  

# **Application Part 1**

## **GENERAL INSTRUCTIONS & CHECKLIST FOR APPLICATION TO THE**

## **TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)**

(Version June 2021)

**Investigator:**  Click here to enter text.

THREB #

* **Deadline** for submission is the **2nd Wednesday** of the month by **4:30pm** for review at the THREB meeting of the following month. Applications received after this will be considered at a subsequent meeting.
* THREB meets at noon normally on the 1st Wednesday of the month, rotating meetings among the three hospitals. THREB does not meet in July or August.
* All submissions must be typed. (**Handwritten submissions will not be accepted**.)
* The submission must include **hard copies of ALL documents** required by this checklist. Submissions will not be reviewed while they are incomplete, and may be returned to the investigator. Call the office if there are questions of what documents are required.
* Number of copies required: Please submit a signed hard-copy original along with an electronic (PDF) of the full application (Parts 1,2,3) including all documents for review. Two (2) additional hard-copies of the package are required (**3 packages in total + electronic copy**). Note: only 1 hard copy of an Investigator Brochure is required
* **NOTE:** For retrospective chart reviews or similar collection of personal health information, use the alternative form, “Application for Retrospective Review of Personal Health Information.”
* **NOTE:** The Local Responsible Investigator or Co-investigator must be present at the meeting in which his or her project is reviewed.

It is the investigator’s obligation to contact the appropriate institutional representative to initiate the Administrative Approval process prior to submission to THREB

The specific requirements for the process at each institution can be obtained by contacting:

For St. Mary’s General Hospital:

Sherri Ferguson

Vice President, Quality, People & Performance

St. Mary’s General Hospital

[911 Queen](https://maps.google.com/?q=911+Queen%E2%80%99s+Blvd.%0D+Kitchener,+Ont.%0D+N2M+1B2&entry=gmail&source=g)’[s Blvd.](https://maps.google.com/?q=911+Queen%E2%80%99s+Blvd.%0D+Kitchener,+Ont.%0D+N2M+1B2&entry=gmail&source=g)

[Kitchener, Ont.](https://maps.google.com/?q=911+Queen%E2%80%99s+Blvd.%0D+Kitchener,+Ont.%0D+N2M+1B2&entry=gmail&source=g)

[N2M 1B2](https://maps.google.com/?q=911+Queen%E2%80%99s+Blvd.%0D+Kitchener,+Ont.%0D+N2M+1B2&entry=gmail&source=g)

519-749-6578 ext. 6403

sferguso@smgh.ca

For Cambridge Memorial Hospital:

Stephanie Pearsall,

Vice President Clinical Programs

Cambridge Memorial Hospital

700 Coronation Blvd.

Cambridge ON.  N1R3G2

(519) 621-2333 ext. 2416

Email: spearsall@cmh.org

For Grand River Hospital:

Sarah Laferriere

Research Office Administrator

Grand River Hospital

835 King Street West

Kitchener, ON N2G 1G3

(519) 749-4300 x2876

sarah.laferriere@grhosp.on.ca

research@grhosp.on.ca

Submissions to THREB: To avoid delay, please ensure that all requested materials have been included. Incomplete applications will be reviewed at a subsequent meeting, resulting in significant delay.

Please send to: Shelley Croth, Administrative Coordinator

 Tri-Hospital Research Ethics Board

 Building-Forty Green, Rm K415

 Grand River Hospital, 835 King Street West

 Kitchener, ON N2G 1G3

 Phone #1-519-749-4300, extension 5367

 Email: shelley.croth@grhosp.on.ca

 Office Open: Monday and Wednesday

**Check List**

[ ] **AVAILABILITY.** The **Investigator** or co-investigator will be available to attend the next THREB meeting.

[ ] **Application Part 1 –** Complete in full andsubmit **1** copy

[ ] **DETERMINATION OF FEE REQUIREMENTS** (page 3 Application Part 1)

 [ ] **REVIEW FEE FOR INDUSTRY-SPONSORED STUDIES**

[ ] Attached – make cheque payable to:

“**St. Mary’s General Hospital: Attn THREB**”

--Or--

[ ] Not applicable (as described on page 3)

[ ] CONSENT FORM REQUIREMENTS CHECKLIST (pages 4-7 Application Part 1)

[ ]  **MATERIAL FOR ETHICS REVIEW**

[ ] **FULL APPLICATION package (Parts 1, 2, 3) with all materials for review as listed below.**

* **1 Original Signed Hard Copy of collated package of materials**
* **2 additional hard copies of collated package of materials**
* **1 Electronic copy (PDF format) of all package materials**

[ ] **RESEARCH PROTOCOL (Required for all projects)**

[ ]  **CONSENT FORM/COVER LETTER** Consent Form must meet the requirements of the Consent Form Requirements Checklist. If using a cover letter for a survey, state within the letter that it is research and that it has been reviewed by the Tri-Hospital Research Ethics Board.

