

For Administrative Use Only:	
File Number: _____	Date Received: _____

## Application for Research Ethics Review

<b>PART 1: IDENTIFICATION</b>		
<b>1.1 Name &amp; Mailing Address of Principal Investigator</b> <small>GN 1.1</small>	<b>1.2 RQHR Affiliation</b> <small>GN 1.2</small> Staff position: Hospital Department: Hospital Division:	
<b>1.3 Phone:</b> _____	<b>1.4 Fax:</b> _____	<b>1.5 Email:</b> _____
<b>1.6 Project Title</b> <small>GN 1.6</small> _____		
<b>1.7 Proposed Project Period: From (MM/DD/YY)</b> _____ <b>to</b> _____		
<b>1.8 If this is a student project, please provide the name and department of your supervisor:</b> Supervisor Name: _____ Telephone: _____ Hospital/University & Department: _____		
<b>1.9 Can this application be considered for an Expedited Review?</b> <small>GN 1.9</small> <input type="checkbox"/> No <input type="checkbox"/> Yes		
<b>1.10 Declaration by Principal Investigator (or Supervisor for student projects):</b>  By signing below, I certify that I have read this application together with its attachments and that all information provided herein is accurate and complete. If circumstances should arise that materially affects the accuracy and completeness of the information provided, I will immediately report the new information in writing. I will abide by all applicable laws, regulations and international guidelines, and the policies of RQHR concerning the conduct of research in humans. In addition, this serves as application for the disclosure of health information to be used in research and I, on behalf of project personnel identified in this document, agree to the following: <ul style="list-style-type: none"> <li>▪ To comply with the local <i>Health Information Protection Act</i> (HIPA) and all regulations under that Act;</li> <li>▪ To comply with all conditions imposed by the RQHR relating to the use, protection, disclosure, return, or disposal of the health information;</li> <li>▪ To comply with all requirements of the RQHR to provide safeguards against the identification, direct, or indirect, or an individual who is the subject of the health information;</li> <li>▪ To use the health information only for the purpose of conducting the proposed research;</li> <li>▪ To not publish the health information in a form that could identify the subject of the health information;</li> <li>▪ To not attempt to contact the subject of the health information except in accordance with the Act;</li> <li>▪ To allow the Custodian of health information access as prescribed by the local HIPA.</li> </ul>		
_____ <b>Signature of Principal Investigator</b>		_____ <b>Date (MM/DD/YY)</b>
<b>1.11 RQHR Department Head:</b> I confirm that the Principal Investigator has the qualifications, experience, and facilities to carry out this research.  _____		
_____ <b>Signature of Department Head</b>	_____ <b>Date (MM/DD/YY)</b>	_____ <b>Printed Name</b>

**1.12 PROJECT PERSONNEL: List all Co-Investigators, Study Coordinators, Research Assistants, Students, and Advisory Committee Members** <sup>GN 1.12</sup>

<p><b>Full Name:</b></p> <p><b>Project Position:</b></p> <p><b>RQHR Department/Division (if applicable):</b></p> <p><b>University Faculty/Department (if applicable):</b></p>	<p><b>Full Name:</b></p> <p><b>Project Position:</b></p> <p><b>RQHR Department/Division (if applicable):</b></p> <p><b>University Faculty/Department (if applicable):</b></p>
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**1.13 Has this project applied for/ received ethical approval from another Research Ethics Board?**

No  Yes (Attach Certificate of Approval)

**1.14 Source of funds** <sup>GN 1.14</sup>  For-profit sponsor  Grant  Grant-in-aid  No funding  Other:

**1.15 Status of Funds:**  Awarded  Pending Provide name of funding source:

**1.16 Institution(s) where the research will be carried out:**  RGH  Pasqua  WRC  Other (list):

**1.17 Is the REB Review Fee included with this Application?** <sup>GN 1.17</sup>  No  Yes  Not applicable

**1.18 Has this research proposal received any independent scientific peer review?** <sup>GN 1.18</sup>  No  Yes (attach)

**1.19 If yes, provide full details below as relevant. Include the names of committees or individuals involved in the review. State whether the peer review process is ongoing or completed.**

**1.20 If the study involves investigational drugs or devices or marketed drugs/devices outside of their indications, indicate whether or not approval has been obtained from the appropriate federal regulatory agency for this purpose?** <sup>GN 1.20</sup>

Yes Name of agency:

Date of approval (MM/DD/YY):

No

Request for Approval submitted. (Notify RQHR REB Chair when approval is obtained)

Not applicable

## PART 2: DEPARTMENT APPROVALS

Obtain signatures of all departments/divisions/services whose operations will be affected by your protocol. This is to ensure that prior to commencement of the investigation, these individuals have had an opportunity to assess the impact of the proposal on their area. This will include reviewing the proposed budget so they can accommodate any additional requirements arising from the protocol. <sup>GN 2.0</sup>

**Project Title (abbreviated):** \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_

**IMPORTANT NOTE TO DEPARTMENT HEADS:**

*Your signature below indicates that you acknowledge and accept the impact (clinical, financial, or otherwise) of the above mentioned research study on your department/division/program/portfolio and that you agree with the costs itemized in the study budget.*

