**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](mailto:REBSubmissions@southlake.ca)

**SECTION 1.0: GENERAL INFORMATION**

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

**SECTION 2.0: 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.).
2. Type of review requested:  Full Board  Delegated
3. 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

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:

Other – Specify:

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:

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

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

**SECTION 3.0: 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 / Description | New Version# / Date |
| Summary of Proposed Changes |  |
| Amended Study Protocol |  |
| **Consent Forms** | |
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| **Clinical Trial Documents** | |
| Investigator’s Brochure |  |
| Product Monograph |  |
| Data Safety Monitoring Board/Committee Report |  |
| **Additional Documents** | |
| REB correspondence(s) |  |
| Sponsor correspondence(s) |  |
| Advertisement(s) |  |
| Telephone script(s) |  |
| Email template(s) |  |
| Interview guide(s) |  |
| Questionnaire(s) |  |
| Pamphlet(s)/Brochure(s) |  |
| Journal/Diary |  |
| Wallet Card |  |
| Information Sheet |  |
| Other (specify): |  |
| Other (specify): |  |
| Other (specify): |  |
| **New Study Personnel** | |
| Change of Principal/Qualified Investigator | Name: |
| Change of Co-Investigator | Name: |
| Other (specify): | Name: |
| Other (specify): | Name: |
| Other (specify): | Name: |

Person completing this form:

|  |  |
| --- | --- |
| First and last name: | Institution: |
| Telephone: | Email: |

**SECTION 4.0: INVESTIGATOR STATEMENT & SIGNATURE**

1. I confirm that the above information is accurate
2. I understand the ethical and safety implications of this submission and its impact on the study procedures
3. 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
4. I assume full responsibility of for the scientific and ethical conduct of this study and agree to conduct this study in compliance with Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, The Ontario Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A, and any other relevant guidelines and regulations
5. Following the initial submission of this application form, a member of the research team may submit edits to this application on my behalf**\***. I acknowledge that I remain ultimately responsible for REB submissions and the overall conduct of the study in accordance with the currently approved documents. I attest that, should a designate sign on my behalf, the responsibility for corresponding with the REB has been appropriately delegated, and the delegation has been documented.
6. I certify that all study team members are appropriately qualified and trained to fulfill their role in this study

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| Site Principal / Qualified Investigator | Signature | Date |

**\***Delegate is authorized to sign below ONLY when submitting edits on behalf of the Site Principal/Qualified Investigator, as per #4.5 above

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Study Research Team Delegate | Signature | Date |