

**TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB) / HEALTH RECORDS
APPLICATION FOR RETROSPECTIVE REVIEW OF
PERSONAL HEALTH INFORMATION (Medical Charts/Health Records)**

INSTRUCTIONS & GUIDELINES

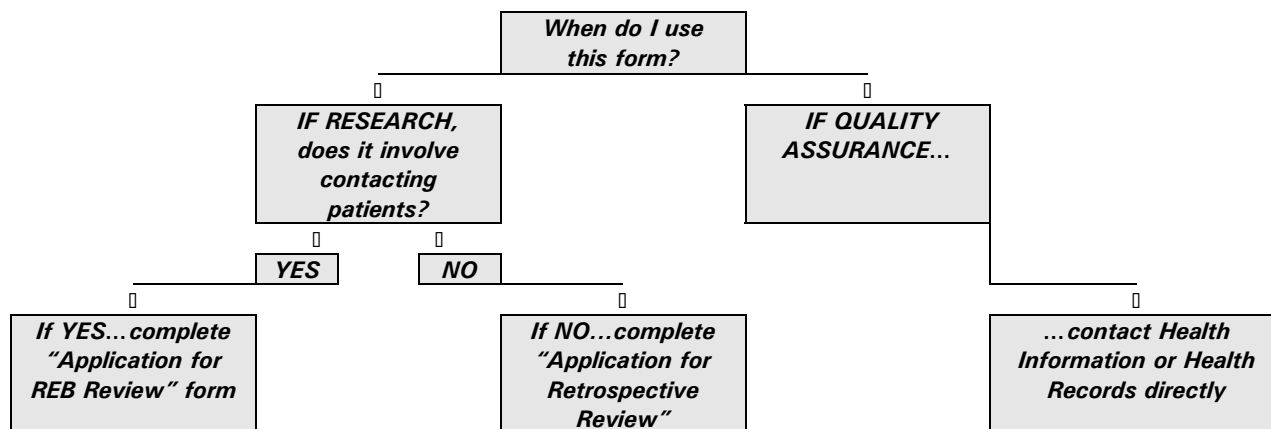
When to use this form?

*Retrospective review pertains to records that exist at this time. Please use this form **ONLY** if you plan to conduct **research** that involves a retrospective review of medical records and if you will **NOT** collect ongoing or other any other information **FROM OR ABOUT** the patient. This form is meant to capture the necessary elements of the **research plan** for this project. If you are proposing to contact patients for consent or for any other purpose, please use the standard "Application Form" instead.*

Is this Quality Assurance or Research?

***Research** involves a systematic investigation to establish facts, principles or generalizable knowledge. Research requiring ethics review according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Article 1.1) includes all research involving living human subjects, as well as research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses.*

***Quality assurance** studies are considered to be internal studies related directly to assessing the performance of the institution or its employees or students within the mandate of the institution. Whenever there is any doubt as to whether a particular study is research or not, the opinion of the Tri-Hospital Research Ethics Board (THREB) should be sought.*



Is this Quality Assurance?	True / False?
<ul style="list-style-type: none"> The study involves the systematic monitoring, assessment or evaluation of the various aspects of an organization (e.g., a service, program, project or facility of the organization, or performance of its employees or students within the mandate of the organization or according to the terms of employment or training) to ensure that standards of quality are being met, or to correct or enhance the various aspects of the organization and does not seek to establish generalizable knowledge. 	

*If you answered **True** to the above statement, there is no need to submit an application to THREB. Contact Health Records or Health Information directly (see below for contact information) and use their application form. If, however, your retrospective review of records is research, this application form will serve also for Health Information or Health Records. When in doubt contact the THREB Office. Applications for projects submitted on this form will be reviewed by at least two members of the REB and, if approved, will be sent to the appropriate Health Information or Health Records Department for their approval.*

Do I need to get patient consent?

Federal and provincial privacy regulations require that all individuals provide informed consent and authorization for the use of their personal health information [For Ontario: Personal Health Information Protection Act (PHIPA - Nov. 1, 2004)]. The provisions of the regulations cannot be waived unless the following criteria are met: (a) the research purposes cannot be achieved without the information; (b) it is impracticable to obtain consent; (c) the information is used in a manner that will ensure its confidentiality; and (d) the public interest in conducting the research exceeds the public interest in protecting the privacy of the individuals. A Research Ethics Board is allowed to waive the requirement for subject consent and authorization if these criteria are met. The THREB will review this application and determine whether consent is required. However, it is the responsibility of the applicant to provide the justification for waiver of consent.

Personal Identifiers

Investigators should plan to collect personal data at the lowest level of identifiability necessary to achieve the study objectives.

The use of personal health information for research is regulated in Ontario by the Personal Health Information Protection Act (PHIPA): http://www.e-laws.gov.on.ca/DBLaws/Statutes/English/04p03_e.htm. The act defines personal health information and for research on personal health information it requires review by a research ethics board and provides some criteria on which the REB should base its decisions.