Service Required?	Department	Department Head		DATE
		Print Name	Signature	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Pharmacy			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Health Records			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Diagnostic Imaging			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Cardiac Diagnostics			
<input type="checkbox"/> Yes <input type="checkbox"/> No	ICU			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Lab Med & Pathology			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Neurodiagnostics			
<input type="checkbox"/> Yes <input type="checkbox"/> No	SWADD			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Nursing Unit- specify			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Nursing Unit – specify			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Nutrition and Dietetics			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Outpatient Services			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Anesthesia			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Respiratory Therapy			
<input type="checkbox"/> Yes <input type="checkbox"/> No	MEDEC			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Palliative Care			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Other:			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Other:			

## PART 3: SUMMARY OF RESEARCH PROPOSAL

The REB requires sufficient background information and clear details of the research design in order to assess the scientific merit of the proposal in relation to ethical issues. <sup>GN 3.0</sup>

Describe the proposed research project using the following headings: a) Introduction, b) Research purpose and objectives, c) Hypotheses, d) Research Methods, e) Analyses, and f) Potential Significance. **Append no more than 2 additional sheets.**

## PART 4: STUDIES INVOLVING THE USE OF RQHR HEALTH INFORMATION

4.1 Does the study consist solely of the review of existing RQHR health information?  Yes  
 No - **PROCEED TO PART 5**

4.2 Will the project require access to personally identifiable health information?  Yes  
 No - **PROCEED TO PART 8**

4.3 Is this a multi-centre study?  Yes  No

4.4 If using identifiable information, indicate why the study could not be completed with de-identified data.

4.5 How many charts /health records will be reviewed in total (from RQHR and, if a multi-site study, across all sites)?

4.6 Describe which records will be selected and the criteria for their inclusion.

4.7 Describe which charts will be excluded from the study.

4.8 Specify who will be responsible for abstracting the data and where the data abstraction will occur.

4.9 Describe the planned return or destruction plans for any original documents you will obtain for the study.

4.10 Who originally collected the data you require and for what purpose was it originally collected?

→ Proceed to Part 8

## PART 5: STUDIES INVOLVING HUMAN SUBJECTS

5.1 Is this a multi-centre study?  Yes  No

5.2 How many subjects in total will be enrolled in the entire study?

5.3 How many subjects will be in the control group?

5.4 How many subjects from the RQHR or your site will be enrolled?

5.5 Describe who will be selected and the criteria for their inclusion. <sup>GN 5.5</sup>

5.6 Describe who will be excluded from participating. <sup>GN 5.6</sup>

5.7 Describe how potential subjects will be identified. Include the source of the contact information, who originally collected the contact information, and for what purpose it was originally collected. <sup>GN 5.7</sup>

**5.8** Describe how, and by whom, potential subjects will be contacted? **Attach** copies of initial letters of contact and any other recruitment documents (e.g. advertisements, flyers, verbal script, etc.). <sup>GN 5.8</sup>

**5.9** Describe the selection and recruitment process for subjects in the control group, if these differ from above. **Attach** letters of contact and any other recruitment documents, if applicable.

**5.10** How much time will a participant be asked to dedicate to the project? (*i.e., how many minutes or hours over how many weeks or months*) <sup>GN 5.10</sup>

**5.11** How much time will a control group member be asked to dedicate to the project? (*i.e., how many minutes or hours over how many weeks or months*) <sup>GN 5.11</sup>

**5.12** If monetary compensation or reimbursements for expenses will be offered to the participants, provide details of amounts and payment schedules. <sup>GN 5.12</sup>

**5.13** Describe your plans for feedback to the subject. <sup>GN 5.13</sup>

## PART 6: PROJECT DETAILS

**6.1** Which of the following procedures are involved in this study? Check all that apply. Projects relying **solely** on the use of medical records or the secondary use of data should proceed to **PART 8**.

<input type="checkbox"/>	Drug administration	<input type="checkbox"/>	Secondary use of data	<input type="checkbox"/>	Experimental medical devices
<input type="checkbox"/>	Collection of blood	<input type="checkbox"/>	Collection of other tissue	<input type="checkbox"/>	Video/audio recording
<input type="checkbox"/>	Surgical procedures	<input type="checkbox"/>	Individual interview	<input type="checkbox"/>	Use of medical records
<input type="checkbox"/>	Imaging studies	<input type="checkbox"/>	Group interview	<input type="checkbox"/>	Questionnaires

**6.2** Provide a description of the procedures that differ from standard care (including manipulations of type, quantity, and route of administration of drugs and radiation, operations, tests, use of medical devices that are prototypes from those in clinical use, interviews, or questionnaires). <sup>GN 6.2</sup>

**6.3** What is known about the risks and benefits of the proposed research? Include any known side effects that may result from the experimental treatment. <sup>GN 6.3</sup>

**6.4** What strategies will be put in place to minimize and/or manage the harms for subjects and other affected individuals? <sup>GN 6.4</sup>

