**LHREB AMENDMENT 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. This document is 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 (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.* Please refer to g*uidelines for submitting amendments* when completing this form. In particular, note that all amendments (including revisions, additions to or deletions from approved studies) must be submitted to the REB for review.

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| **REB No.:** | **Contact Person:** | **Submission Date:** *(dd-mmm-yyyy)* |
|  |  |  |
| **Full Study Title:**  |
|  |
| **LH Principal Investigator:** | **Email:** |
|  |  |
| **Current Study Status:** |
| [ ]  Not Yet Open [ ]  Open to Accrual [ ]  Closed to Accrual |
| **Initial REB Approval Date** (dd-mmm-yyyy): | **Current Number of Amendments:** |
|  |  |
| **Current Number of Enrolled Participants:** | **Breakdown of Enrolled Participants:** |
|  |  | Screening or receiving intervention/observation |
|  |  | In post-intervention follow-up |
|  | Completed the study  |
|  | Transferred to another site |
|  | Withdrew consent |
|  | Expired prior to completing intervention/observation |
|  | Screen-failed |

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| --- | --- | --- | --- |
| **Documents Submitted:** | **New** | **Revised** | **Description of Form** *(name, version & date)* |
| [ ]  | Protocol  | [ ]  | [ ]  |  |
| [ ]  | [ ]  |  |
| [ ]  | Consent Form | [ ]  | [ ]  |  |
| [ ]  | [ ]  |  |
| [ ]  | Participant material  | [ ]  | [ ]  |  |
| [ ]  | [ ]  |  |
| [ ]  | Recruitment material  | [ ]  | [ ]  |  |
| [ ]  | [ ]  |  |
| [ ]  | Other (specify):  | [ ]  | [ ]  |  |
| [ ]  | [ ]  |  |
| [ ]  | [ ]  |  |
| [ ]  | [ ]  |  |

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| 1 | **What changes does this amendment involve?** *(check all that apply)* |
| [ ]  Purpose/objective[ ]  Dosage/sample size[ ]  Conflict of interest[ ]  Consent Form[ ]  Rationale/procedures | [ ]  Inclusion/Exclusion[ ]  Impact assessment[ ]  Recruitment process[ ]  Methodology/design | [ ]  Confidentiality[ ]  Risks/benefits[ ]  End date of study[ ]  Team member (*attach updated team form*) |
| [ ]  Other (specify): |  |
| 2 | **Briefly explain the rationale for the amendment changes:**  |
|  |
| 3 | **How will each amendment affect the study?** |
|  |
| 4 | **Does the amendment require changes to the consent form(s)?** |
| [ ]  Yes [ ]  No *If yes, please attached a tracked and clean copy* |
| 5 | **If study participants need to be informed of changes related to this amendment, describe how and when the participant will be informed:** |
|  |
| 6 | **Does the study involve any of the following?** [ ]  Yes [ ]  No [ ]  N/A (*check all that apply)* |
| [ ]  New drugs [ ]  Biologics [ ]  Natural health products [ ]  Medical devices [ ]  Approved drug for a new indication (i.e., new age group, disease entity etc.) |
| 7 | **Is a NOL or authorization letter from Health Canada required for this amendment?**  |
| [ ]  Yes, is the NOL attached? [ ]  Yes [ ]  Requested from Sponsor | [ ]  No, please explain why the NOL is not applicable: |

**Principal Investigator Declaration:** I accept the amendments as submitted. I have assessed the safety implications of the amendments and the impact on study procedures, and I am prepared to take all necessary steps to implement the changes.

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