



Application for Research Ethics Approval

To submit a research proposal to the Ottawa Hospital Research Ethics Board (OHREB), it is mandatory to submit the actual protocol.

The application forms must be filled out completely. Please bear in mind that some members of the OHREB may not be experts in your own field so please strive, where appropriate, to make your submission understandable to those outside your area of expertise. Information Sheets and Consent Form must be included with the protocol (where appropriate).

Please submit the appropriate number of copies:

For protocols requiring **full review**:

- Application 18 copies (signed original plus 17 copies)
- Patient Information Sheet and/or Consent forms * 18 copies (original plus 17 copies)
(* English version only)
(Once the English version has been approved by the OHREB, the French version may be submitted.)
- Departmental Impact Sheet with applicable attachments 18 copies (signed original plus 17 copies)
- Detailed Budget: 18 copies
- Protocol: 8 copies
- Questionnaires, Case Report Forms, etc : 8 copies
- Investigator's Brochure: 2 copies

For protocols requiring **expedited review** :

(Survey, Chart Reviews, Non-Invasive Testing/Intervention):

- Application: 2 copies (signed original plus 1 copy)
- Patient Information Sheet and/or Consent forms * 2 copies (original plus 1 copy)
- Questionnaires, etc.
(* English version only)
(Once the English version has been approved by the OHREB, the French version may be submitted.)
- Departmental Impact Sheet with applicable attachments 2 copies (signed original plus 1 copy)
- Detailed Budget 2 copies (original plus 1 copy)
- Protocol 2 copies (original plus 1 copy)

N.B. All documentation must be typed. Incomplete protocols will be returned prior to review.

TIPS

The forms have been created in Word, using the Forms tool to allow ease of use in completing them. The following are a few tips on completing the document:

- Please use the “TAB” key to move between fields.
- The “Enter” key will create extra space in the form that is not required.
- The form fields will not accept formatting, normal type will be fine.
- It is hoped that you are able to complete the form in the space allocated, however, if you need additional space, please insert a page where appropriate.
- If you have suggestions to improve this form, please let us know.

Protocol Submission

The application form, the protocol, investigator’s brochure, the consent form, patient information sheet, budget, questionnaires and any other material described above should be submitted to:

Ottawa Hospital Research Ethics Board
c/o Ms. Christine Banyard
Ottawa Hospital, Civic Campus
751 Parkdale Avenue
Suite 106
Ottawa, Ontario K1Y 1J7

or

Ottawa Hospital Research Ethics Board
Drop Box Location: Room 1812-A (in the CEP area on the main floor)
General Campus – Ottawa Hospital
501 Smyth Road, Box 201
Ottawa, Ontario
K1H 8L6

To confirm whether or not we have received your correspondence, or to request a copy of lost correspondence, please contact:

Kathy Millar
Ethics Clerk, Research Ethics Board
Phone: 613-798-5555, extension 17523
Email: kmillar@ohri.ca

For information on the status of your protocol up to and including initial approval, please contact:

Christine Banyard
Protocol Officer II, Research Ethics Board
Phone : 613-798-5555, extension 14902
Email: cbanyard@ohri.ca

Or

Linda Longpré
Protocol Officer II, Research Ethics Board
Phone: 613-798-5555, extension 13523
Email: llongpre@ohri.ca

For general inquiries about research ethics including the status of revised information sheets, amendments, renewals, terminations, etc., please call:

Heather McDonald
Protocol Officer I, Research Ethics Board
Phone: 613-798-5555, extension 14146
Email: heamcdonald@ohri.ca

For information on procedural issues, problematic protocols, compensation clauses, OHREB document changes, etc. please contact:

Mary Ann Laviolette
Ethics Co-ordinator, Research Ethics Board
Phone: 613-798-5555, extension 15072
Email: mlaviolette@ohri.ca

For information on and requests for clinical research space, please contact:

Kim Adams
Director, Research Administration, OHRI
Phone: 613-798-5555, extension 15079
Email: kadams@ohri.ca

The Chair of the OHREB is:

Raphael Saginur, M.D.
Phone: 613-798-5555, extension 14902

The Vice-Chair of the OHREB is:

Francine F-A. Sarazin, Ph.D., C.Psych.
Phone: 613-798-5555, extension 14902

The Chair of the HREB is:

Richard F. Davies, MD, PhD, FRCPC
Phone: 613-798-5555, extension 19865

The Vice-Chair of the HREB is:

James A. Robblee, MD, FRCPC
Phone: 613-798-5555, extension 19865

Protocols **must be signed by the Head of the Department or Division** in which the research projects are to be carried out. **(The Principal Investigator or Co-Investigator should not sign as the Head of the Department or Division for their own research studies)**

Protocols will be reviewed on a bi-monthly basis at the OHREB meeting. Please refer to the list for the exact submission deadlines listed under 'Meeting Dates'.

