SRHC Research Ethics Board (REB)

**ANNUAL RENEWAL FORM**

**INSTRUCTIONS**

* The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and the principles of Good Clinical Practices, as described by the International Conference on Harmonization, require REB review of ongoing studies; this is achieved by the completion of this Annual Renewal Form
* **All sections** of this form **MUST** be completed before it will be considered for REB review. Incomplete submissions will be returned to the Principal Investigator and/or Study Coordinator for completion

**SUBMISSION PROCEDURE**

* Please submit the completed renewal application to REBSubmissions@southlake.ca

**SECTION 1.0: GENERAL INFORMATION**

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| 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: STUDY STATUS**

Please complete the following sections, as applicable:

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| **For Retrospective Medical Chart Review Studies ONLY**:*(complete this section and continue to section C)* |
| What was the planned enrollment target? |       |
| How many participants have been enrolled at your site? |       |
| Has any new personal health information been collected prospectively from study participants’ medical records (i.e. information did not exist at the time of the initial REB approval of the study)? | [ ]  Yes [ ]  No |
| What is the current study status? | [ ]  Data collection ongoing [ ]  Data collection complete, analyzing data only  |

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| **For All Other Studies:** |
| 1. **What is the current study status at your site?**

[ ]  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 enrolment, one or more study participant(s) receiving treatment/intervention [ ]  Permanently closed to enrolment, 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, data analysis only) [ ]  Prematurely terminated [ ]  Is the enrollment of new participants on hold or temporarily suspended [ ]  Yes [ ]  NoIf yes, please explain:      [ ]  Other – Specify       |
| 1. **Overall Conduct of the Study to Date**
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| How many participants were planned to be enrolled at this site?  |       |
| How many participants have been consented in the study at this site to date? *Note: Answer should equal the total of remaining questions in subsection b)* |       |
| How many participants failed screening tests/procedures? |       |
| How many are currently receiving study treatment/intervention? |       |
| How many are currently in the post-intervention period (follow up)? |       |
| How many have completed the study with no further planned contact for study purposes? |       |
| How many participants were lost to follow up? |       |
| How many participants deceased? |       |
| How many have withdrawn consent?Please provide details for each participant:       |       |
| How many participants been taken off the study prematurely (for example, by a local investigator or lead group/sponsor)? |       |
| 1. **Conduct of the Study to Date for this Review Period**

(*since last REB approval)* |
| How many participants consented to take part in this study during this review period  |       |
| Have there been any participant complaints about the study during this review period? *Please provide details for each participant*: Click here to enter text. | [ ]  Yes [ ]  No |

**SECTION 3.0: ONGOING REB REPORTING**

1. Have there been any Amendments (e.g. Protocol, informed consent form(s) revisions, etc.) that the SRHC REB has not been previously notified of? [ ]  Yes [ ]  No
*If “Yes”, please submit the relevant documentation for REB review*
2. Have there been any reportable events (e.g., unanticipated problems) that the SRHC REB has not been previously notified of? [ ]  Yes [ ]  No
*If “Yes”, please explain*:
3. In the opinion of the Principal Investigator, is there a concern or a trend in the reportable events that have occurred at your site? [ ]  Yes [ ]  No [ ]  N/A

*If “Yes”, please provide details and action(s) taken*:

1. Has there been a lapse in REB approval for this study? [ ]  Yes [ ]  No

*If “Yes”, please provide the reason for the lapse and identify steps taken to prevent future lapses (max. 200 words). If applicable and there is a need to continue research-related medical treatment of current research participants for their safety and well-being, provide as much detail as possible about the proposed continued activities:*

1. Since the last SRHC REB renewal, has there been any change in the Conflicts of Interest information provided in the initial (original) SRHC REB application? [ ]  Yes [ ]  No

*If “Yes”, please explain below (max. 200 words):*

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 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
3. 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.
4. 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 #4.3 above

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