

**RESEARCH ETHICS BOARD APPLICATION FORM FOR
 PROSPECTIVE STUDIES INVOLVING LOW RISK TO FAMILIES OR STAFF**

Please submit the **original and one copy** of the application, protocol and applicable documents for review. Please ensure that all questions are answered in full. Only complete applications will be accepted.

PROTOCOL TITLE:		PROTOCOL #	
		<i>For office use only</i>	
PRIMARY CHEO SITE INVESTIGATOR (ONE ONLY):	DIVISION OR PSU	EMAIL ADDRESS	PHONE #
<p>My signature confirms that, as site investigator:</p> <ul style="list-style-type: none"> • I 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 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. • I will notify the REB if one of the investigators leaves the Hospital, the Research Institute, or the project. I will also 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 your access to the research data or right to publish local results is limited in any way. <p>_____</p> <p>_____</p>			
Primary CHEO Site investigator Signature:		Date:	

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SUMMARY OF PROSPECTIVE STUDIES INVOLVING LOW RISK TO FAMILIES OR STAFF

Please provide a synopsis and description of the ethical considerations as well as a brief description of the proposed research (approximately one page) which includes the following information:

- Rationale and hypotheses
- Study design and methods
- Subject selection
- Specify the number of participants drawn from CHEO and other centres
- Delineate the outcomes to be measured and analyzed
- Anticipated benefits/harms and how these will be addressed
- Data fields (if any) to be abstracted from the patient's health record. (Should not collect Name, Date of Birth, Postal Code, etc.)

Informed consent documents and any advertisement notices must be appended to the application.

PRIVACY & CONFIDENTIALITY

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

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: It is good practice to assign a unique study number to each subject. The study number can be linked to the CHEO unique hospital number in a separate password-protected file. The study data would be held in a file in which only the study number appears. This then ensures that the study data are completely de-identified and decreases the risk of personal information becoming accessible should it be lost or stolen.

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PROSPECTIVE STUDIES INVOLVING LOW RISK TO FAMILIES OR STAFF – CONT'D

RESOURCE IMPLICATIONS AND SCIENTIFIC MERIT OF PROJECT

If one of the individuals below is also an investigator in this project, the signature of the next immediate supervisor must be obtained.

For prospective studies involving low risk to families or staff, the appropriate authorization from the Clinical Director responsible for the staff or the clinical population is required.

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

POSITION	PRINT NAME	SIGNATURE	PHONE #	DATE
Clinical Director				

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 services provided through this research protocol meet minimal standards for the provision of care.
- The proposed research has sufficient quality and merit to warrant the implementation of this project.

SIGNATURES: Authorization must be obtained for all personnel directly or indirectly involved in the study (i.e. Laboratory, Nursing, Allied Health).

POSITION	PRINT NAME	SIGNATURE	PHONE NUMBER	DATE
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.

Please forward to:
Mrs. Sharon Haig, Ethics Coordinator
Research Ethics Board
Children's Hospital of Eastern Ontario
Room R250F, 401 Smyth Road, Ottawa, Ontario, K1H 8L1
Telephone: (613) 737-7600, ext. 3272

This page must be included with your submission.