Protocols submitted for '**Expedited Review**' are normally processed within two to four weeks of submission. Applications may be submitted at any time – **the submission dates do not apply** to 'expedited' studies.

Protocols submitted for '**Chart Review**' are normally processed within 24 to 48 hours of submission. Applications may be submitted at any time – **the submission dates do not apply** to 'chart review' studies.

(Revised January 23, 2009)

RESEARCH ETHICS APPLICATION
NOTE: ALL DOCUMENTATION MUST BE TYPE WRITTEN.
 Use the "TAB" key to move between fields.

1. PROTOCOL TITLE

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2. PRIMARY INVESTIGATOR FOR MULTICENTRE TRIALS

Last Name		First Name	
Title/Position		Department & Location (or full mailing address)	
Tel.			
Email		Fax	

3. PRINCIPAL INVESTIGATOR AT THE OTTAWA HOSPITAL

If the Principal Investigator does not hold an academic appointment, indicate who the responsible investigator will be.
Investigators must complete the *Tri-Council Policy Statement On-line Tutorial* and submit a copy of their certificate to Hillary Falconer at hfalconer@ohri.ca. The tutorial can be found at: www.pre.ethics.gc.ca

Last Name		First Name	
Title/Position		Tel. () - ext.	
		Fax () -	
Dept/Unit & Location (full mailing address)		Email	
Division/ Portfolio		Signature:	

4. CO-INVESTIGATORS AT THE OTTAWA HOSPITAL

Last Name		First Name	
Title/Position		Tel. () - ext.	
		Fax () -	
Dept/Unit & Location (full mailing address)		Email	
Division/ Portfolio		Signature:	

Last Name		First Name	
Title/Position		Tel.	() - ext.
		Fax	() -
Dept/Unit & Location (full mailing address)		Email	
Division/ Portfolio		Signature:	

Last Name		First Name	
Title/Position		Tel.	() - ext.
		Fax	() -
Dept/Unit & Location (full mailing address)		Email	
Division/ Portfolio		Signature:	

Last Name		First Name	
Title/Position		Tel.	() - ext.
		Fax	() -
Dept/Unit & Location (full mailing address)		Email	
Division/ Portfolio		Signature:	

Last Name		First Name	
Title/Position		Tel.	() - ext.
		Fax	() -
Dept/Unit & Location (full mailing address)		Email	
Division/ Portfolio		Signature:	

If you need more space an additional form for co-investigators is available on the website.

**5. APPROVAL BY INVESTIGATOR'S DEPARTMENT/DIVISION HEAD/
CLINICAL MANAGER/CHIEF (THIS SHOULD NOT BE THE PRINCIPAL INVESTIGATOR AND/OR CO-INVESTIGATOR)**

Hospital and university division and department administrators are responsible for academic activities within their unit, and may provide guidance and support to investigators. The purpose of this signature section is to ensure that administrators are aware of research activities and the impact of these activities.

- The study answers a reasonable scientific/clinical question and is consistent with hospital/faculty policies and mission.
- The study resources (budget, space, support staff) are adequate to support the study.
- The local investigators are qualified to perform the study.
- There are an adequate number of research participants suitable to be approached for enrolment for this study. This population is not already over-subscribed in clinical research.

I have reviewed this application and agree it should be submitted for ethics approval.

Name		Contact Number : () - ext .
Title/Position		Signature
Dept/Unit & Location (full mailing address)		
Date		

6. REVIEW TYPE

Please indicate whether you are requesting full or expedited review. (Please see our website www.ohri.ca/ohreb for more information on what qualifies for expedited review.)

<input type="checkbox"/> Full Review
<input type="checkbox"/> Expedited Review

7. STUDY TYPE

Describe the Research Project by checking as many of the following as apply: Study Type:	
<input type="checkbox"/>	Investigator driven and sponsored by OHRI
<input type="checkbox"/>	Experimental Research/Clinical Trial
<input type="checkbox"/>	Interventional Research
<input type="checkbox"/>	Non-Interventional Research
<input type="checkbox"/>	Observational Research
<input type="checkbox"/>	Pilot
<input type="checkbox"/>	Sequel to previously approved project (Protocol #: _____)
<input type="checkbox"/>	Genetic Research (Addendum 1 <u>must</u> be included with completed application)
<input type="checkbox"/>	Program Evaluation