Data identifiability can be characterized as a continuum or sliding scale, in which the divisions between degrees of "identifiability" and "anonymity" are not always clear-cut. 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 further information, consult the "Guidelines for Protecting Privacy and Confidentiality in the Design, Conduct and Evaluation of Health Research: Best Practices" from the Canadian Institutes of Health Research: <http://www.cihr-irsc.gc.ca/e/about/22085.shtml>

Approval Process

Applications are submitted to THREB. Please send original and 2 copies. Following review and approval by THREB, the application form with the signature of the Chair will be sent to the appropriate Manager(s) for further review and final approval. Once approval is given by the Manager(s), a copy of the application form signed by both THREB and Health Records/Information will be sent to the investigator and will constitute final approval. A copy of the signed sheet(s) will also be returned to THREB to complete their records.

Mail completed research 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

Contacts for Health Information/Health Records:

Cambridge Memorial Hospital: Betty Devenny, Manager of Health Records and Chief	Grand River Hospital: Brennan Hardy Privacy Analyst	St. Mary's General Hospital: Pam Hyde Supervisor, Health Records
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Privacy Officer 519-621-2333 ext. 2507	Phone: 519-749-4300 ext. 2103 Fax: 519-749-4311 brennan.hardy@grhosp.on.ca	519-744-3311 ext. 6658 phyde@smgh.ca
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**TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)
APPLICATION FOR RETROSPECTIVE REVIEW OF PERSONAL HEALTH INFORMATION
(MEDICAL CHARTS/HEALTH RECORDS)**

Project # _____
(assigned by THREB)

1. a) Title of Study:

b) List up to 5 keywords that describe this project:

2. Is this a student project? [] Yes [] No

<u>Name(s) & Degree(s) of Investigator(s)</u>	<u>Title(s) or Position(s)</u>	<u>Clinical Program</u>	<u>Hospital Affiliation</u>	<u>Phone #</u>	<u>FAX#</u>	<u>Email</u>
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(a) Locally Responsible Investigator: (Only one person can be designated as the Locally Responsible Investigator. If more than one name is listed, the first name will be assigned the role of Locally Responsible Investigator. The Locally Responsible Investigator must have an appointment at the institution where the application is being submitted for review)

<i>Name & Degree(s)</i>	<i>Title or Position</i>	<i>Clinical Program</i>	<i>Hospital Affiliation</i>	<i>Phone #</i>	<i>FAX #</i>	<i>Email</i>

(b) Funding Source (Name of research sponsor/funding agency/industry partner – state full name):

(c) Indicate location(s) where the study will be conducted:

- [] Cambridge Memorial Hospital
- [] Grand River Hospital
- [] St. Mary's General Hospital
- [] Community – specify:
- [] Other – specify:

(d) Will this study be reviewed by another Research Ethics Board or Institution? [] YES [] NO
If YES, please attach any other REB or institutional approvals. [] Attached [] To follow

(e) Conflict of Interest: Will any investigators, members of the study team, or their partners or immediate family members:

- (i) Function as an advisor, employee, officer, director or consultant for the sponsor? [] YES [] NO
- (ii) Have direct or indirect financial interest in the drug, device or technology employed

- (including patents or stocks) in this study? YES NO
- (iii) Receive an honorarium or other benefits from the sponsor (apart from fees for service)? YES NO
- (iv) If the answer is YES to any of the above, please describe and explain how that conflict of interest is being managed to ensure that participant rights and welfare are not affected.

Attached

4. Individual(s) who will be reviewing/abstracting medical records/charts:

<i>Name and Degree(s)</i>	<i>Staff Affiliation? (Specify CMH,GRH, SMGH or None)</i>	<i>Profession</i>	<i>Precise Role on Project</i>	
				<i>Leave this</i>
				<i>column blank</i>

5. Additional individuals on the research team who will be given access to the collected data:

<i>Name and Degree(s)</i>	<i>Staff Affiliation? (Specify CMH,GRH, SMGH or None)</i>	<i>Profession</i>	<i>Precise Role on Project</i>	
				<i>Leave this</i>
				<i>column blank</i>

6. What is the purpose of the study, the research objectives and the research question(s)? (Describe briefly)

7. Risks and Benefits of the Proposed Study.

(a) What are the anticipated public and scientific benefits of the study? (Describe briefly)

(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)

8. 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)

9. What type of data do you need?

- Aggregate** (i.e. you do not need to view individual medical charts/health records, e.g. you want to determine how many post-op wound infections occurred in patients with hip replacement surgery?)
- or **Person level data** (i.e. you need to view individual medical charts/health records?)

10. If you require only aggregate data (i.e. no access to individual health records), indicate your search criteria (e.g. diagnosis, procedure, time period, other):

COMPLETE FOR AGGREGATE DATA ONLY:

There is no further information required at this time if you require only aggregate data. Please 1) sign here to verify that you will not be abstracting personally identifiable information from patient charts, 2) sign the Confidentiality agreement at the end of the Application and submit the Application to the THREB. Otherwise continue completing the Application.