[ ]  **RECRUITMENT ANNOUNCEMENT** Any recruitment announcement.

[ ]  **SURVEY INSTRUMENTS** Any questionnaire, interview schedule, or other testing instruments to be used unless they have been previously published in a peer reviewed journal. If so, give citation.

[ ]  **SPONSOR’S PROJECT BUDGET** The sponsor-approved project budget for the study site with a breakdown of costs. The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2 (TCPS2), Article 7.4 dictates that it is the responsibility of every institution to review the budgets for research to ensure that ethical duties concerning conflict of interest are respected.A template is provided in Application Part 3

[ ]  **INVESTIGATOR’S BROCHURE for CLINICAL DRUG TRIALS Submit 1 hard copy** This is for information only and will be acknowledged but not reviewed for approval.

[ ]  **HEALTH CANADA NO OBJECTION LETTER (NOL)** For Clinical Trials requiring Health Canada review, a copy of the Health Canada NOL must be submitted before approval is given.

[ ] **CURRICULUM VITAE Submit 1 copy** of a current CV for the Local Responsible Investigator and sub-investigators *if not previously submitted*.

[ ] **OTHER REB APPROVALS Submit 1 copy** of any official letter(s) indicating completion of a review by another REB may be requested.

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**TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)**

**DETERMINATION OF FEE REQUIREMENTS**

THREB # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Investigator:** Click here to enter text.

**IS THIS STUDY INDUSTRY-SPONSORED?** [ ] **YES** [ ] **NO**

1. **REVIEW FEES – INDUSTRY-SPONSORED STUDIES**
* The application review fee for any industry-sponsored study is $3000. Such studies include any research activity that receives financial support from private, for-profit industry, for example, pharmaceutical industry-funded projects such as clinical trials, the testing of new pharmaceutical agents or devices, the development of diagnostic tests, or new pharmacological agents.
* Please attach your cheque made payable to “St. Mary’s General Hospital: Attn THREB” This cheque must be received by THREB before approval will be given.
* In addition any changes to protocol or consent requiring a significant review (i.e. requiring full board review) of the study will be charged $400.
1. **PEER REVIEWED GRANTS**
* There will be no charge for the review of these studies. This includes any competitive peer reviewed basic or applied research projects such as those funded by CIHR, NCIC, PSI, MOHLTC or Heart and Stroke Foundation.
1. **RESEARCH GIFTS**
* There will be no charge for the review of these studies. This includes donations to support research fellows, donations or bequests to research projects, or self-funded student projects.

Elements Required for a Consent Form or Cover Letter to

Potential Participants

THREB # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Investigator:** Click here to enter text.

Is a Consent Form required for this project? [ ] YES [ ] NO

General Features (Check if included)

[ ] **Include a version date or version number** at the bottom of all pages. **The consent form must be given a new version date or version number whenever changes are made to it.**

[ ] **Print on letterhead**: use hospital letterhead for studies involving contact with hospital patients, or other appropriate clinic/institutional letterhead if suitable (check with REB office).

[ ] **Use plain language:** write the document in language that is easy for your potential participants to understand. Describe any medical/scientific/professional terms in ordinary terms. In general consent statements should be written in the second person (i.e. *You*…)

[ ] **Include signature and date lines for the Participant** or, where applicable, participant’s legally authorized representative.

[ ] **Include signature and date lines for person obtaining consent.**

[ ] (Include signature and date lines for a Witness if the level of risk warrants it.)

[ ] **Include signature and date lines for the Locally Responsible Investigator** involved in interventional studies (i.e., that involve a “regulated act”).

[ ] For studies involving children or others with diminished capacity, there should also be, in addition to the “consent” form, an “assent” form for them to sign. For further information, see Health Canada: <http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/consent/index-eng.php>

As a minimum, the document should also contain the following:

**Project Information**

[ ] Name of Local Responsible Investigator (e.g. Health Canada’s “Qualified Investigator”) and Student Investigator, where applicable.

[ ] Departmental affiliationand contact number for Local Responsible Investigator.

[ ] Study Title

[ ] Name of Sponsor if study is externally funded

[ ] A statement as to whether the investigator or the institution is receiving payment for doing the research.

[ ] Approximate total number of participants expected to take part in this study as well as the anticipated number of local participants.

[ ] A statement inviting the participation in the study and any specific reason the person is being approached (e.g. *You are being invited to participate in this study because you have been diagnosed with heart disease and we are looking at a new treatment)*.

[ ] Purpose of the study. Include several sentences outlining the rationale for the study in clear lay terms.