<input type="checkbox"/>	New therapeutic method		
<input type="checkbox"/>	Medical Device Research Please attach a letter from sponsor indicating Health Canada application/approval. This is mandatory prior to final REB approval.		
<input type="checkbox"/>	Health Canada Application/Approval is attached (insert as next page)		
<input type="checkbox"/>	Health Canada Application/Approval will be forwarded.		
Location of the Study:			
<input type="checkbox"/>	Single Centre Trial		<input type="checkbox"/> Multicentre Trial
Study Design:			
<input type="checkbox"/>	Randomized, controlled trial		
<input type="checkbox"/>	Phase I	<input type="checkbox"/> Phase II	<input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV
<input type="checkbox"/>	Open Label	<input type="checkbox"/> Single Blinded	<input type="checkbox"/> Double Blinded (or more)
<input type="checkbox"/>	Case-Control study		
<input type="checkbox"/>	Cohort study		
<input type="checkbox"/>	Interview, survey or questionnaire, observation		
<input type="checkbox"/>	Database Research	<input type="checkbox"/> New	<input type="checkbox"/> Existing
<input type="checkbox"/>	Chart Review		
<input type="checkbox"/>	Compassionate Use		
<input type="checkbox"/>	N of 1 Study		
<input type="checkbox"/>	Quality Assurance		
Drug Study: <input type="checkbox"/> Yes <input type="checkbox"/> No			
<input type="checkbox"/>	Involves unusually elevated doses of available drugs		
<input type="checkbox"/>	Involves anticipated high incidence of toxicity		
<input type="checkbox"/>	Drug being used for currently approved indication		
<input type="checkbox"/>	Approved Drug being used for a non-approved indication Please attach a letter from sponsor indicating Health Canada application/approval. This is mandatory prior to final REB approval.		
<input type="checkbox"/>	Health Canada Application/Approval is attached (insert as next page)		
<input type="checkbox"/>	Health Canada Application/Approval will be forwarded.		
<input type="checkbox"/>	Investigational non-approved drug: Please attach a letter from sponsor indicating Health Canada application/approval. This is mandatory prior to final REB approval.		
<input type="checkbox"/>	Health Canada Application/Approval is attached (insert as next page)		
<input type="checkbox"/>	Health Canada Application/Approval will be forwarded.		

8. PURPOSE AND OBJECTIVES

Please state clearly the hypothesis to be tested, in lay terms.

Provide the rationale for the study.

STUDY DURATION

Start Date: / /
DD/MM/YYYY

End Date: / /
DD/MM/YYYY

9. RECRUITMENT

Describe how these research participants will be identified and recruited. **(Only members of the participant's health care team should contact patients at the Ottawa Hospital.)**

In addition, please ensure you address the following:

- If initial contact is by letter or if an **advertisement** is to be used, attach a copy.
- How will the researcher ensure that there are no breaches of patient **privacy**?
- How will the possibility of **coercion**, duress or undue incentive be avoided or minimized?

Are recruitment incentives provided? Yes No
If yes, please describe what they are, and when they will be provided.

Are controls involved? Yes No
Does the study include subjects in a control group? Yes No
If controls are involved, if their selection and/or recruitment differs from the above, provide details.

Does the research include research participants who may not be competent to give informed consent? Yes No If yes, justify and explain how consent will be obtained and from whom.

• Number of Centres recruiting globally:

National Study – Country

International Study – Country

• Total number of research participants being recruited at all centres globally:

- Number of research participants to be recruited at each Ottawa Hospital campus:

Civic

General

Riverside

Other

Provide the rationale for the selected sample size and the methodology used to calculate the sample size:

10. DESCRIPTION OF POPULATION

Inclusion Criteria - Who is being recruited and what are the criteria for their selection?

Exclusion Criteria - What research participants are excluded from participation?

11. DESCRIPTION OF METHODS AND PROCEDURES

If additional space is required, insert one additional page)

Summary of Methods and Procedures. Please include a summary of the following:

- any specific manipulations;
- type, quantity, and route of administration of drugs and radiation; operations; tests; use of medical devices that are prototype or altered from those in clinical use;
- type, and number of interviews or questionnaires; are the questionnaires validated, reliable and have they been pilot tested?
- Are procedures/treatments standard practice or new, what is the risk level?

(Flow diagrams and point form discussion are encouraged and should be appended separately.)

12. RISKS

Describe the discomfort or risks that participants may incur as a result of their participation in this research. Also note the following:

- particular risks associated with each procedure, drug, test or other aspect of the protocol.
- delineate, when appropriate, what risks relate to standard care,
- what risks relate to participation in the study.
- quantify risks where possible by providing percentages, or by describing as rare, common, etc.

