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

**LHREB ANNUAL RENEWAL FORM**

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.*

The intent of this form is to update the REB on the progress of the study. It is the responsibility of the PI to submit this form to the REB a month prior to the REB expiry date for review and approval before the study can continue at LH. This form notifies the REB of the status of the study to date, and any potential amendments to the protocol. If there are changes, then the *Amendment Form* must be submitted. If the study is closed (i.e., completed as scheduled or prematurely terminated) the *Study Closure Form* must be submitted*.*

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| **Full Study Title & Protocol No.:**  |       |
| **LH Principal Investigator:**  |       | **Email:** |       |
| **Version Code & Date of Current Protocol:**  | **Version Code & Date of Current Informed Consent Form(s):** |
|       |       |

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| **Date of Initial REB Approval**:      | **Start Date of Study**:      | **End Date of Study**: *(estimate if enrolling)*      |
| **Expiry Date of REB Approval**:      | **Is this study closed to accrual?** [ ]  YES [ ]  NO *(when study is completed, submit the study closure form)* |

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| **Please specify the nature of the study. Check all that apply:** |
| [ ]  | Interventional | [ ]  | Case Study | [ ]  | Chart Review |
| [ ]  | Prospective | [ ]  | Educational | [ ]  | Human Tissue and Biological Specimens |
| [ ]  | Clinical Trial | [ ]  | Observational | [ ]  | Epidemiological |
| [ ]  | Qualitative | [ ]  | Retrospective | [ ]  | Quality Improvement/ Program Evaluation |
| [ ]  | Other (specify): |       |

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| 1. | **Please provide a lay summary of the study:**      |

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| 2. | **In less than 200 words, please provide a brief summary of the study activity, progress or any interim findings over the past 12 months** (i.e., data is being analyzed, change in sponsor, recruitment is slower than expected globally)?      |

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| 3. | **Was there a lapse in REB Approval?** [ ] YES [ ]  NO |
| a. | If Yes, when was the last date of REB approval?       |
| b. | Were study related activities performed during lapsed timeframe (*i.e., data collection*)? [ ] YES [ ]  NO If Yes, please justify the continuation of data collection or treatment:       |
| c. | Provide the reason for the lapse and identify the steps taken to prevent future lapses:       |

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| 4. **Summary of Study Participants at Lakeridge Health to date:**  |
| 1 | Number of participants originally planned |       | N/A |
| 2 | Number of participants currently receiving study intervention/observation  |       | [ ]  |
| 3 | Number of participants in post-intervention follow-up  |       | [ ]  |
| 4 | Number of participants screen failed |       | [ ]  |
| 5 | Number of participants completed the study |       | [ ]  |
| 6 | Number of participants transferred to another site |       | [ ]  |
| 7 | Number of participants withdrew consent |       | [ ]  |
| 8 | Number of participants expired |       | [ ]  |
| 9 | Number of participants planned for chart review (retrospective/prospective) |       | [ ]  |
| 10 | Number of participants included in a chart review (retrospective/prospective) |       | [ ]  |
| 11. | Number of participants enrolled (lines 2-8 or 10 alone should equal line 11) |       |  |

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| Additional Notes/Comments:  |       |

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| 5. | **Since the last renewal, check if there have been any change(s) to any of the following:** |
| [ ]  PI / Research Team *(research team form)* |
| [ ]  Impact on LH Programs *(DIA form)* |
| [ ]  Conflict of Interest/Privacy Breach, explain:  |

|  |  |
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| 6. | **Have all reportable Serious Adverse Events (SAEs) and protocol deviations/violations experienced by Lakeridge Health participants been reported to the REB over the past 12 months?** |
| [ ]  | YES, How many SAEs  |       | and/or Protocol Deviations/Violations |       |  |
| [ ]  | NO reportable SAEs have occurred  |
| [ ]  | NO significant deviations/violations  |
| [ ]  | NO, will submit immediately. *Please provide a reason below for the delay in reporting and identify the steps taken to prevent future delays.*  |

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| 7. | **In the opinion of the PI, are there any safety concerns (local or global) or trends with the SAEs that could pose a risk to Lakeridge Health participants?** |
| [ ]  | YES, please provide details and action taken:       |
| [ ]  | NO |

**Principal Investigator Declaration:** I confirm that during the course of the study, I have reviewed and reported any adverse events and/or any revisions to the study protocol, consent form, and impact on Lakeridge Health programs to the Research Ethics Board in a timely fashion. At this time, I am not aware of any new information that may affect the continuation of the study or require changes to the protocol. I will continue to report any future amendments, adverse events, protocol deviations, and privacy breaches.

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