**6.5** Does the study involve research to be carried out in physician's private offices?  Yes  No

## PART 7: INFORMED CONSENT

7.1 Describe the consent process: a) Who will ask for consent? b) Where, and under what circumstances? <sup>GN 7.1</sup>

7.2 Is the person obtaining consent in a perceived position of power or authority in relation to the participant? <sup>GN 7.2</sup>  
 No  Yes  
If **YES**, indicate how coercion of participants will be avoided:

7.3 How long will the subject have to decide whether or not to participate? If this will be less than twenty-four hours, provide an explanation. <sup>GN 7.3</sup>

7.4 Will the subjects have any problems giving informed consent on their own behalf? <sup>GN 7.4</sup>  Yes  No  
◆ **If No**, skip to Box 7.5.  
◆ **If Yes**, provide details of the nature of the incompetence (for instance, young age, mental or physical condition).

7.4a If the subjects are not competent to give fully informed consent, who will consent on their behalf?

7.4b Will the subject be able to give assent to participate?  No  Yes (Explain how assent will be sought. Attach copies of the assent form as necessary.)

**7.5** Describe any situation in this research in which the renewal of consent might be appropriate, and how this would take place. <sup>GN 7.5</sup>

**7.6** What provisions are planned for subjects, or those consenting on a subject's behalf, to have special assistance, if needed, during the consent process (e.g., consent forms in Braille, or in languages other than English)? <sup>GN 7.6</sup>

**7.7** Describe the circumstances under which the study could be stopped early. Should this occur, describe what provisions will be put in place to ensure that the subjects are fully informed of the reasons for stopping the study. <sup>GN 7.7</sup>

**7.8** Describe the provisions made to break the code of a double-blind study in an emergency situation, and indicate who has the code. <sup>GN 7.8</sup>

## PART 8: PRIVACY PROTECTION

This section **MUST** be completed for all research studies. <sup>GN 8.0</sup> The local **Health Information Protection Act** requires an assessment of the risk to privacy and how the risk will be reduced (see examples on the following page).

**8.1** List all personal and health information sources and major data elements that will be collected for the study.

**8.2** For each information source and major data element collected, describe the purpose for its collection and use of data (please relate purposes to information listed above).

**8.3** List the project personnel who have access to the information listed above. <sup>GN 8.3</sup>

**8.4** Will information be disclosed to anyone other than project personnel, or for any purpose other than the purpose included in this application?  No  Yes **If yes, please explain:**

**8.5** Will you seek consent to access existing patient information, for example, Health records? <sup>GN 8.5</sup>  Yes  No **If yes, this should be incorporated in the consent form included with the application. If no, indicate the reason for not seeking individual consent (i.e. unreasonable, impractical, or not feasible) and provide justification.**

**8.6** Describe the storage arrangements and final disposition of information collected for research purposes. <sup>GN 8.6</sup>

**8.7** How will the confidentiality of the original data as well as the subjects' identities be protected? <sup>GN 8.7</sup>

**8.8** Who will have access to any list that links subject names to their study ID number, consent form, enrolment log, etc.? <sup>GN 8.8</sup>

**8.9** Provide an assessment of privacy risks and controls used to mitigate these risks for the project. (You may use the examples below if applicable.) <sup>GN 8.9</sup>

**Examples of Potential Privacy Risks and Potential Safeguards**

Potential Risk	Potential Safeguard/Solution
Unauthorized external or internal access to identifying information through: - Active use - Transmission - Storage - Disposal	- project personnel screening/agreements - access authorization procedures - designated systems administrator - passwords/screen timeouts - system access audits/disclosure logs - secure mail/transport - firewall/virus protect - encrypted transmission - secure paper-based storage - shredding/wiping
Identification through publication or release	- Aggregation levels - Alternate identifiers
Identification through data-matching	Use of non-linkable elements or identifiers
Loss of data control outside jurisdiction	Confidentiality and security agreements for out-of-province recipients or storage providers
Loss of data control through non custodian contractors	Confidentiality and security agreements (e.g. information managers, ASP's)

## PART 9: INVESTIGATOR PROFILE

If research is a student project, please provide the following information for both the student and the supervisor.

### EDUCATION:

#### 9.1a Principal Investigator:

Degree	University or Institution and Location	Field	Year

#### 9.1b Student (if applicable):

Degree	University or Institution and Location	Field	Year

### 9.2 PUBLICATIONS:

List papers published **during last five years**. Include papers accepted for publication. Abstracts should be identified as such (append additional pages as needed). <sup>GN 9.2</sup>

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## PART 10: ATTACHMENTS

Provide a full and accurate listing of all documents submitted with this application. GN 10.0

Document	Included?	Comments
Certificate of Approval from another REB	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Peer Review reports	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Subject Consent Form	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Control Subject Consent Form	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Assent Form	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Tissue/Blood Banking Consent Form	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Letter of Initial Contact	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Advertisement to Recruit Subjects	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Questionnaires, tests, interview scripts, etc.	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	
Other- please specify:		
Other- please specify:		