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|  | RID No.:  |       |
|  | Contact Person:  |       |
|  | Submission Date:  |       |

**LHREB INTERNAL SERIOUS ADVERSE EVENT (SAE) REPORT FORM**

**\*\*\* Use separate Report Form for each event AND**

**Use the SAE Report Log as one continuous log for all SAEs \*\*\***

The Lakeridge Health Research Ethics Board (REB) exists to ensure that all research involving human participants conducted at LH meets the highest ethical and acceptable scientific and safety standards. These guidelines are in compliance with the requirements for continuing ethical review as set out in the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans Version 2 (TCPS),* the *International Conference on Harmonization Good Clinical Practice (ICH/GCP)*, and *Part C, Division 5 of the Food and Drug Regulations of Health Canada.*

All internal SAEs, and only those external SAEs both serious and unexpected and related to the study treatment and as such SAEs deemed by the PI to have direct implications to the current study at LH, must be reported to the REB for review and approval that the research remains scientifically and ethically sound. Refer to *Guidelines for Reporting Serious Adverse Events.* Always submit the *internal continuous SAE Report Log* with this form. **Please attach sponsor reporting form, if applicable.**

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| --- | --- |
| **Full Study Title & Protocol No.:**  |       |
| **Principal Investigator:**  |       | **Email:** |       |

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| **Sponsor:**      | **Drug/ Device/ Intervention:**      | **Is there a Data Safety Monitoring Board?** [ ]  YES [ ]  NO |
| **Date of Report:**      | **Onset Date of SAE:**      | **SAE Resolution Date:**      | *Internal SAE Participant Code*:       |
| *External SAE Participant Code:*       |
| **Type of SAE (Initial, FU1, FU2, etc.):**  |       |
| **Number of Participants Enrolled:**  |       |
| **Name or Medical Term of SAE:**  |       |
| **Participant Outcome:**[ ]  Death (*attach sponsor report form if relationship to study intervention is related*)[ ]  Hospitalization[ ]  Medical Intervention[ ]  Recovered[ ]  Other (specify):       | **Response to Event:**[ ]  None[ ]  Dose Adjusted[ ]  Discontinued from Study[ ]  Oher (specify):       | **Relationship to Study Intervention:**[ ]  Definitely/Probably Related[ ]  Possibly/Related[ ]  Unlikely/Unrelated[ ]  Study Action *Recommended\** |

|  |
| --- |
| ***\** Specify study action recommended by PI:**       |
| **Is the event listed on the Informed Consent Form**? [ ]  YES [ ]  NO |
| **Provide narrative description of the event if:**1. SAE is External, definitely/probably related
2. SAE is Internal, definitely/probably related or possibly related

      |
| **Does PI recommend changes to the:** |
| Protocol: | [ ]  YES [ ]  NO |
| Consent Form: | [ ]  YES [ ]  NO |
| Other:       |

**Principal Investigator Declaration:** I attest that I have reviewed the SAE and its safety implications, and have assessed the relationship to the study intervention of the SAE. I have submitted an *Amendment Form and/or Protocol Deviation Form as applicable*. If this SAE is related, it will be discuss with the participants who are/will be enrolled in this study.

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|       |       |       |
| Print Name | Signature of Principal Investigator  | Date |