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

**For each event use a separate report form & list each in the SAE report log for one continuous log then submit with the report forms**

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 the relationship to study intervention is related.**

|  |  |  |
| --- | --- | --- |
| **REB No.:** | **Contact Person:** | **Submission Date:** *(dd-mmm-yyyy)* |
|  |  |  |
| **Full Study Title:**  |
|  |
| **LH Principal Investigator:** | **Email:** |
|  |  |
| **Name of Sponsor:** | **Name of Drug / Device / Intervention:** |
|  |  |
| **Is there a Data Safety Monitoring Board?** | **Current Number of Participants Enrolled:** |
| [ ]  Yes [ ]  No |  |
| **Participant Study ID Number:**  | **Date Reported to REB** *(dd-mmm-yyyy)*: |
|  |  |
| **SAE Onset Date** *(dd-mmm-yyyy)*: | **SAE Resolution Date** *(dd-mmm-yyyy)*: |
|  |  |
| **Type of SAE (Initial, FU, etc.)** | **Name/Medical Term of SAE:** |
|  |  |
| **Participant Outcome:**  | **Response to Event:** | **Relationship to Study Intervention:** |
| [ ]  Death  | [ ]  None  | [ ]  Definitely / Probably Related  |
| [ ]  Hospitalization  | [ ]  Dose Adjustment  | [ ]  Possibly/ Related  |
| [ ]  Medical Intervention  | [ ]  Discontinued from Study  | [ ]  Unlikely/ Unrelated  |
| [ ]  Recovered  | [ ]  Other (specify):  | [ ]  Study *Action Recommended*\*\*  |
| [ ]  Other (specify):  |  |
| **\*\*Specify study action recommended by PI:** | **Is the event listed on the consent forms?** |
|  | [ ]  Yes [ ]  No |
| **Provide narrative description of the event if SAE is external and definitely/probably related or SAE is internal and definitely/probably related or possibly related.** |
|  |
| **Does the PI recommend changes to any of the following:** |
| Protocol: | [ ]  Yes [ ]  No |
| Consent Form: | [ ]  Yes [ ]  No |
| Other (specify): |  |

**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 discussed with the participants who are/will be enrolled in this study.

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| --- | --- | --- |
|  |  |  |
| Print Name | Signature of Principal Investigator  | Date *(dd-mmm-yyyy)* |