



REB PROPOSAL # _____

**RESEARCH ETHICS BOARD APPLICATION FORM
FOR PROTOCOLS BEING REVIEWED BY THE FULL BOARD**

TITLE OF RESEARCH STUDY:

**PRIMARY CHEO SITE
INVESTIGATOR (ONE ONLY):**

DEPARTMENT/PSU

EMAIL ADDRESS

PHONE #

1. As primary CHEO site investigator I will assume:

- Full responsibility for the research as outlined in this application.
- I will maintain copies of all pertinent information related to the research activities in this project, including copies of the informed consent agreements obtained from all participants.
- I will notify the REB if one of the investigators leaves the Hospital, the Research Institute, or the project.
- I will notify the REB of any developments in the project including an annual report, reports of adverse events, reports of subject recruitment, reports of any study amendments, and a study termination report.

2. Conflict of Interest Statement

Please indicate if the Primary CHEO Site Investigator(s) or co-investigators:

- Function as advisors, employees, directors or consultants for the sponsor? Yes No
- Have direct or indirect financial interest in the drug, device or technology employed (including patents or stocks) in this research study? Yes No
- Will receive honoraria or other benefits from the sponsor (apart from fees for service)? Yes No
- If Yes to any of the above, please describe how the potential conflict of interest is being managed to ensure that participants' rights and welfare are not adversely affected:

- I will notify the REB if my contract with the study sponsor changes in any way.
- If there is a signed contract agreement with the study sponsor, please indicate if access to the research data or right to publish local results is limited in any way.

Continued on the following page. This page must be included with the full proposal.

3. Privacy and Confidentiality Statement

Investigators must comply with the conditions outlined in the CHEO policies on “Privacy and Confidentiality of Patient Personal Health Information” and “Access to and Disclosure of Patient Health Information”. <http://cheonet/data/1/rec_docs/2329_Admin%20010%20Confidentiality.doc> and

<http://cheonet/data/1/rec_docs/3242_HREC%20067%20Access%20to%20and%20Disclosure%20of%20Patient%20Health%20Information.doc>

- The personal health information collected in this study will not:
 - Be encoded in such a way that would be identifying of the individual. Codes based on date of birth, ethnicity, hospital record number, and residency should be avoided. Variables that can be identifying of the person either alone or in combination will similarly be avoided.
 - Be used for future projects without prior approval of the Research Ethics Board.
 - Be published in such a way that could reasonably allow others to identify the patient whose personal health information is being researched.
 - Be disclosed except as required or permitted by law.

Note: The CHEO unique number rather than the patient's name should be retained for subject identification. This allows projects to fall into compliance with the existing hospital privacy policies. The data if lost or stolen would therefore, be de-identified. As an additional safeguard the hospital unique number can be linked to the study subject number in a separate password-protected document. This further decreases the risk of personal information becoming accessible should it be lost or stolen.

Primary CHEO Site investigator Signature:

Date:

Secondary CHEO Co-Investigators *(use supplementary pages as required)*

NAME	DIVISION OR PSU	EMAIL ADDRESS	PHONE #
1.			
Signature:			
2.			
Signature:			
3.			
Signature:			
4.			
Signature:			

The signatures above confirm that the co-investigators have read the research protocol and agree to participate in the research described in this application.

Continued on the following page. This page must be included with the full proposal.

PLEASE PROVIDE BELOW A ONE-PAGE SYNOPSIS IN LAY TERMS. ALSO, IDENTIFY ANY ETHICAL CONSIDERATION TO THE RESEARCH.

Continued on the following page. This page must be included with the full proposal.

PLEASE PROVIDE A DETAILED EXPLANATION HOW SUBJECTS WILL BE IDENTIFIED AND RECRUITED INTO THE STUDY. DOCUMENTATION USED FOR RECRUITMENT PURPOSES SHOULD BE PROVIDED TO THE BOARD FOR REVIEW (SEE PAGE 8 FOR FURTHER EXPLANATION)

PLEASE DESCRIBE HOW THE INVESTIGATORS WILL DEAL WITH CLINICALLY - RELEVANT INFORMATION ACQUIRED DURING THE COURSE OF THE STUDY (E.G., ABNORMAL LABORATORY RESULTS, INDICATIONS OF PSYCHOPATHOLOGY).

TYPE OF RESEARCH:

Clinical Drug Trial

Phase II

Phase III

Phase IV

Health Canada must approve all Phase I, II and III clinical drug trials **prior to** their commencement. Please refer to the HPFB website (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index_e.html) for further information. The Clinical Trial Application (CTA) can be obtained through this website. A Clinical Trial Application must be filed with Health Canada **prior to** submission to the board. A copy of the Health Canada Non-Objection Letter must be forwarded to the REB office prior to final approval of the protocol.

Health Canada Non-Objection Letter attached.

