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|  | REB No.: |  |
|  | Contact Person: |  |

**LHREB INTERNAL SERIOUS ADVERSE EVENT (SAE) LOG**

**\*\*\* Use a separate SAE report form for each event and attach this running log to the submission \*\*\***

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.*

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| **Subject ID** | **Date Reported to REB** | **Type of SAE** (i.e., Initial, FU1, etc.) | **Onset Date of SAE** | **Name or Medical Term of SAE** | **Patient Outcome:**   1. Death 2. Hospitalization 3. Medical Intervention 4. Recovered 5. Other (specify) | **Response to Event:**   1. None 2. Dose Adjusted 3. Discontinued from the Study 4. Other (specify) | **Relationship to Study Intervention:**   1. Definitely/Probably Related 2. Possibly/ Related 3. Unlikely/Unrelated | **REB Approval Date** |
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