SRHC Research Ethics Board (REB)

**REPORTABLE EVENT FORM**

* Please submit the completed form along with any related documents to REBSubmissions@southlake.ca

**REB Reporting Guidance**

1. The Researcher is responsible for submitting reportable events that meet the REB’s reporting criteria according to the local procedures;
2. Local AEs: The Researcher must report the following to the REB in a timely manner:
	* Any local adverse event that in the opinion of the Researcher meets the definition of an unanticipated problem,
	* All reports submitted to the REB must have all research participant identifiers removed (i.e., participant research number only),
	* Once a local AE is acknowledged by the REB, subsequent important follow-up reports related to the AE should be submitted when relevant information is available as an AE update(s). All initial and subsequent follow-up reports will be retained with the reportable event;
3. Non-Local (External) Adverse Events: Upon receipt of an external adverse event (EAE) or a periodic safety update or safety summary report, the Researcher must determine if it meets the REB reporting criteria:
	* Non-local adverse event reports are reportable to the REB, if in the opinion of the Researcher, it meets the definition of an unanticipated problem AND requires a change to the research and/or informed consent form and/or requires immediate notification to participants for safety reasons
4. Other Reportable Events: The Researcher is responsible for reporting to the REB other events or findings, such as:
* Any new information (e.g., sponsor’s safety notice or action letter) that would cause the sponsor to modify the Investigator’s Brochure, the research or the consent form, or would prompt other action by the REB to ensure protection of research participants,
* Any changes to the risks or potential benefits of the research, such as:
	+ - An interim analysis indicates that participants have a lower rate of response to treatment than initially expected,
		- Safety monitoring indicates that a particular side effect is more severe, or more frequent than initially expected,
		- Information is published from another research project that shows that an arm of the research is of no therapeutic value,
* A change in Health Canada or FDA safety labeling or withdrawal from marketing of a drug, device, health product, genetic therapy or biologic used in research,
* The Researcher is also responsible for submitting to the REB other types of reportable events, such as:
	+ DSMB reports,
	+ Interim analysis results,
	+ Any unanticipated problems or other events that could significantly impact the overall conduct of the research or alter the REB’s approval or favorable opinion to continue the research,
* A change to the research that was initiated without prior REB review to eliminate an apparent immediate hazard to a research participant,
* Any unanticipated problems or other events that could significantly impact the conduct of the research at the site (e.g., concerns of non-compliance)
1. Deviations to Previously Approved Research: The Researcher must report to the REB any deviations that meet the following reporting criteria:
	* Deviations that in the opinion of the Researcher jeopardize the safety of research participants, or that jeopardize the research efficacy or data integrity,
	* Any sponsor-approved waivers to the participant eligibility criteria,
	* Any change in the approved process for obtaining consent (e.g., improper translation, current ICF not implemented),
	* Any deviations that lead to an SAE,
2. Privacy Breaches: The Researcher must report to the REB any unauthorized collection, use, or disclosure of personal information (PI) including, but not limited to:
* The collection, use and disclosure of PI that is not in compliance with the jurisdictional legislation or its regulation,
* Circumstances where PI is stolen, lost or subject to unauthorized use or disclosure or where records of PI are subjected to unauthorized copying, modifications or disposal,
* In the Researcher context, any unauthorized collection, use or disclosure of PI that was not authorized under the research and approved in the plan that was submitted to the REB

The breach must be reported to the REB and to the appropriate Organizational Official as soon as the Researcher becomes aware of the breach;

1. Audit or Inspection Findings: The Researcher must report to the REB a summary of any relevant audit or inspection findings following a Health Canada inspection, an FDA or other regulatory audit, an internal QA audit or other audits at the site;
2. Research Participant Complaint: The Researcher must report to the REB, and to the organization if required by local procedures, a complaint from a participant when the participant reports concerns about their rights as a research participant or about ethical issues related to the research.

**SECTION 1.0: GENERAL INFORMATION**

|  |
| --- |
| Full Study Title:  |
| Abbreviated Study Title (max. 10 words):            | Study Sponsor:             | Protocol/ID #       |
| 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: EVENT DETAILS**

* 1. Is this application associated with or related to a previously submitted Reportable Event[ ] Yes\*[ ] No
	*\*If “Yes” enter the REB submission date of the corresponding Reportable Event* Click or tap to enter a date.
	2. Type of Event

[ ]  DSMB/C Report or Interim Analysis Results (*complete section* [*3.0*](#Section3)*)*

[ ]  Safety Notice/Update (e.g., Action Letter) (*complete section* [*4.0*](#Section4)*)*

[ ]  External (Non-Local) Serious Adverse Event (SAE) (*complete section* [*5.0*](#Section5)*)*

[ ]  Local (Internal) Serious Adverse Event (SAE) (*complete section* [*6.0*](#Section6)*)*

