# REB#

REB Use Only



## **Baycrest Research Ethics Board**

### Annual Review and/or Termination Form

**PLEASE ATTACH A COPY OF THE CURRENT INFORMATION-CONSENT FORM(S)**

Annual Renewal and/or Termination Form will not be accepted without copy(ies) of informed consent form(s)

(if applicable)

|  |  |
| --- | --- |
| Principal Investigator: | Department/Division: |
| REB number: | Expiry date of REB approval: / /  (DD/MM/YYYY)  |
| Study title: |
| **STATUS** |
| **ENROLLMENT** |
| [ ]  No enrollment to date Reason for no enrollment: |
| [ ]  Enrolling participants |
| [ ]  Enrollment complete but study is ongoing (check all boxes that apply 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 Baycrest participants – data clarification and/or data transfer ongoing (i.e., sponsors or coordinating centers) |
|  |
| [ ]  Premature termination of the study by investigator or sponsor Reason for premature termination: |
| Termination date: / /  (DD/MM/YYYY) | Total enrolled at Baycrest: |
|  |
| [ ]  Study completed (i.e., no further participant involvement/data collection, clarification & transfer) |
| Date closed: / /  (DD/MM/YYYY) | Total enrolled at Baycrest: |
| Attach a copy of a final report, if available |

|  |
| --- |
| SUMMARY OF Participants at all sitesYou must fill in all the boxes to the left with a number, "0" or "N/A" |
|  | Number of participants planned |
|  | Number of participants consented |
|  | Number of participants consented but did not meet inclusion criteria |
|  | Number of participants prematurely withdrawn from study |
|  | Number of participants receiving study intervention |
|  | Number of participants in post-intervention follow-up |
|  | Number of participants that have completed follow-up |
|  | Number of participants included in retrospective review (for chart review studies only) |
|  | Number of individuals that declined to open science sharing of their data / Number of participants that were asked (e.g. 1/10) |

###### STUDY SUMMARY

1. Please provide a brief summary of the progress of the study to date (i.e., recruitment issues, preliminary findings).
2. 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 is standard or care, new information about side effects, approval of another drug for this indication, etc.)?
3. If any participants have been withdrawn from the study prematurely or withdrawn consent provide the reasons for withdrawal.
4. Have there been any participant complaints or feedback about the research? If yes, please describe.
5. 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).
6. Has the study now changed to include collection or banking of tissue or other specimens (i.e., fetal tissue, placenta, blood, and other body fluids)?
7. Is the contact information on the consent form current?
8. Please provide current PI and study coordinator address, telephone and fax numbers, and email addresses.

If all the information is the same since the last time (original application or a previous annual review-termination report), check the box below. If any of the information has changed, please provide the details.

[ ]  PI and study coordinator address, telephone & fax numbers and email addresses have not changed.

1. a) Briefly, summarize all internal serious adverse events (SAEs)[[1]](#footnote-1) since the last approval, the action taken in response to the SAEs, and any resulting changes in procedures to detect such SAEs.

[ ]  N/A

b) In the opinion of the Principal Investigator, is there a trend in the internal SAEs? If so, identify.

c) Have there been any deaths related to, or not to study intervention?

1. Have participants been provided with interim or final plain language of the summary of results? If so, please provide details.
	1. If no, please specify if there is a plan to provide participants with the result summaries.

CLINICAL TRIALS ONLY

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

[ ]   **Current consent form(s) attached** [ ]   **No consent form(s) for this study**

**This must be the last approved consent form.**

**If you have made changes to the informed consent form since its last REB approval, you must submit a separate Amendment request for the changes, which must be highlighted (bold, underline or track-it) on the form. The Request for Amendment form must be used.**

[ ]  **Terminate REB file**

[ ]  **Keep REB file open**

INVESTIGATOR’S SIGNATURE

I confirm that I have reviewed any adverse events, if applicable, in a timely fashion during the course of 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.

Investigator

 Print Name Signature Date

 (DD/MM/YYYY)

**REMINDER:**

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

1. ) **Serious Adverse Events (SAEs)**

These events include any of the following:

	* 1. Any hospital admission (unless hospitalization is pre-planned)
		2. Unanticipated or life-threatening drug reaction including but not limited to one that necessitates discontinuation of study participation or that results in death
		3. Congenital anomaly occurring in the offspring of a research participant who had taken a study drug
		4. Events or medical occurrences exceeding the nature, severity, or frequency described in the investigator’s brochure or protocol
		5. Events or medical occurrences that prolong a stay in a health care facility
		6. Significant, persistent, or permanent harm or disability, either physical or psychological
		7. Death [↑](#footnote-ref-1)