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

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

**ANNUAL RENEWAL APPLICATION FORM**

**INSTRUCTIONS**

1. Please email completed form with original signature of the Local Principal Investigator to: WWREB Administrative Coordinator, wwreb@grhosp.on.ca
2. Handwritten applications will not be accepted; please submit as a MS Word document
3. Please attach a copy of the current consent form(s).

**SECTION 1: Study Information**

WWREB Study #:

Study Title:

Name of Local (Site) Principal Investigator:

Initial Approval Date:

Expiry date of WWREB approval:

Site(s) involved:

[ ]  GRH – KWHC

[ ]  GRH – Freeport

[ ]  GRH – GRRCC

[ ]  SMGH

[ ]  CMH

[ ]  UW

[ ]  Other: Click or tap here to enter text.

Sponsor/Funder:

Please specify the type of review requested:

[ ]  Full Board

[ ]  Delegated

Is this study subject to Health Canada (HC) 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 a 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 an Industry-Sponsored/Supported study?

[ ]  No
[ ]  Yes: if YES, a $500 fee (subject to change) will be invoiced.

 Please provide the details below:

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| Industry sponsor company name: |
| Contact Name: |  |
| Telephone: | Email: |
| Street Address: | Suite: |
| City: | Province/State: |
| Country: | Postal/Zip Code |

[ ]  Current consent form(s) attached

[ ]  No consent form(s) for this study

[ ]  All Research Staff Members have completed and submitted proof of completion of all applicable training requirements to the Administrative Review Committee at the hospital where the research is taking place

**SECTION 2: Status of the Open Study (check all that apply)**

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| [ ] Not yet activated |
| [ ]  No enrollment to date |
| [ ]  Actively Recruiting participants |
| [ ]  Actively Enrolling participants |
| [ ]  Study intervention/procedures/Data Collection is ongoing |
| [ ]  Permanently closed to enrolment, one or more participants receiving study intervention |
| [ ]  Permanently closed to enrolment, no local participants are receiving study intervention, all participants are in long term follow-up or data collection continues |
| [ ]  Study completed, Intervention & follow-up complete for all local participants – data analysis and/or data transfer to (i.e. sponsors or coordinating centres) |
| [ ] Prematurely Terminated |
| [ ] Suspended |

**SECTION 3: Summary of Participants at this site**

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|       Number of participants/Charts planned  |
|       Number of participants screened  |
|       Number of participants consented (if applicable) |
|       Number of participants consented but did not meet inclusion criteria (if applicable) |
|       Number of participants prematurely withdrawn from study |
|       Number of participants receiving study intervention / actively completing study procedures |
|       Number of participants in post-intervention/procedural follow-up |
|       Number of participants that have completed follow-up |
|       Number of participants that were enrolled since the last renewal |

**SECTION 4: Study Summary**

1. Has the WWREB approval lapsed?

[ ]  No [ ]  Yes

If Yes, Provide the reason for the lapse and describe all actions taken to prevent a lapse from occurring in the future.

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If Yes, was there a need to continue research activity or treatment for current study participants for their safety and well-being?

[ ]  No [ ]  Yes

If Yes, describe what study activities or treatments occurred with a clear explanation as to why it was

necessary to continue treatment during the lapse in approval.

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1. Please provide a brief summary of the progress of the study to date (i.e. recruitment issues, preliminary findings, a description of amendments which have been submitted).

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1. Is there any new information in the literature or from other recent studies that would change the rationale or risk/benefit ratio for this study (e.g. changes in standard of care, new information about side effects, approval of another drug for this indication)?
 [ ]  Yes [ ]  No

If yes, please explain and provide any applicable references

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1. Have there been any participant complaints or feedback about the research?
[ ]  Yes [ ]  No

If yes, please describe.

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1. Have there been any internal serious adverse events (SAEs) since the last approval?
[ ]  Yes [ ]  No

If yes, please state the action taken in response to the SAEs, and any resulting changes in procedures to detect such SAEs.

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* 1. In the opinion of the Principal Investigator, is there a trend in the internal SAEs?

 [ ]  Yes [ ]  No
 If yes, describe.

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* 1. Have there been any deaths related, or not related, to study intervention?

[ ]  Yes [ ]  No
If yes, provide details.

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1. Has there been a change in the frequency and/or severity of adverse events that would result in a change to the protocol or consent form?

[ ]  Yes [ ]  No

1. Is there a data safety monitoring committee/board (DSMC/DSMB) for this project?

[ ]  Yes [ ]  No (If yes, please attach a copy of the most recent DSMB/DSMC report)

If yes, how often does this committee meet? If the DSMB/DSMC has not met in the last year, please provide an explanation/justification or state when the next meeting is planned.

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1. Since the last renewal, has there been any change in the Conflict of Interest information provided to the WWREB for investigators involved in this study? (Potential Conflicts of Interest can include functioning as an employee or consultant to the study sponsor, direct or indirect financial interest in the drug/device or technology involved in the study or receiving honorarium or other benefits from the sponsor).

[ ]  Yes [ ]  No

If yes, please specify

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1. Has the study now changed to include collection or banking of tissue or other specimens (i.e. fetal tissue, placenta, blood or other body fluids)?
[ ]  Yes [ ]  No

If yes, please specify

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1. Is the contact information on the consent form current?
[ ]  Yes [ ]  No
2. Please provide current local PI and study coordinator/research assistant address, telephone numbers, and e-mail addresses
3. Study Contact Information (If different from above i.e. research coordinator, research assistant, research nurse, etc.)

Name:
Address:
Phone Number:
Email:

**SECTION 5: Study Personnel (In addition to those listed above. Add rows if needed)**

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| --- | --- | --- | --- |
| **Name:** | **Site/Department:** | **Role in the study:** | **Contact information:** |
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**SECTION 6: Local PI Attestation**

I confirm that I have reviewed any adverse events, if applicable, in a timely fashion during the course of the study and these have been reported to WWREB. All revisions to the study protocol and consent form(s) have been submitted. I am not aware of any new information that may affect the continuation of the study or require change in the study protocol.

*Print Name of Local Responsible Investigator Signature Date (dd/mm/yyyy)*