SRHC Research Ethics Board (REB)

**ANNUAL RENEWAL FORM**

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

**SECTION A: GENERAL INFORMATION**

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| Full Study Title: Click here.  |
| Abbreviated Study Title (max. 10 words): Click here. | Study Sponsor:Click here.  | Protocol/ID # 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: 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? | Click here  |
| How many participants have been enrolled at your site? | Click here  |
| 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: Click here.[ ] Other – Specify Click here. |
| 1. **Overall Conduct of the Study to Date**
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| How many participants were planned to be enrolled at this site?  | Click here |
| 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)* | Click here |
| How many participants failed screening tests/procedures? | Click here |
| How many are currently receiving study treatment/intervention? | Click here |
| How many are currently in the post-intervention period (follow up)? | Click here |
| How many have completed the study with no further planned contact for study purposes? | Click here |
| How many participants were lost to follow up? | Click here |
| How many participants deceased? | Click here |
| How many have withdrawn consent?Please provide details for each participant: Click here to enter text.  | Click here |
| How many participants been taken off the study prematurely (for example, by a local investigator or lead group/sponsor)? | Click here |
| 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  | Click here |
| 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 C: 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*:

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| Click here to enter text. |

1. 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*:

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| Click here to enter text. |

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:*

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| Click here to enter text. |

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?

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

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

Person completing this form:

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

**SECTION D: INVESTIGATOR STATEMENT & SIGNATURE**

* I confirm that the above information is accurate
* 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
* 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 |