Yes, the Clinical Trial Application (CTA) has been Submitted to Health Canada on: _____
(date submitted)

Clinical Device Trial

Class I

Class II

Class III

Class IV

Class I devices present the lowest potential risk (e.g. thermometers) and do not require investigational testing authorization from Health Canada. Class II, III, and IV devices present higher risks to the individual and do require such authorization. Health Canada maintains a directory of all devices approved for use in Canada (<http://webprod.hc-sc.gc.ca/el-le/index-eng.jsp>).

Clinical Trial (Other)

Please specify nature of intervention being studied:

Is the above trial placebo-controlled? Yes No

The Board adheres to the guidelines proffered by the TCPS – 2nd edition and the National Placebo Working Committee on the Appropriate Use of Placebos in Clinical Trials in Canada (July 2004) <http://www.cihr-irsc.gc.ca/e/25139.html>

All clinical trials must be registered at either (please check one):

<http://www.clinicaltrials.gov>

<http://www.controlled-trials.com>

Registration Number: _____

Pandemic planning: The trial holds out the prospect of immediate (physiologic) benefit (that relates to improved disease state / morbidity etc) to the research subject. Yes No

The trial involves the provision of optimal care to research subjects that would otherwise not be available off-study. Yes No

Non-Interventional Research

Please specify nature of study: _____

Continued on the following page. This page must be included with the full proposal.

SCIENTIFIC PEER REVIEW AND FUNDING OR SPONSORSHIP OF RESEARCH PROJECTS PRESENTING MORE THAN MINIMAL RISK TO CHILDREN

Research proposals presenting more than minimal risk to subjects must have first undergone scientific peer review prior to submission to the Board.

Funded Protocols:

Funded proposals are generally considered to have successfully undergone independent, scientific peer review. Copies of these reviews should be appended to the full Board submission.

Funding Source:

Research Granting Agency, please specify source and type of award: _____

Other Private funding sources, please specify: _____

Industry Sponsored (Pharmaceutical or other), specify company name: _____

For Industry sponsored trials, please provide the name and address of contact person/company in order for us to invoice the company for the REB Review fee: _____

A fee of \$3,000.00 Canadian will be charged for the review of any research project partially or fully funded by private industry, and is applied whether the study is submitted to full Board or expedited review. Consideration will be made for exemption from the review fee, on a case-by-case basis. Requests for an exemption must be made in writing to the Chair. This review fee is not normally applied to investigator-initiated studies.

Un-funded projects and those having received funding without prior scientific, peer review REB submission for projects falling under this category must include two independent, scientific peer reviews. The CHEO Science Sub-Committee (through the RI administrative office) can facilitate the process of securing scientific peer review.

Please specify the source of scientific peer reviews (two): _____

Continued on the following page. This page must be included with the full proposal.

RESOURCE IMPLICATIONS AND MERIT OF PROJECT

Authorization must be obtained for all personnel directly or indirectly involved in the study (i.e. Laboratory, Nursing, Allied Health, etc.). The Director of Pharmacy must approve all clinical drug trials.

An application will only be considered complete when all necessary authorizations have been obtained.

If one of the individuals below is also an investigator on a proposal, the signature of his/her next immediate supervisor must be obtained.

POSITION	PRINT NAME	SIGNATURE	PHONE #	DATE
PSU Operations Director				

My signature above attests to the following:

My Department or Service has the resources (e.g.; materials, equipment, personnel and patient population) to support this research.

POSITION	PRINT NAME	SIGNATURE	PHONE #	DATE
Department Chief <i>(For physicians)</i>				
Division Chief <i>(For physicians)</i>				
Professional Practice Leader <i>(For allied health professionals)</i>				
Clinical Director <i>(Only if different from above)</i>				
Clinical Director <i>(Only if different from above)</i>				

My signature above attests that I am satisfied that within the scope of my profession:

- The investigator is in good standing at the Children's Hospital of Eastern Ontario or CHEO Research Institute, and that they have the credentials/expertise to conduct the research being proposed in this application.
- Any clinical service provided through this research protocol meet minimal standards for the provision of care.
- The proposed research has sufficient quality and merit to be implemented.

Continued on the following page. This page must be included with the full proposal.

SIGNATURES: An application is considered complete when all signatures and authorizations have been obtained. Authorization must be obtained for all personnel directly or indirectly involved in the study (i.e. Laboratory, Nursing, Allied Health). The Director of Pharmacy must approve all clinical drug studies. The Medical Director of Diagnostic Imaging must approval all studies requiring radiological tests not subsumed under standard of care.

POSITION	PRINT NAME	SIGNATURE	PHONE #	DATE
Director of Pharmacy <i>(For drug studies)</i>				
Medical Director of Diagnostic Imaging <i>(For studies involving radiological services)</i>				
Director of Laboratory Medicine <i>(For studies involving laboratory services)</i>				
Other Resource Managers <i>(Please specify)</i>				
Other Resource Managers <i>(Please specify)</i>				

My signature above attests to the following:

- My Department or Service has the resources (e.g.; materials, equipment, personnel and patient population) to support this research.

This page must be included with the full proposal