

**AMENDMENTS, NOTIFICATIONS, ONGOING**

**COMMUNICATION FORM**

**INSTRUCTIONS**

* This form is required for the submission of all amendments, notifications, and ongoing communication related to research (interventional or observational) that has received prior approval from the Royal Victoria Regional Health Centre (RVH) Research Ethics Board (REB).
* Applicants are responsible for ensuring that all documents requiring RVH REB approval accompany this form.
* All changes to study documents must be submitted using track changes to clearly demonstrate revisions made to previously approved documents.

**SUBMISSION PROCEDURE**

* Please submit three (3) paper copies and one (1) scanned or electronic copy of this form accompanied by any supporting documentation to the address below. Do not staple any sections of your submission; use paperclips to keep copies together.

RVH Research Ethics Board

Centre for Education & Research, Room 3357

Royal Victoria Regional Health Centre

201 Georgian Drive, Barrie, ON

L4M 6M2

Email: [ethics@rvh.on.ca](mailto:ethics@rvh.on.ca)

Phone: 705-728-9090 Ext. 43318

**SECTION A: STUDY INFORMATION**

**REB STUDY NUMBER: (Internal Use Only) only)**

|  |  |  |
| --- | --- | --- |
| Full Study Title: Click here. | | |
| Abbreviated Study Title (max. 10 words):  Click here. | Study Sponsor:  Click here. | Protocol #  Click here. |
| Principal Investigator Name: Click here. | Clinical Trial  Observational Trial  Chart Review  Other: Click here. | |
| RVH REB Study #: Click here. | Start Date: Click to enter a date. | |
| Anticipated Local Enrollment: Click here. | Anticipated End Date: Click to enter a date. | |
| Name of Primary Contact: Click here. | Primary Contact Email: Click here. | |

**SECTION B: AMENDMENT, NOTIFICATION, OR COMMUNCIATION DETAILS**

1. Select the reason for this submission (e.g., administrative change, change in study plan, revised safety information, sponsor update, change in privacy, new relationship/conflict declaration etc.).

Administrative Change

DSMB/C Report

Interim Analysis Results

Safety Notice or Update

Other (specify): Click here to enter text.

1. Has a sponsor or collaborator provided you with a summary of proposed changes?  Yes  No

If “Yes”, please attach the summary of proposed changes with this form

If “No”, please provide more information about the proposed changes directly below

|  |
| --- |
| Click here to enter text. |

1. Provide an update on the status of enrollment/participation (e.g., open, closed, or on hold to enrollment, number of participants enrolled, number of participants on study drug/treatment etc.)

|  |
| --- |
| Click here to enter text. |

1. Describe the changes to the risk profile for participants (max. 200 words):  Not applicable

|  |
| --- |
| Click here to enter text. |

1. Will any new and/or updated study information be communicated to current and/or past study participants?

Yes  No

If “Yes”, please describe how study participants will be notified (max. 200 words):

|  |
| --- |
| Click here to enter text. |

If “No”, please explain why study participants do not need to be contacted (max. 200 words):

|  |
| --- |
| Click here to enter text. |

**SECTION C: SUPPORTING DOCUMENTATION**

* Please identify and assign a ***new*** version number and/or date to ***all*** documents that have been impacted by the amendment in the table below
* Provide “clean” and “tracked changes” copies of the following documents with this form

|  |  |
| --- | --- |
| Document Type  Provide “clean” and “tracked changes” copies | New Version# / Date |
| Summary of Proposed Changes (required) | Click here to enter text. |
| Amended Study Protocol (required) | Click here to enter text. |
| Amended Research Impact Form  (required when the amendment significantly alters the role of departments already participating in the study or impacts new departments) | Click here to enter text. |
| Consent Forms | |
| Participant | Click here to enter text. |
| Parent/Guardian | Click here to enter text. |
| Assent | Click here to enter text. |
| Other | Click here to enter text. |
| Clinical Trial Documents | |
| Investigator’s Brochure | Click here to enter text. |
| Product Monograph | Click here to enter text. |
| Health Canada No Objection Letter (NOL) or other regulatory authorization | Date: Click or tap to enter a date.  Control Number: Click here to enter text. |
| Data Safety Monitoring Board/Committee Report | Click here to enter text. |
| General Documents | |
| Relevant ethics certification(s) (e.g., TCPS 2 CORE, CITI GCP) for new study personnel | Click here to enter text. |
| Signed and dated Curriculum Vitae for new study personnel | Click here to enter text. |
| REB correspondence(s) | Click here to enter text. |
| Advertisement(s) | Click here to enter text. |
| Telephone script(s) | Click here to enter text. |
| Email template(s) | Click here to enter text. |
| Interview guide(s) | Click here to enter text. |
| Questionnaire(s) | Click here to enter text. |
| Case Report Form(s) | Click here to enter text. |
| Pamphlet(s)/Brochure(s) | Click here to enter text. |
| Participant Materials | |
| Journal/Diary/Memoir | Click here to enter text. |
| Wallet Card | Click here to enter text. |
| Information Sheet | Click here to enter text. |
| Other (specify): Click here to enter text. | Click here to enter text. |
| Other documents (please specify; add additional as needed): | |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |

1. Contact information of individual submitting this form:

|  |  |  |
| --- | --- | --- |
| First: Click here. | Last: Click here. | Degree(s): Click here. |
| Institution: Click here. | Program: Click here. | Department: Click here. |
| Street Address: Click here. | Room/Suite #: Click here. | City: Click here. |
| Province: Click here. | Postal Code: Click here. | Email: Click here. |
| Telephone: Click here. | Fax: Click here. | RVH Affiliated?  Yes  No |

**SECTION D: INVESTIGATOR SIGNATURE**

* I understand the ethical and safety implications of this submission and its impact on the study procedures
* I understand that the attached document(s) must undergo REB review and approval prior to implementation, except where necessary to ensure the ongoing safety of study participants

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| --- | --- | --- |
|  |  |  |
| Principal Investigator | Signature | Date |