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

**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. 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 revisions, additions or deletions to approved studies are considered amendments, and must be submitted by the PI to the REB for review and approval that the research remains scientifically and ethically sound. Refer to *Guidelines for Submitting Amendments.*

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

|  |  |
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| **Date of Initial REB Approval:** |       |
| **Current Study Status:** | [ ]  Not Yet Open [ ]  Open to Accrual [ ]  Closed to Accrual |
| **Current # of Amendments:** |       |
| **Current # of Participants Enrolled:** |       |
| **Breakdown of Enrollment to Date:** |       | Screen Failed |
|       | Receiving Intervention/Observation |
|       | Post Intervention Follow-Up |
|       | Completed Study |
|       | Withdrew Consent |
|       | Transferred to Another Site |
|       | Expired |

**DOCUMENTS SUBMITTED:**

|  |  |
| --- | --- |
| **Document Type** | **Document Description** *(name, version & date)* |
| [ ]  | Protocol  |       |
| [ ]  | Informed Consent Form |       |
| [ ]  | Participant Material *(i.e., wallet card, etc.)*  |       |
| [ ]  | Recruitment Material *(i.e., brochure, etc.)*  |       |
| [ ]  | Other (Specify):       |

The amendment involves changes to (***check all that apply***):

|  |  |
| --- | --- |
| GENERAL INFORMATION | BENEFITS/RISKS |
| [ ]  Study | [ ]  Potential Benefits of the Study |
| [ ]  Principal Investigator | [ ]  Known/Anticipated Risks of the Study |
| [ ]  Research Team Members | [ ]  Procedures for Risks in Place |
| [ ]  Conflict of Interest  | INFORMATION/CONSENT PROCESS |
| [ ]  Budget | [ ]  Informed Consent/Absence of Consent |
| [ ]  Impact Assessment (programs/fees) | [ ]  Process for Parental/Guardian Consent  |
| STUDY SUMMARY | [ ]  Process for Withdrawal of Consent |
| [ ]  Purpose/Rationale/Objectives | CONFIDENTIALITY |
| [ ]  Methodology/Design | [ ]  Procedures to Ensure Confidentiality |
| [ ]  Dosage/Procedures | **OTHER (*Specify*)** |
| [ ]  Sample Size | [ ]        |
| [ ]  Inclusion/Exclusion Criteria | [ ]        |
| [ ]  Recruitment Process | [ ]        |

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| 1. | **For amendments listed above:** |
| a. | Briefly explain the rationale for the changes:       |
| b. | How will each affect the study?       |
|  | c. | Attached:  | [ ]  Revised Informed Consent Form (Tracked Changes)[ ]  Revised Informed Consent Form (Clean)[ ]  Not Required |

|  |  |
| --- | --- |
| 2. | **If study participants need to be informed of changes related to this application, describe how and when the participant will be informed:**      |

|  |  |
| --- | --- |
| 3. | **Does this involve investigational drugs or devices?** **[ ]  NO** **[ ]  YES** *If yes, complete questions below:* |
| a. | Does the study involve any of the following (please check all that apply)?[ ]  Investigational new drugs[ ]  Investigational biologics[ ]  Investigational natural health products[ ]  Investigational medical devices[ ]  Approved drug for a new indication (e.g., new age group, disease entity) |
| b. | If the amendment involves any of the above, is a “*No Objection Letter*” (NOL) or authorization letter from Health Canada required?[ ]  YES, Health Canada NOL is attached. [ ]  Yes [ ]  No [ ]  In Progress[ ]  NO, Please explain why NOL is not applicable:       |
| c. | Provide FDA IND No. (drug studies):  |       | or PMA No. (device studies): |       |

**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 |