#  Logo for Cambridge Memorial Hospital Logo for Grand River Hospital

# TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)

## ANNUAL RENEWAL PROGRESS REPORT FORM

### FOR ONGOING RESEARCH STUDIES

#### *This form is available in MS WORD and can be downloaded at: www.grandriverhospital.on.ca*

##### **All submissions must be typed.** (Handwritten submissions will not be accepted.)

Use this form if data are being collected or participants are still being followed and renewal of approval is being requested. If all data collection and participant follow-up has ended or study is cancelled, submit a Study Completion Report even if data analysis continues.

THREB Study #:

Full Research Study Title:

Name of Local Responsible Investigator and Contact Information:

Initial Approval Date:

Date Approval Renewal Required (Anniversary Date):

Site(s) involved:

[ ] GRH – KWHC

[ ] GRH – Freeport

[ ] GRH – GRRCC

[ ] SMGH

[ ] CMH

[ ] Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please answer all questions.

**Local Study Status:**  Check [ **✓ ]** (one only)

 Actively enrolling participants [ ]

 Enrolment completed, but participants being followed [ ]

 Chart review only [ ]

 Other (Attach explanation [ ]

1. **Enrollment**:

How many participants have been enrolled to date? \_\_\_\_\_

How many participants have left study for reasons other than completing it: \_\_\_\_\_

 (i.e., died, withdrew due to AE or for personal reasons, etc. Give explanation.)

NOTE: For chart research, state # of charts under “enrolled” field.

1. Please provide a brief summary of the study results to date,

including any difficulties encountered conducting the study,

i.e. funding, study design, recruitment, data management,

interactions with the sponsor(s). [ ]Attached

1. Has an interim data analysis been done? [ ] Yes [ ] No

If yes, attach a summary. [ ] Attached

1. Have any articles been published or presentations given

using the results of the study? [ ] Yes [ ] No

If yes, please submit a copy of the abstract(s) or a list of references. [ ] Attached

1. Have there been any changes to the study protocol or

consent form since the last approval? [ ] Yes [ ] No

If yes, have these changes been approved by THREB? [ ] Yes [ ] No

 If no, attach completed Amendment Form. [ ] Attached

What is the version date of the consent form currently being used? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] N/A

1. Have there been any local serious adverse events? [ ] Yes [ ] No

If yes, has the THREB been notified? [ ] Yes [ ] No

 If no, submit Local SAE Report now. [ ] Attached

1. For clinical trials, the most recent DSMB or Sponsor-generated

 report is required. Is it attached? [ ] Yes [ ] No [ ] N/A

1. Has there been any new literature which would change

your assessment of risk/benefit for participants? [ ] Yes [ ] No

If yes, and your assessment of risk has increased, have

your participants been informed? [ ] Yes [ ] No

 If no, indicate when and how this will take place. [ ] Attached

1. Have there been any changes in investigators since the

last approval? [ ] Yes [ ] No

If yes, has the THREB been notified? [ ] Yes [ ] No

 If no, submit changes now on an Amendment Form. [ ] Attached

1. Is there new evidence from other studies that impact

your study? [ ] Yes [ ] No

If yes, provide. [ ] Attached

 11. Has any further conflict of interest arisen in the study? [ ] Yes [ ] No

If yes, provide explanation. [ ] Attached

It is the responsibility of the researcher to notify the Tri-Hospital Research Ethics Board of **any procedural change** in research involving human participants.

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*Signature of Local Responsible Investigator Date*

Please sign and submit this completed form to:

 Laurie Dietrich, Administrative Coordinator

 Tri-Hospital Research Ethics Board

 Grand River Hospital, Kaufman Building, Rm K503

 835 King Street West

 Kitchener, ON N2G 1G3

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