[ ]  Protocol Deviation/Violation (*complete section* [*7.0*](#Section7)*)*

[ ]  Privacy Breach (*complete section* [*8.0*](#Section8)*)*

[ ]  Audit/Inspection Report (*complete section* [*9.0*](#Section9)*)*

[ ]  Complaint (*complete section* *[10.0](#Section10))*

[ ]  Other (*complete section* [*11.0*](#Section11)*)*

**SECTION 3.0: DATA SAFETY and MONITORING BOARD/COMMITTEE (DSMB/C) REPORT or INTERIM ANALYSIS RESULTS**

* 1. Does the information suggest that the research puts participants at greater risk of harm than previously known or recognized?
	[ ]  Yes [ ]  No
	2. Describe the corrective action(s) taken or the proposed corrective action(s) to be taken by the lead researcher/group/sponsor and/or PIs in response to the event (select all that apply):

[ ]  No action required

[ ]  Suspend study enrollment

[ ]  Revise the study protocol

[ ]  Revise the consent form(s)

[ ]  Immediately implement changes to reduce/eliminate hazards to current participants

[ ]  Immediately notify research participants (i.e., orally) (*if this option is selected and an oral script has been provided by the sponsor, include it as part of this submission)*

[ ]  Other:

**SECTION 4.0: SAFETY NOTICE / UPDATE**

* 1. Does the information suggest that the research puts participants at greater risk of harm than previously known or recognized?
	[ ]  Yes [ ]  No
	2. Describe the corrective action(s) taken or the proposed corrective action(s) to be taken in response to the event (select all that apply):

[ ]  No action required\*
*\*If “no action required” justify:*
[ ]  Suspend study enrollment
[ ]  Revise the study protocol
[ ]  Revise the consent form(s)
[ ]  Immediately implement changes to reduce/eliminate hazards to current participants
[ ]  Immediately notify research participants (i.e., orally) *(if this option is selected and an oral script has been provided by the sponsor, include it as part of this submission)*
[ ]  Other:

**SECTION 5.0: EXTERNAL (NON-LOCAL) SERIOUS ADVERSE EVENT (SAE)**

[ENSURE THAT THE NON-LOCAL SAE MEETS REB REPORTING REQUIREMENTS as described at the beginning of this form](#ExternalSAE" \o "See Instructions on page 1)

* 1. Describe the corrective action(s) taken or the proposed corrective action(s) to be taken in response to the event (select all that apply):

[ ]  No action required\*
*\*If “no action required” justify:*      [ ]  Suspend study enrollment
[ ]  Revise study protocol
[ ]  Revise the consent form(s)
[ ]  Immediately implement changes to reduce/eliminate hazard to current participants
[ ]  Immediately notify research participants (i.e., orally) *(if this option is selected and an oral script has been provided by the sponsor, include it as part of this submission)*
[ ]  Other:

**SECTION 6.0: LOCAL (Internal) SERIOUS ADVERSE EVENT (SAE)**

*[ENSURE THAT THE LOCAL SAE MEETS REB REPORTING REQUIREMENTS as described at the beginning of this form](#LocalSAE" \o "See Instructions on page 1)*

* 1. Is the event suggesting that the research puts participants at greater risk of harm than previously known or recognized?
	[ ]  Yes\* [ ]  No
	*\*If “Yes”,* *describe:*
	2. Action taken (select all that apply):
	 [ ]  None
	 [ ]  Hospitalization (initial or prolonged)
	 [ ]  Study treatment/intervention temporarily altered
	 [ ]  Study treatment/intervention permanently altered
	 [ ]  Study treatment/intervention temporarily stopped
	 [ ]  Study treatment/intervention permanently stopped
	 [ ]  Study blind broken
	 [ ]  Other:
	3. Outcome of event
	 [ ]  Complete resolution [ ]  Ongoing/unresolved
	 [ ]  Partial recovery [ ]  Disability or impairment
	 [ ]  Death [ ]  Other:
	4. Will any additional corrective action be taken by the PI at this site:
	[ ]  Yes\* [ ]  No
	*\*If “Yes”, describe:*
	5. Is it expected that this local (internal) SAE will result in a corrective action (e.g., changes to the protocol or consent form(s))?
	[ ]  Yes\* [ ]  No [ ]  Unknown

		1. \**If “Yes”,* Which of the following types of corrective action are anticipated (select all that apply):

[ ]  Suspension of study enrollment and further investigation
[ ]  Revisions to the protocol

[ ]  Revisions to the consent forms

[ ]  Immediate notification of research participants (i.e. orally) *(if this option is selected and an oral script has been provided by the sponsor, include it as part of this submission)*
[ ]  Other:

