**AMENDMENTS, NOTIFICATIONS, ONGOING**

**COMMUNICATION FORM**

**INSTRUCTIONS**

* This form is required for the submission of all amendments, notifications, and ongoing communication related to research that has received prior approval from the Southlake Regional Health Centre (SRHC) Research Ethics Board (REB).
* Applicants are responsible for ensuring that all documents requiring SRHC 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 this form and all supporting documentation to REBSubmissions@southlake.ca

**SECTION A: STUDY INFORMATION**

|  |
| --- |
| Full Study Title: Click here.  |
| Abbreviated Study Title (max. 10 words): Click here. | Study Sponsor:Click here.  | Protocol # Click here. |
| Principal/Qualified Investigator Name: Click here. | [ ]  Regulated Clinical Trial (e.g. Health Canada, FDA) [ ]  Minimal Risk Research |
| SRHC Project#: Click here.  | Date of initial SRHC REB approval:Click to enter a date. |
| Name of Primary Contact: Click here.  | Primary Contact Email: Click here.  |

**SECTION B: AMENDMENT DETAILS**

1. Describe the reason for this submission (e.g., administrative change, change in study plan (Protocol), revised safety information, revised or new study documents, etc.).

|  |
| --- |
| 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:

[ ]  Observational study with data collection ongoing

[ ]  No participants enrolled to date

[ ]  Open to enrollment, participants have been enrolled but none are currently receiving study treatment/intervention

[ ]  Open to enrollment with one or more study participant(s) receiving study treatment/intervention

[ ]  Open to enrollment with current participants in follow up only

[ ]  Permanently closed to enrollment, one or more study participant(s) receiving treatment/intervention

[ ]  Permanently closed to enrollment, no participants are receiving treatment/intervention, and all study participants are in long-term follow up or data collection continues

[ ]  Study completed (i.e., no further involvement of study participants and no further data collection)

[ ]  Prematurely terminated

[ ]  Is the enrollment of new participants on hold or temporarily suspended [ ]  Yes [ ]  No

If yes, please explain:

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

[ ]  Other – Specify:

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

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

[ ]  Yes [ ]  No [ ]  N/A

If “No”, please explain why:

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

If “Yes”, please describe the proposed communication method to: (max. 200 words):

1. participants who are currently enrolled in the study and receiving study treatment or intervention

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

1. participants who are currently being followed for the purposes of the study but are no longer receiving study treatment or intervention

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

1. participants who are no longer being followed for the purposes of the study

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

**SECTION C: DOCUMENTS LIST**

* 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 all revised participant materials (e.g. consent forms)

|  |  |
| --- | --- |
| Document Type | New Version# / Date |
| [ ]  Summary of Proposed Changes | Click here to enter text. |
| [ ]  Amended Study Protocol | Click here to enter text. |
| Consent Forms  |
| [ ]   | 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. |
| [ ]   | Click here to enter text. |
| [ ]   | Click here to enter text. |
| Clinical Trial Documents |
| [ ]  Investigator’s Brochure | Click here to enter text. |
| [ ]  Product Monograph | Click here to enter text. |
| [ ]  Data Safety Monitoring Board/Committee Report | Click here to enter text. |
| Additional Documents |
| [ ]  REB correspondence(s) | Click here to enter text. |
| [ ]  Sponsor 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. |
| [ ]  Pamphlet(s)/Brochure(s) | Click here to enter text. |
| [ ]  Journal/Diary | 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 (specify): Click here to enter text. | Click here to enter text. |
| [ ]  Other (specify): Click here to enter text. | Click here to enter text. |
| New Study Personnel |
| [ ]  Change of Principal/Qualified Investigator | Name: Click here to enter text. |
| [ ]  Change of Co-Investigator | Name: Click here to enter text. |
| [ ]  Other (specify): Click here to enter text. | Name: Click here to enter text. |
| [ ]  Other (specify): Click here to enter text. | Name: Click here to enter text. |
| [ ]  Other (specify): Click here to enter text. | Name: Click here to enter text. |

Contact information of individual submitting this form:

|  |  |
| --- | --- |
| First and last name: Click here. | Institution: Click here. |
| Telephone: Click here. | Email: Click here. |

**SECTION D: INVESTIGATOR STATEMENT & 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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| --- | --- | --- |
|  |  |  |
| Site Principal / Qualified Investigator | Signature | Date |