**WATERLOO-WELLINGTON RESEARCH ETHICS BOARD (WWREB)**

**Formerly known as Tri-Hospital Research Ethics Board (THREB)**

**AMENDMENT APPLICATION FORM**

**INSTRUCTIONS**

1. Submit this form via email with original local PI signature and all applicable revised documents (clean and tracked changes versions) to the WWREB Administrative Coordinator at wwreb@grhosp.on.ca
2. Indicate the number associated with your submission (if this is the first, second, third, etc. amendment for this study)
3. Please note that requested changes cannot be implemented before WWREB approval.

**SECTION 1: Study Information**

WWREB Study #:

Study title:

Local Principal Investigator:

Expiry date of WWREB approval:

Sponsor/funder:

Study Amendment number (Amendment 1, 2, 3, etc.):

**SECTION 2: Contact Information**

Name of Person Completing this form:

Email:

Telephone Number:

**SECTION 3: Review Information**

**Type of change:** [ ]  Major Change [ ]  Minor/Administrative Change

Please specify the type of review requested: [ ]  Full Board [ ]  Delegated

Is this a coordinated review with the University of Waterloo? [ ]  Yes [ ]  No

If yes, please provide the UWaterloo ORE #:

Is this study subject to Health Canada Regulations?

[ ]  No

[ ]  Yes, Clinical Trial Application (CTA) under the Food and Drug Regulations or CTA under the Natural Health Product Regulations or Investigational Testing Application (ITA) under the Medical Device Regulations

Is this study subject to the US Food and Drug Administration (FDA) Regulations?

[ ]  No

[ ]  Yes, Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) or Pre-Market Approval (PMA) Application

Is this study supported by the United States federal government? E.g. National Institute of Health (NIH), National Cancer Institute (NCI), Department of Justice (DOJ), Department of Health and Human Services (DHHS)

[ ]  No

[ ]  Yes

Is this study an Industry sponsored/supported study?

[ ]  No

[ ]  Yes If Yes, a $500 review fee (subject to change) will be invoiced.

**SECTION 4: Amendment Summary**

Does this change have safety implications on the participants of the study? [ ]  Yes [ ] No

Has this amendment already been implemented to eliminate an immediate hazard? If yes, describe in section 6. [ ]  Yes [ ] No

Is this amendment related to a protocol deviation or adverse event? [ ]  Yes [ ]  No

If yes, was this reported to the WWREB? [ ]  Yes [ ]  No

Enrollment status for WWREB site participants only. Check all that apply.

[ ]  Not Yet Activated

[ ]  Enrolling Participants

[ ]  Enrollment Complete

[ ]  Participants Receiving Intervention

[ ]  Participant Follow-Up Only

[ ]  Participant Follow-Up Complete

[ ]  Study Prematurely Terminated

[ ]  Study suspended

[ ]  Other:

|  |
| --- |
| a. Summarize in lay terms the proposed changes to the study: |
| b. Provide justification/rationale for the change(s):c. Describe any change to the risk, discomfort or inconvenience to study participants: d. Describe if and how study participants will be informed of the change(s): |

**SECTION 5: Applicable Changes**

**Select all that apply and include all affected documents.**

|  |  |
| --- | --- |
| [ ]  Change to the Protocol – version date:[ ]  Change to the Main Consent Form – version date:[ ]  Change to the Genetic Consent Form – version date:[ ]  Change to an Optional Consent Form – version date:[ ]  Change to the Assent Form –version date:[ ]  Change to data or biological specimens access, collection, use or storage[ ]  Change in study funding or participant compensation[ ]  Change/update related to commercialization[ ]  New information about a refusal to approve or suspension of the study by another REB[ ]  Change related to Conflict of Interest [ ]  Other Forms: (Specify – version date): *
*
*

Has Health Canada been notified?[ ]  N/A [ ]  Yes [ ]  NoHealth Canada “No Objection Letter” or equivalent[ ]  N/A [ ]  Yes [ ]  No | [ ]  Change to the Investigator’s Brochure/ Product Monograph – version date:[ ]  Change to Recruitment Tools (ads, flyers, brochures, scripts, websites, etc..)Specify – version date:[ ]  Change to Questionnaires, Interview/focus group guides, Diaries, Surveys, etc.Specify – version date:[ ]  Change to Study Budget – version date:[ ]  Other (specify) |

**SECTION 6: Additional Comments/Notes**

**SECTION 7: Local Investigator Attestation**

This signature attests that the Local Investigator has assessed the safety implications of this amendment, its impact on study procedures and is prepared to take any necessary steps to implement the change(s). Further, the local Principal Investigator will not implement any changes to, or deviations from the protocol without Waterloo-Wellington Research Ethics Board approval of this amendment except to eliminate an immediate hazard to study participants or when changes involve only logistical or administrative aspects of the study.

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Print Name Signature Date (dd/mm/yyyy)