**NOTE: Include a copy of the SAE reporting form that was submitted to the sponsor and any sponsor analysis of the event, if available: (ALL DOCUMENTS MUST BE DE-IDENTIFIED. DO NOT APPEND COPIES OF ANY MEDICAL RECORDS, NOTES, REPORTS OR ANY INDIVIDUAL IDENTIFYING INFORMATION)**

**SECTION 7.0: PROTOCOL DEVIATION / VIOLATION**

ENSURE THAT THE PROTOCOL DEVIATION/VIOLATION MEETS REB REPORTING REQUIREMENTS as described at the beginning of this form

* 1. Does the protocol deviation/violation include any of the following (select all that apply)?
		1. [ ]  Eligibility (inclusion/exclusion criteria) waiver
		*If the above option is selected, describe eligibility (inclusion/exclusion criteria) waiver:*
		2. [ ]  Increased risk or possibility of risk for the research participant(s)
		*If the above option is selected, describe increased risk or possibility of risk for the research participant(s):*
		3. [ ]  Compromises the scientific integrity (e.g., study validity or data integrity) of the study
		*If the above option is selected, describe how the deviation compromises the scientific integrity (study efficacy or data integrity) of the study:*
		4. [ ]  Other:
	2. Were study participant(s) adversely affected by the deviation/violation?
	[ ]  Yes\* [ ]  No
	*\*If “Yes”, describe:*
	3. Were study participant(s) informed of the deviation/violation?
	[ ]  Yes [ ]  No\*
	\**If “No”, explain why participant(s) were not informed:*
	4. Describe what measures have been, or will be, taken to reduce the likelihood that similar deviations will occur in the future:

**SECTION 8.0: PRIVACY BREACH**

* 1. Date of privacy breach: Click or tap to enter a date.
	2. Describe the privacy breach, including nature of information that was released:
	3. How many research participants are affected?
	4. Has the site institution’s privacy officer been notified of the breach?
		1. [ ]  Yes
		*If “Yes”, describe the privacy officer’s response and recommendations****:***
		2. [ ]  Yes, privacy officer’s response and recommendations pending
		3. [ ]  No
		*If “No”, explain why the privacy officer has not been notified:*
	5. Describe what measures have been, or will be, taken to reduce the likelihood that similar breaches will occur in the future:

**SECTION 9.0: AUDIT / INSPECTION REPORT**

* 1. Select the type of audit or inspection that was conducted:
	 [ ]  Health Canada Inspection
	 [ ]  ‘For Cause’ audit (do not include standard monitoring visits)
	 [ ]  FDA Audit
	 [ ]  Other:
	2. Are there findings that suggest that the research participants are at greater risk of harm than was previously known or recognized?
	 [ ]  Yes\*
	 [ ]  No
	 [ ]  Other:

	*\*If “Yes”, answer questions below:*

Describe the increased risk:

Describe the proposed corrective action(s) taken or to be taken in response (select all that apply):
[ ]  Suspend study enrollment at this site and investigate further
[ ]  Implement immediate changes to reduce/eliminate hazards to current participants
[ ]  Other:

**SECTION 10.0: COMPLAINTS**

*DO NOT INCLUDE ANY INDIVIDUAL IDENTIFYING INFORMATION*

* 1. Participant study ID number/code (if known):
	2. Please indicate who the complaint was made by:
	 [ ]  The study participant
	 [ ]  A family member of the study participant
	 [ ]  A friend of the study participant
	 [ ]  Member of the general public
	 [ ]  Other\*
	 \**If “Other”, provide the relationship to the study participant:*
	3. Date of complaint: Click or tap to enter a date.
	4. Please describe the nature of the complaint including to whom the complaint was made:
	5. Please describe how the complaint was handled, including who was involved in reviewing the complaint:
	6. Please describe any corrective actions taken:
	7. Is any REB follow-up with the study participant being requested?
	8. Any additional comments:

**SECTION 11.0: OTHER REPORTABLE EVENT**

*ENSURE THAT THE EVENT MEETS REB REPORTING REQUIREMENTS as described at the beginning of this form*

* 1. Type of reportable event:
	2. Date of reportable event: Click or tap to enter a date.
	3. Description of event:
	4. Describe the corrective action(s) taken or the proposed corrective action(s) to be taken in response to the event (select all that apply):

[ ]  No action required\*
*\*If “no action required” justify:*      [ ]  Suspend study enrollment
[ ]  Revise study protocol
[ ]  Revise the consent form(s)
[ ]  Immediately implement changes to reduce/eliminate hazard to current participants
[ ]  Immediately notify research participants (i.e., orally) *(if this option is selected, attach the oral script, if required)*
[ ]  Other:

**SECTION 12.0: DOCUMENTS INCLUDED WITH THIS SUBMISSION**

|  |  |
| --- | --- |
| Document Type | Version# / Date |
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**SECTION 13.0: 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 #13.3 above

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