Locally Responsible Investigator

Date

11. *If you require person level data, are you planning to obtain consent from each patient for access to and use of their personal health information?*

YES – If YES, this is the incorrect form – refer to the Instructions on “When to use this form”.

NO – If NO, provide justification for a waiver of consent (see Instructions under “Do I need to get patient consent?”)

12. *If you require person level data, are you collecting any of the following 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:

13. *How will relevant patient records be identified?*

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.*

14. *How many patient records will be reviewed?*

15. **Data to be abstracted for the time period of (from when to when?):**

Start date _____ **End date** _____

16. **Attach data collection form or list of fields to be abstracted.** (NOTE: This is mandatory: Application will be returned if this information has not been included.)

17. **How will study subjects be identified on data collection forms (e.g. study number, initials...)?**

18. **Are any sensitive issues raised in this study which may require subject consent?** (e.g. HIV status, mental health problem or diagnosis, subjects identifiable, e.g. pedigrees, other)

YES If yes, justify not getting patient consent and specify additional safeguards for confidentiality:

NO

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

- a) identify the data set(s),
- b) explain how the linkage will occur,
- c) justify why the linkage is necessary, and
- d) provide a list of data items used.

20. **Will a portable device (e.g. laptop computer, USB key) be used to collect or transfer data?** Yes No
If yes, justify:

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

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

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

22. **(a) Will data be sent outside of the institution where it was collected?**

YES

NO -- go to Question 23.

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

- (c) **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):

(d) **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:**

(e) **Attached a copy of the User Agreement with the recipient. Also, please forward a signed and dated copy before transfer is made.**

23. Will this chart review be entered into an ongoing electronic database for future use in another research study?

(Please note: Any secondary analysis must be approved by the THREB 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

24. (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?** _____

Confidentiality Agreement

THE FOLLOWING REPRESENTS THE TERMS AND CONDITIONS UNDER WHICH THE HANDLING OF CONFIDENTIAL INFORMATION FOR THE PROJECT SHALL PROCEED. THESE TERMS AND CONDITIONS HAVE BEEN DRAFTED IN COMPLIANCE WITH THE *PERSONAL HEALTH INFORMATION PROTECTION ACT* AND OTHER PRIVACY LEGISLATION.

1. All information received or exchanged will be held in strict confidence.
2. Information will not be used for any purpose other than for the project for which it was provided. The information will be shared only with those individuals listed on this form, who are working directly on the project, except for authorized oversight of the study.
3. No attempt will be made to contact any individual to whom the information relates, directly or indirectly.
4. Information will be stored in a location that is physically and/or technically secure and to which access is given only to the individual(s) listed on this form.
5. All direct identifiers will be segregated/stripped from clinical data; a unique study identifier (i.e. a randomly generated or unique identifying number) will be assigned to each patient record; the Master list linking the ID with identifiable material will be stored in a separate computer file and/or physical location; the Master list will be locked, and password protected and encrypted if information is to be put on any portable device.
6. Data sent outside of the institution will require that the parties enter into an information transfer agreement before the data transfer takes place.
7. Policies and procedures on the retention and destruction of information must be in place by the party undertaking the project.
9. It is strongly recommended that members of the research team and any individual(s) listed below read the *Personal Health Information Protection Act*.
10. Publication of confidential information regarding the institution requires adherence to the following principles:
 - The institution agrees to allow the publication of the information as it pertains to the project providing that the institution or its practices are not the main focus of the publication.
 - In cases where the publication focuses on the institution, the institution reserves the right to review and approve the use of this information prior to publication.
 - The institution will be acknowledged within any publication as providing the source information.
 - A copy of the publication will be given to the institution.
11. Information that is lost or stolen must be reported to the Chief Privacy Officer of the appropriate institution at the first reasonable opportunity.
12. A breach of institutional policy regarding access to information and protection of privacy may have serious consequences or be just cause for termination of my employment and/or affiliation with the institution.

Signature of the Locally Responsible Investigator

Date

Signatures of Research Team members:

Print Name	Signature	Date Signed

For REB/Health Information/Health Records Use only (when patient record source is Health Records or Health Information Dept)

THREB Project # _____

Title of Study:

Locally Responsible Investigator:

[] Requires further review by Research Ethics Board: _____
THREB Chair Date

[] Approved by REB – forward to Manager,
Health Records/Health Information _____
THREB Chair Date
Michael D. Coughlin, Ph.D.

[] Approved by Health Records/Information _____
Manager, Health Records/Information Date
Print Name _____

Comments:

FINAL APPROVAL: Following approval by THREB the application form with the signature of the Chair will be sent to the appropriate Manager for further review and final approval. Once approval is given by the Manager, a copy of the application form signed by both THREB and Health Records/Information will be returned to THREB to complete their records and THREB will send out a final letter of approval.