SRHC Research Ethics Board (REB)

**STUDY CLOSURE 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 a final report for the closure/termination of research studies. This is achieved by the completion of this Study Closure Form
* This form may be used to close, terminate, or withdraw a study from further SRHC REB review. This form should be submitted when there is no further participant involvement and all data collection, clarification, and transfer is complete (including all access to the study participant’s medical record). Submission of this form indicates that these activities have ceased, the study does not require continuing ethics approval, and that the SRHC REB study file can be closed
* **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 your completed application to 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: GENERAL STUDY INFORMATION**

1. Date study completed or terminated at your site: Click or tap to enter a date.
2. Was this study completed or terminated prematurely or never opened for enrollment (select each that apply)?

[ ]  Yes, this study was never opened for enrollment

[ ]  Yes, this study was terminated prematurely

[ ]  No

If “Yes”, please provide details (max. 200 words):

1. Have all the study closeout procedures been completed at your site?

[ ]  Yes [ ]  No [ ]  N/A
2. Were there any participant complaints received by your site since the last REB study renewal date?

[ ]  Yes [ ]  No

If “Yes”, please provide details of each complaint (max. 200 words):
3. Have reports of all formal inspections or audits been submitted for REB review?

[ ]  Yes [ ]  No [ ]  N/A (none have taken place)

If “No”, please explain (max. 200 words):
4. 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 7)* |
| How many participants were enrolled at your site? |       |

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| **For All Other Studies** |
| **How many study participants at your site:** |
| 1. Were consented?

*Answer should equal the total of questions b. through g.* |       |
| 1. Failed screening tests/procedures?
 |       |
| 1. Completed the study?
 |       |
| 1. Were lost to follow-up?
 |       |
| 1. Deceased?
 |       |
| 1. Withdrew consent?
 |       |
| 1. Have been taken off the study prematurely (for example, by a local investigator or lead group/sponsor)?
 |       |
| Have there been any Amendments and/or changes to the informed consent form(s) that the SRHC REB has not been previously notified of? If “No”, please explain:       | [ ]  Yes [ ]  No |
| Have there been any reportable events (e.g., unanticipated problems) that the SRHC REB has not been previously notified of?If “No”, please explain:       | [ ]  Yes [ ]  No |
| In the opinion of the Principal/Qualified Investigator, is there a concern or trend in the reportable events that have occurred with study participants at your site?If “Yes”, please provide details and action(s) taken:       | [ ]  Yes [ ]  No[ ]  N/A |

1. Has there been any change in the Conflicts of Interest information since the initial (original) REB application or last Annual Renewal?

[ ]  Yes [ ]  No

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

1. If desired, please provide any additional information relevant to the closure of this study:

Person completing this form:

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

**SECTION 3.0: INVESTIGATOR STATEMENT & SIGNATURE**

1. I confirm that there is no further participant involvement and all data collection, clarification, and transfer is complete (including access to the study participant’s medical record)
2. I certify that the study data will be retained and disseminated according to applicable guidelines and regulations
3. I request that the SRHC REB study file be closed
4. 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.

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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 #3.4 above

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