[ ] Description and identification of all experimental procedures. For studies involving questionnaires or interviews, provide examples of the types of questions to be asked.

[ ] Details of the time commitment required for participation in the project.

[ ] Details about any plan to re-contact participants for follow-up sessions or subsequent related project.

[ ] List where the participant may obtain more information, e.g. website

**Free and Informed Consent**

[ ] Identification of alternatives to enrollment in the research. (E.g.: Instead of being in this study, you have these options: and list the alternatives including standard therapy) Trade names of commonly used medications should be listed. A discussion of the risks and benefits of the alternatives or a statement indicating that the study doctor will discuss the risks and benefits of the alternatives with the participant must be included.

[ ] A statement which indicates participation is voluntary and participants may withdraw at anytime during the study without reprisal or compromise of patient care. Include directions explaining how to communicate this to the researcher.

[ ] A statement which indicates participants may decline answering any question(s).

**Risks and Benefits**

[ ] Description of any benefits the participant or others may reasonably expect from the research.

[ ] Description of known and/or anticipated *material* risks arising from participation. For clinical trials especially, some useful quantification of risk must be given, e.g. *common (>20%), moderate (5 to 20%), rare (<5%), very rare (<1%).*

[ ] Details concerning financial or other compensation (payment) for participants as well as details concerning reimbursement for participant expenses.

**Compensation for Injury**

[ ] For research involving more than minimal risk state whether any compensation and medical treatment is available if injury occurs.

[ ] Any “**compensation for injury clause**” must be consistent, at a minimum, with the following:

*“There will be no cost to you for the treatment received as part of this protocol. If you are injured as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost to you. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. Your signature on this consent form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate. However, this does not constitute a waiver of any legal right you may have under federal or provincial laws and regulations.”*

There may be no exculpatory language whereby the participant waives or appears to waive any of his or her legal rights, including any release of the sponsor, institution or its agents from liability for negligence.

**Note:** The above statement assumes coverage by OHIP. Lack of coverage by OHIP is assumed to be an exclusion criterion.

[ ] If there is to be a clause regarding **prevention of pregnancy**, the preferred approach is to provide the rationale and state that they must therefore use a medically acceptable method as determined through consultation with their doctor, preferably something such as:

*“You must not get pregnant during this study. If you are sexually active, you agree to use highly effective methods of preventing pregnancy as determined in discussion with your physician.”*

If examples are required, the statement should follow this model language.

*“You must not get pregnant during this study. You agree to use highly effective methods of preventing pregnancy. These include complete abstinence from sexual intercourse, tubal ligation or vasectomy, birth control pills, and barrier methods such as condoms, vaginal diaphragm with spermicidal jelly, IUDs, or vaginal contraceptive sponge or film”.*

**Privacy and Confidentiality**

[ ] Study participants must be clearly informed if their family or other physician will be contacted for information and that, in clinical trials, the family physician will need to be contacted.

[ ] Explanation of who will have access to information collected and to the identity of the participant, including a description of how confidentiality will be protected. The THREB must be included as having access to the information.

[ ] Procedures to ensure confidentiality of data or material, how patient information is stored, and the disposition of this information at the completion of the study should be clearly described for study participants. This must be included in all consents.

[ ] Information on length of retention of data or material, particularly for recordings or blood or tissue samples.

[ ] Any statement related to information being accessed must specifically address a timeframe, or be related to an incident, treatment or surgery.

[ ] All persons who view any or all of the medical record must be clearly identified in the consent. If information needs to be photocopied a statement such as “inspected, printed and removed by *[the company*] etc.” should be considered.

[ ] In the confidentiality section there should be a statement to the effect that the research participant has a **right to review** their study records and correct any misinformation: e.g.:

*“You have the right to ask the study doctor about the data being collected about you for the study and about the purpose of this data. Your also have the right to ask the study doctor to let you see your personal information and to make any necessary corrections to it.”*

**Contact Information**

[ ] A statement detailing who to contact in case of injury or adverse event or for questions about the research. The contact number needs to be a local number or an 800 number (i.e., no cost to caller)

[ ] A statement indicating that the project has been reviewed and received ethics approval through the Tri-Hospital Research Ethics Board, and that participants who have concerns or questions about their rights as a research participant in the study may contact the **Chair of the Tri-Hospital Research Ethics Board, Alison Williams at 519-749-4300 ext. 5367.**

**Templates** and other aids and suggestions for developing consent forms can be found at:

1) Health Canada: <http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/consent/index-eng.php>

2) Western University: <https://www.uwo.ca/research/ethics/human/board_guidelines.html>

3) McMaster University: Information and Consent under: <https://hireb.ca/forms-downloads/>

4) U.S. Federal Drug Agency: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery>