



Application Part 1

CHECKLIST FOR APPLICATION TO THE TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)

(Version January 2010)

Investigator _____

THREB # _____

- **Deadline** for submission is the **2nd Wednesday** of the month by **4pm** 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 on the **1st Wednesday** of the month, rotating meetings among the three hospitals.
- THREB does not meet in July or August.
- 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.
- Copies: **15 copies** of all documents for review must be submitted.
- **NOTE:** For retrospective chart reviews or similar collection of personal health information, use the alternative form, "Application for Retrospective Review of Personal Health Information."
- The Local Responsible Investigator or Co-investigator must be present at the meeting in which his or her project is reviewed.

Check

- THIS CHECKLIST (Application Part 1)** Submit 1 copy.
- APPLICATION FORM BODY (Application Part 2)** – Submit the typed original signed by the investigator with 15 copies.
- ADMINISTRATIVE/INSTITUTIONAL APPROVAL (Application Part 3)**
Submit the signed original (available as separate form) with 15 copies.
- DETERMINATION OF FEE REQUIREMENTS (Application Part 4)** Submit 1 copy.
- CONSENT FORM REQUIREMENTS CHECKLIST** Submit 1 copy.
- APPLICATION REVIEW FEE**
 - Attached – make cheque payable to "Cashier, Grand River Hospital"
 - Or--**
 - Not applicable (as described in Application Part 4)
- RESEARCH PROTOCOL** Submit 15 copies .
- AVAILABILITY** The **Investigator** or co-investigator will be available to attend the next THREB meeting.

- INVESTIGATOR'S BROCHURE** Submit **1 copy**
- CONSENT FORM/COVER LETTER** Submit **15** copies of a Consent Form that meets the requirements of the Consent Form Requirements Checklist. If using a cover letter for a survey study, state within the letter that it has been reviewed by the Tri-Hospital Research Ethics Board.
- RECRUITMENT ANNOUNCEMENT** Submit **15** copies of any recruitment announcement.
- SURVEY INSTRUMENTS** Submit **15** copies of any questionnaire, interview schedule, or other testing instruments to be used in the proposed research *unless previously published in a peer reviewed journal.*
- 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 **15** copies of any official letter(s) indicating completion of a formal review and granting acceptance/approval by other Research Ethics Boards with respect to this study proposal.
- SPONSOR'S PROJECT BUDGET** For industry sponsored studies, submit **15** copies of 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, Article 7.3 dictates that it is the responsibility of every research ethics board to review the budgets of all clinical trials to ensure that ethical duties concerning conflict of interest are respected.*

To **avoid delay** in review of this application, please ensure that all requested materials have been included, typed and carefully proofread. **Incomplete applications will be reviewed at a subsequent meeting, resulting in significant delay.**

Please send 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



TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB) APPLICATION FORM Part 2

All applicable requested information must be provided within the application from itself.
If a question is considered "not applicable" to the study, state that.

Incomplete applications will be returned.

For THREB Office Use Only

DATE Received:

THREB #

1. FULL TITLE OF RESEARCH PROJECT (Include Version #, Study Code and Protocol date if applicable)

2. LOCAL RESPONSIBLE INVESTIGATOR (Site Investigator or Health Canada's "Qualified Investigator")	
NAME:	TEL:
HOSPITAL	FAX:
UNIVERSITY AFFILIATION & DEPT:	EMAIL:
PRINCIPAL INVESTIGATOR if different from above	
NAME:	TEL:
INSTITUTION:	FAX:
UNIVERSITY AFFILIATION & DEPT:	EMAIL:
CO-INVESTIGATOR(S)	
NAME:	TEL:
INSTITUTION:	FAX:
UNIVERSITY AFFILIATION & DEPT	EMAIL:
STUDY COORDINATOR	
NAME:	TEL:

7. **Expected start date:** _____ **Expected completion date:** _____

8. **HAS THIS STUDY BEEN REVIEWED BY ANOTHER RESEARCH ETHICS BOARD OR INSTITUTION?** YES NO
If YES, please attach any other REB or institutional approvals. Attached To follow

9. **CONFLICT OF INTEREST:**
Does the principal investigator(s) or any co-investigators involved in this research study:

- (a) Function as an advisor, employee, officer, director or consultant for the sponsor? YES NO
- (b) Have direct or indirect financial interest in the drug, device or technology employed (including patents or stocks) in this research study? YES NO
- (c) Receive an honorarium or other benefits from the sponsor (apart from fees for service)? YES NO
- (d) If the answer is YES to any of the above, please describe and explain how that conflict is being managed to ensure that participant rights and welfare are not affected. Attached

SUMMARY OF PROPOSED RESEARCH

10. **PURPOSE AND/OR RATIONALE:** Summarize (10 lines maximum):
a) the main research question, b) what is being studied, and c) why the research is important.

11. **HYPOTHESES/OBJECTIVES:** (must be filled out in entirety)

12. **STUDY PARTICIPANTS** (describe the sample in terms of number, sex, age range, diagnostic criterion, and any special circumstances – must be filled out in entirety)
13. **RECRUITMENT OF PARTICIPANTS:** How, and from where/what source will participants be recruited? How will participants be identified and contacted? Attach copies of any advertisements or letters used for recruitment)
Advertisements to recruit subjects should be limited to:
- The name and address of the clinical investigator;
 - The purpose of the research, and in summary form, the eligibility criteria that will be used to admit subjects into the study;
 - A straightforward and truthful description of the benefits (such as payments or free treatments) to the subject for participation in the study;
 - The location of the research and the person to contact for further information.
14. **HOW MUCH TIME WILL BE REQUIRED FROM HOSPITAL PATIENTS AND/OR THEIR FAMILIES?**
15. **WHO WILL BE CONDUCTING THE STUDY** (clearly identify investigators' and/or assistants who will have direct contact with hospital staff or patients)

- 16. EXPERIMENTAL PROCEDURES** (Outline in detail and provide brief justification for the procedures in which participants will be involved, e.g., physical manipulation, doses, and methods of administration of drugs, physiological tests, paper and pencil tasks, interviews, questionnaires, time requirements, etc.) A copy of any questionnaires or test instruments to be used in the research must be appended to this application *unless they have been previously published in a peer reviewed journal.*
- 17. WHAT METHODS WERE USED TO CALCULATE SAMPLE SIZE?** (must be filled out in entirety)
- 18. DESCRIBE HOW THE DATA WILL BE ANALYZED STATISTICALLY** (must be filled out in entirety)
- 19. INFORMED CONSENT: IS THERE A CONSENT FORM?** Yes No

If **YES**, attach a copy of an Informed Consent Form to be signed by participants. Make sure the form follows the requirements set out in Application Part 5.

If **NO**, justify the reason.

20. BRIEFLY OUTLINE THE POTENTIAL BENEFITS OF YOUR RESEARCH: Participants, hospital and/or broader community)

21. POTENTIAL RISKS FROM THE STUDY: Outline in adequate detail any potential risks to participants in this study. Potential risks can be of a physical or psychological nature. Indicate whether the anticipated level of risk is considered to be low, moderate, or high – if high, explain why alternate approaches involving less risk cannot be used.

22. COMPENSATION OF PARTICIPANTS:
Will participants be compensated? Yes No

Indicate and give details if participants will be compensated financially.

23. DECEPTION: Is deception of participants involved in the study? Yes No

If any deception is involved in the design of the study, please describe it, and justify its use. How will the use of deception be explained to participants in your debriefing procedure?

24. REPORT- BACK TO PARTICIPANTS: How will participants be informed of the results of the study? Written feedback about the study should be provided to the participants ensuring that their participation minimally becomes an educational experience. Any use of deception should be described.

PROTECTION OF PERSONAL HEALTH INFORMATION

Investigators must comply with the duties set out for researchers in the Personal Health Information Protection ACT (PHIPA – effective in Ontario Nov. 1, 2004).

- 25. PERSONAL HEALTH INFORMATION:** List all personal health information, personal identifiers (e.g. name, DOB) required to be collected, and identify all potential sources of this information. For all non-clinical trials, attach data collection forms.

a) Personal health information:

b) *personal identifiers?* (Please check all applicable):

<i>DIRECT IDENTIFIERS</i>	Y	<i>INDIRECT IDENTIFIERS</i>	Y
<i>Full Name (Recommend initials)</i>		<i>Initials</i>	
<i>Address</i>		<i>Full Date of Birth (day/month/year)</i>	
<i>Telephone Number</i>		<i>Age at time of data collection or year of birth</i>	
<i>OHIP #</i>		<i>Full Postal Code (recommend first 3 digits only)</i>	
<i>Social Insurance Number</i>		<i>Healthcare Provider (recommend type of provider, eg. Family Physician, VON)</i>	
<i>Email address</i>		<i>Discharge Date</i>	
<i>Medical Record Number</i>		<i>Other date (e.g. date of service)</i>	
<i>Full Face Photograph</i>		<i>Fax Number</i>	
		<i>Medical Device Identifier</i>	
		<i>Certificate/License number</i>	
		<i>Vehicle Identification¹</i>	

¹ Vehicle identification numbers (VIN) and serial numbers including license plates.

Investigators should plan to collect personal data at the lowest level of identifiability necessary to achieve the study objectives. Even a dataset without direct identifiers may present a risk of indirectly identifying data subjects if the dataset contains sufficient information about the individuals concerned. For advice, consult the CIHR Best Practice Guidelines for Protecting Privacy and Confidentiality: http://www.cihr-irsc.gc.ca/e/pdf_22427.htm

- ***If you are collecting any of the above personal identifiers, justify why each item is required:***

c) ***What patient information source are you accessing?***

- Health Records/Clinic/Office Files? (Specify which)
 Electronic Database (Specify which)
 Outside Institution (Specify which)
 Other (Specify which)

- 26. SUBJECT IDENTIFICATION:** Indicate how study subjects will be identified on data collection forms (e.g. study number, initials).

27. DATA STORAGE: How will data be stored?

- Computerized files (specify): Server Desktop Laptop Other device (e.g. USB key)
 Audio recordings
 Hard copy

- Videotape
- Other (e.g. PDA):
- If a portable device is to be used, justify:

28. SECURITY:

a) Indicate the steps to be taken to ensure security of data with personal identifiers. Please check all that apply.

<i>PROCEDURAL MEASURES</i>	
<input type="checkbox"/> Data access to the segregated/identified data will be limited to a "need to know" basis ²	
<input type="checkbox"/> There will be an audit trail of access to electronic records	
<i>PHYSICAL</i>	
<input type="checkbox"/> Completed data abstraction forms will be stored in locked filing cabinets in secure location – Specify:	
<input type="checkbox"/> Computers will be housed in a locked secure location – Specify:	
<input type="checkbox"/> Data file backup will be stored in a separate, locked secure location – Specify:	
<input type="checkbox"/> Other – Specify:	
<i>TECHNICAL</i>	
<input type="checkbox"/> Data will be stored on a computer which is password protected	
<input type="checkbox"/> Data will be stored in a computer file which is password protected	
<input type="checkbox"/> Data will be encrypted (at least 128 bit encryption protocol)	
<input type="checkbox"/> Frequent backups of data will occur	
<input type="checkbox"/> Data will be stored on computer systems with virus protection	
<input type="checkbox"/> Data will be stored on computer systems with uninterrupted power source	

² Reminder: All amendments to previously approved research plans require REB approval, including any subsequent amendment affecting who is given access to the data.

b) What are the possible harms/risks to patients if personal health information was inappropriately released and how will you manage the risks? (Describe briefly)

29. ACCESS: Who other than those named in Item #2 will have access to the data?

30. PRIVACY TUTORIAL: Have all those who have access to personal health information completed the Grand River Privacy Tutorial? YES NO

or

Have those accessing personal health information completed an equivalent type of privacy tutorial? (e.g. <http://ethics.mcmaster.ca/chart/>) YES NO

If yes, which one? _____

NOTE: As of January 1, 2008 those requiring access to personal health information must successfully complete a privacy tutorial. Those requiring access to personal health information at Grand River Hospital must successfully complete that tutorial.

31. TRANSFER OF INFORMATION: Will personal health information data be sent outside of the institution where it was collected?

YES NO -- go to Question 32.

a) Why is it necessary to send data outside of the institution where it was collected?

b) How will the data be sent?

- Fax (Describe security at the receptor site)
- Private Courier (must be able to trace delivery)
- Canada Post – Xpresspost or Priority Courier (Regular mail may not be used.)
- Other (Please specify):

c) Where will data be sent? Specify the names and affiliations of persons outside of your research team (e.g. technical service providers, other researchers) who will have access to the data:

d) Attach a copy of the User Agreement with the recipient. Also, please forward a signed and dated copy before transfer is made.

32. LINKAGE: Do you plan to link the locally collected data with any other data set(s) (e.g. OHIP data, census tract data)?

YES

If YES, a) identify the data set, b) justify why the linkage is necessary, c) explain how it will occur and d) provide a list of data items used:

NO

33. ONGOING USE: Will this data be entered into an ongoing electronic database for future use in another research study? (Please note: Any secondary analysis must be approved by the REB prior to implementation.)

YES. If yes, specify where it will be stored, who will be the custodian (i.e. the person responsible for data storage and integrity), who will have access to it, and security measures:

NO

34. STORAGE TIME:

(a) How long do you plan to keep the data? – Specify:
(Please note: You are required to destroy identifiers [or links] at the earliest possible time.)

(b) Will data be destroyed or irreversibly anonymized (i.e. the key identifying the link between data and the individual's identity is deleted)? When? _____

AGREEMENT

I agree to abide by the ethical guidelines and procedures of the Tri-Hospital Research Ethics Board, of the *Tri-Council Policy Statement*, of my profession or discipline, as well as of the institution in which the research is undertaken. I am aware of my responsibility to be familiar with these standards.

Approval by the THREB to conduct research at Cambridge Memorial Hospital and/or Grand River Hospital and/or St. Mary's General Hospital is limited to the conditions and details outlined within this Application Form. Approval from the THREB must be granted prior to any departures from this protocol. The principal investigator assumes full responsibility for this study as detailed and will notify the THREB should any unexpected results, serious medical events, or complaints arise. Any new information learned about potential risks must also be communicated (i.e., information concerning risks learned from new publications or from other current research projects).

I understand that **for clinical trials** both 1) approval by THREB and 2) separate approval by the Hospital Administration of the contract or Clinical Trial Agreement must be obtained before beginning the project.

I further agree to **notify the Tri-Hospital Research Ethics Board of any change** in the **methodology** or **status** of the research project and to comply with requests made by the **THREB** during the life of this research.

The principal investigator further agrees to submit the entire protocol for review **ANNUALLY. A final report of the study is to be provided to the THREB within three months of study completion.** (Submission forms are available on the THREB website or from the THREB office.)

Signature of Local Responsible Investigator

Date

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

TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)
Application – Part 3
ADMINISTRATIVE/INSTITUTIONAL APPROVAL OF RESEARCH PROJECT
(Projects must receive separate approval from each institution involved.)

This part of the application is found as a separate document in the forms list and must be completed by the institution and be received by THREB before the project can be accepted for review.

For sponsored studies, a budget must also be included with the application.

It is the investigator's obligation to contact the appropriate institutional representative to initiate the administrative impact review of the project.

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

For Grand River Hospital:

Tyla Fullerton
Research Coordinator
Decision Support Consultant
Grand River Hospital
835 King Street West
Kitchener, Ontario, N2G 1G3
Phone: 519-749-4300 ext.
5167
tvla.fullerton@arhosp.on.ca

**For Cambridge Memorial
Hospital:**

Cheryl Vandervalk
Administrative Assistant to the
VP, Patient Services and CNE
Cambridge Memorial Hospital
700 Coronation Blvd.*
Cambridge, ON * N1R 3G2
P - 519-621-2330 ext. 2350
cvandervalk@cmh.org

**For St. Mary's General
Hospital:**

Don Shilton
VP Patient Services
St. Mary's General Hospital
911 Queen's Blvd.
Kitchener, ON N2M 1B3
dshilton@smgh.ca

Application Part 4
TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)
DETERMINATION OF FEE REQUIREMENTS

Investigator _____

THREB # _____

IS THIS STUDY INDUSTRY-SPONSORED? YES NO**1. REVIEW FEES – NON-PEER REVIEWED STUDIES**

- The application review fee for any of these studies submitted after August 31, 2007 will be \$2000. 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, the development of diagnostic tests, or new pharmacological agents.
- Please attach your **cheque made payable to “Cashier, Grand River Hospital.”** This cheque must be received by THREB before approval will be given.
- In addition any changes to protocol requiring a full review of the study will be charged \$300.

2. 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.

3. 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.
-