Will the management of the participant's condition be prolonged or delayed as a result of the research? Yes No

If yes, explain, specifying any risks associated with prolongation or delay.

Are there any standard therapies, diagnostic procedures or information to be withheld from participants for the purpose of the study? Yes No

If yes, explain, specifying the risks and benefits to the participants and justify.

Are there stopping rules for the study? **(This does not apply to individual patient withdrawal, but to the study as a whole)** Yes No

If yes, please describe.

Is there a data safety monitoring board in place? Yes No

If yes, describe the composition of the board.

What procedures in this protocol are additional to those required for **routine** patient care? **(Include the Impact Sheet with applicable attachments for all procedures which are attributable to this study)**

Is a placebo used? Yes No

If yes, please justify:

13. POSSIBLE BENEFITS

Describe any possible benefits to the participant as a result of their participation in this research.

14. CONFIDENTIALITY

It is the policy of the OHREB that no records with the patient's name leave the Ottawa Hospital.

How will data be protected against breaches in security/privacy? **Be sure to include the following information:**

- If the information will be housed in a database, will it be password protected?
- Confirm that an independent study number will be assigned to each patient record.
- What information will be collected? (A 'Case Report Form' may be provided with these details). No identifying information should be used such as hospital unique number, OHIP #, etc. if any identifying information is required, justification must be provided.
- Date of birth is also considered a personal identifier. Confirm that you are not using date of birth. If it is required, clarify whether month and year of birth will suffice? If you require full date of birth, justification must be provided.
- Indicate how the master list linking the patient to the independent study number will be maintained and safeguarded, and confirm that it will be stored separately and securely.
- Indicate how data containing Personal Health Information (PHI) will be protected against breaches of privacy. (i.e. locked cabinets? password protected?)
- Indicate who will have access to the study data, and which organizations and/or individuals will have access to PHI for audit purposes. Add the OHREB and Ottawa Health Research Institute (OHRI) to the list of possible reviewers.
- Confirm that no PHI will be leaving the Ottawa Hospital.

- Indicate how long information will be kept after the close of the study? (**25 years** for investigational drug and device studies regulated by Health Canada as outlined in Health Canada's Food and Drug Regulations, Division 5 – Drugs for Clinical Trials Involving Human Subjects, Section C.05.012. For all other studies, records must be kept by the investigator for **15 years.**)
- Indicate how paper and electronic data will be destroyed once the storage date has expired (shredded? deleted?)

15. BUDGET

Has this research been funded? <input type="checkbox"/> YES <input type="checkbox"/> NO	
<input type="checkbox"/> If YES provide the: Name of the Agency/Sponsor: Amount of funding received: \$	<input type="checkbox"/> If NO complete the following: Has funding been applied for: <input type="checkbox"/> YES <input type="checkbox"/> NO Name of the Agency/Sponsor: Amount of funding applied for: \$ _____ Date submitted: ____/____/____ <div style="text-align: center;">DD/MM/YYYY</div>
If no funding has been applied for, how will the research be supported? If the study was peer-reviewed, please provide the name of the individual or agency that completed the review.	
Does the industry-sponsored budget contain appropriate overhead? <input type="checkbox"/> A Clinical Trial Agreement has been forwarded to the Contracts Officer <input type="checkbox"/> A Clinical Trial Agreement is attached to the OHREB application Have you included a budget summary for the protocol? (If this is not included, approval of protocol will be delayed. Details on the disbursement of any excess funds received for this study should also be provided.)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Does the REB review fee apply to this study? <input type="checkbox"/> A cheque is enclosed <input type="checkbox"/> An invoice request is enclosed <input type="checkbox"/> A transfer request is enclosed (All industry sponsored research projects are subject to a \$3,000.00 administration fee, and any cooperative group studies that are funded in excess of \$3,000.00 per patient.)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
<p>POTENTIAL CONFLICTS OF INTEREST</p> Please indicate if you have a conflict of interest or separate financial agreements with the sponsor of this study. If yes, please explain.	
<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	

16. STAFFING

What staffing will be required? All staff should be listed and this list maintained during the course of the study. Staff must complete the *Tri-Council Policy Statement On-line Tutorial* and submit a copy of their certificate to Hillary Falconer at hfalconer@ohri.ca. It can be found at www.pre.ethics.gc.ca

This includes research nurses, research co-ordinators, etc. Research nurses should provide a copy of their Nursing Certificate for the current year, to the Research Services Office if this has not already been done for another study.

