



**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

Handwritten submissions are NOT acceptable

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 and the study is either completed or cancelled, submit a Study Completion Report.

THREB Study #:

Full Research Study Title:

Name of Local Responsible Investigator and Contact Information:

Initial Approval Date:

Date Approval Renewal Required (Anniversary Date):

Please answer all questions.

Study Status:

Check []
(one only)

- Actively enrolling participants []
- Enrolment completed, but participants being followed []
- Other (Attach explanation) []

1. Number of study participants enrolled at:

Specify Number
(where appropriate)

Cambridge Memorial Hospital

Currently: _____

Since study initiated: _____

How many participants have completed the study to-date: _____

How many participants have withdrawn (attach explanation): _____

Grand River Hospital

Currently: _____

Since study initiated: _____

How many participants have completed the study to-date: _____

How many participants have withdrawn (attach explanation): _____

St. Mary's General Hospital

Currently: _____

Since study initiated: _____

How many participants have completed the study to-date: _____

How many participants have withdrawn (attach explanation): _____

2. 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

- | | | |
|---|------------------------------------|------------------|
| 3. Has an interim data analysis been done?
If yes, attach a summary. | [] Yes
[] Attached | [] No |
| 4. Have any articles been published or presentations given using the results of the study?
If yes, please submit a copy of the abstract(s) or a list of references. | [] Yes
[] Attached | [] No |
| 5. Have there been any changes to the study protocol or consent form since the last approval?
If yes, have these changes been approved by THREB?
If no, attach completed Amendment Form. | [] Yes
[] Yes
[] Attached | [] No
[] No |
| 6. Have there been any local serious adverse events?
If yes, has the THREB been notified?
If no, submit Local SAE Report now. | [] Yes
[] Yes
[] Attached | [] No
[] No |
| 7. For clinical trials, is the most recent DSMB or Sponsor-generated report attached? | [] Yes | [] No [] N/A |
| 8. Has there been any new literature which would change your assessment of risk/benefit for participants?
If yes, and your assessment of risk has increased, have your participants been informed?
If no, indicate when and how this will take place. | [] Yes
[] Yes
[] Attached | [] No
[] No |
| 9. Have there been any changes in investigators since the last approval?
If yes, has the THREB been notified?
If no, submit changes now on an Amendment Form. | [] Yes
[] Yes
[] Attached | [] No
[] No |
| 10. Is there new evidence from other studies that impact your study?
If yes, provide. | [] Yes
[] Attached | [] No |
| 11. Has any further conflict of interest arisen in the study?
If yes, provide explanation. | [] Yes
[] Attached | [] No |

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

Signature of Local Responsible Investigator

Date

Please sign and submit this completed form to:

Karen
 Tri-Hospital
 Kaufm

835
 Kitchener,
 Phone
 FAX
 E

Goerz, Administrative Coordinator
 Research Ethics Board
 an Building, Rm K615
 Grand River Hospital
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