



TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB) GENERAL INFORMATION AND GUIDELINES

Dear Investigator:

Thank you for your interest in conducting research at Cambridge Memorial Hospital and/or Grand River Hospital and/or St. Mary's General Hospital. All research involving human subjects at these hospitals is reviewed by the Tri-Hospital Research Ethics Board (THREB). In order to facilitate this review, it is essential that all the necessary documentation be included in your application (see **Application Form** and its instructions). THREB meets the first Wednesday of the month except during July and August. To provide sufficient time for research review, your completed application package must be received by the 2nd Wednesday of the month prior to the meeting date. A checklist outlining the required steps is included as the first part of the Application Form: <http://www.grandriverhospital.on.ca/research/reas-ethic.cfm>

The Application Form has 5 parts, all of which must be complete.

For **Retrospective Record Reviews**, a different application form should be used (Application for Retrospective Review of Health Records) found at the same website.

In general, the THREB requires **15 copies** of all documents that must be reviewed (except for the Investigator's Brochure for Clinical Trials).

For industry sponsored studies the cost associated with this review is \$2000 (see Part 4 of the Application Form). Please attach your **cheque made payable to "Cashier, Grand River Hospital"**. Similarly, there is a charge of \$300.00 for any amendment or protocol change that requires the committee to review more than minor changes in the protocol or the consent form.

In addition to completing this application package please provide us with information outlining any specific requirements for the final ethics approval letter.

*THREB meets on the first Wednesday of every month. You are requested to attend the meeting to provide a brief overview (5 minutes) and to answer any questions. To provide sufficient time for research review, your completed application package **must be received by the deadline in the month prior** to the meeting, that is, 4pm on the 2nd Wednesday of the month. The Chair of the THREB will strive to notify applicants of THREB decisions by mail or fax within 10 business days of the meeting. Please keep in mind that the administrative support for THREB is a part-time position.*

Once the protocol has been reviewed and approved by the committee, you will be required to submit the following reports and forms, all of which are available at our website:
<http://www.grandriverhospital.on.ca/research/reas-ethic.cfm>

- 1. Annual Renewal Progress Report (15 copies)** – A progress report and review of the project will be required should the study extend longer than one year from date of approval. You will be sent a reminder letter approximately **8 weeks** prior to this date. ***This review is essential for ongoing approval.***

2. **Study Completion Report (15 copies)** – The study completion form is submitted to close out the study.
3. **Amendments or Revisions (15 copies)** – Send copies of the Amendment Form along with any amended document containing the proposed changes (e.g. protocol, information sheet/consent form, drug or device brochure, advertisement, study instrument, questionnaire, etc.) and a detailed explanation and justification for each change, *indicating their impact on burdens or risks to participants, and implications for the consent form.*
4. **Local Serious Adverse Events (SAEs) (15 copies)** – Use this form to report local serious adverse events. Please provide a summary of the burden or risk(s) to participants and indicate the impact or implications for the consent form. Provide a detailed report of any SAE occurring within CMH &/or GRH &/or SMGH. The THREB does not receive or acknowledge reports of non-local SAEs. Rather it requires at least annual DSMB or Sponsor-generated safety reports. (See SOP 4.4 Continuing Review.)
5. The trial can commence once THREB issues a written approval of the trial, and, where necessary, Administrative Approval of contracts or clinical trial agreements has been received.

Mail completed applications to:

Karen Goerz, Administrative Coordinator
Tri-Hospital Research Ethics Board
Kaufman Building, Rm K615
Grand River Hospital
835 King Street West
Kitchener, ON N2G 1G3

Phone #1-519-749-4300, extension 5367
FAX #1-519-749-4250
Email: karen.goerz@grhosp.on.ca

The Administrative Coordinator is in the office normally only on Mondays and Wednesdays, 8:30am to 4:30pm.

Please do not hesitate to contact me if you require any further information. The best way to reach me is by email.

Sincerely,

Michael D. Coughlin, Ph.D.
Chair, Tri-Hospital Research Ethics Board
Email: coughlin.michael@gmail.com