	Name & Role in Study	Already Employed?	Full-time vs. Part-time	Office/Laboratory Location and Telephone Number
1.		<input type="checkbox"/> YES	<input type="checkbox"/> FT	<p>If <u>new office or laboratory space</u> is required, the Space Planning & Management section of the Departmental Impact form must be signed and submitted</p> <p>Campus:</p>
		<input type="checkbox"/> NO	<input type="checkbox"/> PT	<p>Office/Lab #</p> <p>() - x.</p>
2.		<input type="checkbox"/> YES	<input type="checkbox"/> FT	Campus:
		<input type="checkbox"/> NO	<input type="checkbox"/> PT	<p>Office/Lab #</p> <p>() - x.</p>
3.		<input type="checkbox"/> YES	<input type="checkbox"/> FT	Campus:
		<input type="checkbox"/> NO	<input type="checkbox"/> PT	<p>Office/Lab #</p> <p>() - x.</p>
4.		<input type="checkbox"/> YES	<input type="checkbox"/> FT	Campus:
		<input type="checkbox"/> NO	<input type="checkbox"/> PT	<p>Office/Lab #</p> <p>() - x.</p>
5.		<input type="checkbox"/> YES	<input type="checkbox"/> FT	Campus:
		<input type="checkbox"/> NO	<input type="checkbox"/> PT	<p>Office/Lab #</p> <p>() - x.</p>

In the space below please provide:

a) a list of their qualifications:

b) a list of the duties to be performed, including delegated/sanctioned medical acts and acts performed under the Regulated Health Professions Act if this has not already been done for another study:



DEPARTMENTAL IMPACT

Protocol Title:

Does the protocol require use of Hospital and/or OHRI resources (equipment, staff, space) over and above those normally required in the standard care of a patient?

- | | | |
|-----------|------------------------------|-----------------------------|
| Equipment | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Staff | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Space | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

Will hospitalization or outpatient visits be required beyond what is required for standard care?

- | | | |
|-------------------|------------------------------|-----------------------------|
| Outpatient Visits | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Hospitalization | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

Indicate impacts associated with this Protocol, by Department:

IF YES is indicated, a signature of an individual authorized to sign for the department must be obtained. (Please see our website for a list of contact names <http://www.ohri.ca/ohreb/>)

Signature:

- | | | |
|---------|------------------------------|-----------------------------|
| Nursing | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|---------|------------------------------|-----------------------------|

Please submit Clinical Director's Acknowledgment
www.ohri.ca/ohreb/forms.htm

- | | | |
|----------------------|------------------------------|-----------------------------|
| Emergency Department | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|----------------------|------------------------------|-----------------------------|

- | | | |
|------------------------------------|------------------------------|-----------------------------|
| Health Records
(See Appendix A) | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|------------------------------------|------------------------------|-----------------------------|

Please submit signed Health Records form. www.ohri.ca/ohreb/forms.htm

- | | | |
|---------------------|------------------------------|-----------------------------|
| Laboratory Services | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|---------------------|------------------------------|-----------------------------|

Please submit signed Lab Impact form. www.ohri.ca/ohreb/forms.htm

- | | | |
|-----------------------------------|------------------------------|-----------------------------|
| Radioisotopes
(See Appendix B) | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|-----------------------------------|------------------------------|-----------------------------|

Please submit Radiation Safety form. www.ohri.ca/ohreb/forms.htm

- | | | |
|--|------------------------------|-----------------------------|
| Diagnostic Imaging
(See Appendix B and C) | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|--|------------------------------|-----------------------------|

Please submit signed Diagnostic Imaging form. www.ohri.ca/ohreb/forms.htm

- | | | |
|----------|------------------------------|-----------------------------|
| Pharmacy | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|----------|------------------------------|-----------------------------|

Please submit signed Pharmacy form www.ohri.ca/ohreb/forms.htm

- | | | |
|-----------------------------|------------------------------|-----------------------------|
| Nutrition And Food Services | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|-----------------------------|------------------------------|-----------------------------|

- | | | |
|---------------|------------------------------|-----------------------------|
| Ophthalmology | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|---------------|------------------------------|-----------------------------|

Please submit signed Ophthalmology form www.ohri.ca/ohreb/forms.htm

- | | | |
|-----------------------------|------------------------------|-----------------------------|
| Space Planning & Management | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|-----------------------------|------------------------------|-----------------------------|

- | | | |
|-----------------------------|------------------------------|-----------------------------|
| Clinical Investigation Unit | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|-----------------------------|------------------------------|-----------------------------|

- | | | |
|--------------------------|------------------------------|-----------------------------|
| Cardiopulmonary Services | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
|--------------------------|------------------------------|-----------------------------|