study to date (i.e., recruitment issues, preliminary findings, site staff changes)

1. Is there any new information in the literature or from other recent studies that would change the rationale or risk/benefit ratio for this study (e.g., changes in standard of care, new information about side effects, approval of another drug for this indication, etc)?

[ ]  No

[ ]  Yes

 Describe:

1. Have any patients been withdrawn from the study prematurely or withdrawn consent?

[ ]  No

[ ]  Yes

 Describe:

1. Have there been any participant complaints or feedback about the research? If yes, please describe.

[ ]  No

[ ]  Yes

 Describe:

1. Briefly, summarize all serious adverse events (SAEs) that have occurred at HRH only since the last approval, action taken in response to the SAEs, and any resulting changes in procedures to detect such SAEs.

1. Has there been a change in the frequency and/or severity of adverse events that would result in a change to the protocol or consent form?

[ ]  No

[ ]  Yes

 If an amendment has not been submitted, please complete and attach an Amendment Form.

1. If applicable, has there been any report from the data safety monitoring committee? Please include the most recent report.

[ ]  No DSMB

 [ ]  No

[ ]  Yes

 If not yet submitted, please include the most recent report(s).

1. Has the study now changed to include collection or banking of tissue or other specimens (i.e., fetal tissue, placenta, blood, other body fluids)?

 [ ]  No

[ ]  Yes

 If an amendment has not been submitted, please complete and attach an Amendment Form.

1. Since the last renewal, has there been any change in the Conflict of Interest information provided to the REB for investigators involved in this study? (Potential Conflicts of Interest can include functioning as an employee or consultant to the study sponsor, direct or indirect financial interest in the drug/device or technology involved in the study or receiving honorarium or other benefits from the sponsor.)

 [ ]  No

[ ]  Yes

 Describe:

1. Is the contact information on the Consent Form current?

 [ ]  Yes, Current Consent Form(s) Attached

 [ ]  No, Revised Consent Form(s) Attached

 [ ]  N/A, No Consent Form(s) Approved For This Study

1. Will participants be provided with a lay summary of study results?

[ ]  Yes, **must be submitted to the REB as an Amendment for review and approval prior to implementation.**

[ ]  No, please explain

1. Please provide a contact name, address, telephone number and e-mail address of the individual to whom we should send study correspondence.

**PRINCIPAL INVESTIGATOR'S SIGNATURE**

I confirm that I have reviewed any adverse events, if applicable, in a timely fashion during the course of the study and these have been reported to the REB. All revisions to the study protocol and consent form have been submitted. I am not aware of any new information that may affect the continuation of the study or require change in the study protocol.

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**Print Name Signature Date (DD/MMM/YYYY)**

**Reminders:**

**Attach a copy of the consent form(s) currently being used and retain a copy of the signed form for your records.**

**All changes to the study protocol, consent form(s) and all other study related documents must be submitted for REB review and approval prior to implementation.**