

## PROCEDURES FOR DELEGATED RESEARCH PROTOCOLS

1. Protocols that present only minimal or very low risk to subjects are reviewed by the Chair or a subcommittee of the Board. Minimal or low risk is ordinarily taken to mean those risks normally encountered in everyday life by the research subject.
2. The turn-around time upon receipt of completed submissions that receive delegated review is generally within three (3) weeks. Submissions that are incomplete or require modifications will necessarily delay this process.
3. There are three streams of delegated review:
  - A. Research projects involving minimal risk that proposes a prospective collection of data involving families or staff. The appropriate authorization from the manager responsible for the staff or the clinical population involved in the study is required. Please use the application form *Research Ethics Board Application for Prospective Studies Involving Low Risk to Families or Staff* (see page 40).
  - B. Retrospective chart reviews/secondary use of clinical data. The *Research Ethics Board Application For Retrospective Chart Review and Secondary Use of Clinical Data must be submitted.* (See page 43).
  - C. Databases. The *Research Ethics Board Application For Databases must be submitted.* (See page 45).
4. 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. Materials should be double-sided and pages numbered consecutively; collated in complete packages, and each document stapled individually and then black-clipped in complete packages. Only complete applications will be accepted.

## THE DISTINCTION BETWEEN QUALITY ASSURANCE AND RESEARCH

The REB oversees all human research conducted at or through the hospital. In defining its scope, the REB adheres to Tri-Council definition of research as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. This is distinct from quality assurance activities that are intended to assess the performance of an organization or its staff, within the mandate of the organization. Recognizing that there can be overlap between these two concepts, the REB should be consulted to determine whether or not a specific activity constitutes research.

The Interagency Advisory Panel on Research Ethics PRE has provided guidance on the distinction between quality assurance and research. The Panel states that quality assurance studies may share characteristics with research and in fact, may use scientific methods. In quality assurance, however, the data are used to advance the needs and functioning of the organization. By contrast, in research, data are used to answer a scientific question. The primary distinction between research and quality assurance is therefore, in their respective objectives, rather than the methods used. Studies that intend to disseminate their findings beyond the organization are more typically categorized as research.

## DEFINITION OF SECONDARY ANALYSES OF CLINICAL DATA

The secondary use of data refers to the use in research of clinical data already contained in subject's health record and collected through the normal provision of routine care.

The Provincial Personal Health Information Protection Act of Ontario (PHIPA) sets forth the following requirements for the secondary use of clinical data in research: :

- The scientific question being asked is valuable and justifiable;
- Appropriate measures are being taken to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harm to subjects;
- The patients regarding whom the data refer will **not** be directly contacted by the researchers without their prior express and informed consent;
- Identifying information will not be released to researchers outside the hospital without the patient's express and informed consent;
- Individuals to whom the data refers have not previously objected to such secondary use;
- The data being collected would normally be obtained in the provision of care (section 29 (2)). As a consequence, the REB must ensure that the research plan limits its analysis to those data fields that would normally be available in the health record (departmental or centralized chart). If an investigator wishes to look at variables that are supplemental to care (e.g., in many instances, this could include race and SES), the individual's express and informed consent must first be obtained and the research plan approved by the board.
- It should be noted that PHIPA (health privacy legislation in Ontario) allows researchers to use clinical data to answer questions on the basis of 'implied consent'. Implied consent can be assumed if the institution has posted public notices to advise patients of the different uses that it makes of personal health information & that an REB has approved the research plan. CHEO has fully implemented the legislation and posted notices are found in high traffic areas around the hospital.

## PROCEDURES FOR DATABASE ANALYSIS PROJECTS

Database Analysis refers to the use in research of data contained in a previously created data set, whether it is retrospective or prospective. Database projects often use the same data set to answer several, related research questions. The REB requires that investigators submit a general description of the project including all the elements specified above (study rationale, identifiers to be retained, etc.). The overall database project is reviewed under the 'delegated' stream (previously expedited review). In an addendum to the application, investigators must describe each publication or sub-study relating to the database. For instance, in a database looking at job satisfaction of REB staff (protocol number 000X), a study looking at the quality of life of REB chairs would be treated as a sub-study (protocol 000Xa). In this example, the quality of life study would be described in a one-page summary submitted to the Board for approval.

Access to the database should be limited to the investigator and his/her delegates as outlined in the application. REB approval should be obtained prior to any release of the data to other investigators.

These submissions require the following:

- A duly completed database application form, including the data abstraction form or the list of data fields to be collected.
- A description of the scope and purpose of the database.
- Authorization from the appropriate division head from which the database information would be obtained.

**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.

<b>PROTOCOL TITLE:</b>			<b>PROTOCOL #</b>  <i>For office use only</i>
<b>PRIMARY CHEO SITE INVESTIGATOR (ONE ONLY):</b>	<b>DIVISION OR PSU</b>	<b>EMAIL ADDRESS</b>	<b>PHONE #</b>
<p>My signature confirms that, as site investigator:</p> <ul style="list-style-type: none"> <li>• I assume full responsibility for the research as outlined in this application.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>▪ 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.</li> </ul> <p>_____</p> <p>_____</p>			
<b>Primary CHEO Site investigator Signature:</b>		<b>Date:</b>	

*Continued on the following page*

**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/2329_Admin%20010%20Confidentiality.doc)

[http://cheonet/data/1/rec\\_docs/3242\\_HREC%20067%20Access%20to%20and%20Disclosure%20of%20Patient%20Health%20Information.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.]*

## RESEARCH ETHICS BOARD APPLICATION FORM FOR RETROSPECTIVE CHART REVIEW AND SECONDARY ANALYSES OF CLINICAL DATA

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.

<b>PROTOCOL TITLE:</b>			<b>PROTOCOL #</b>
			<i>For office use only</i>
Indicate nature of project <input type="checkbox"/> Retrospective <input type="checkbox"/> Prospective secondary use of clinical data			
<b>PRIMARY CHEO SITE INVESTIGATOR:</b>			
<b>NAME</b>	<b>DIVISION OR PSU</b>	<b>PHONE #</b>	<b>SIGNATURE</b>
<b>SECONDARY CHEO CO-INVESTIGATORS</b> <i>(use supplementary pages as required.)</i>			
<b>NAME</b>	<b>DIVISION OR PSU</b>	<b>PHONE #</b>	<b>SIGNATURE</b>
<b>MEMBERS OF THE RESEARCH TEAM WHO WILL HAVE ACCESS TO THE INFORMATION</b> <i>(Other than those named above)</i>			
<b>NAME</b>	<b>ROLE ON THE RESEARCH TEAM</b>	<b>PHONE #</b>	<b>SIGNATURE</b>
<b>SUMMARY OF CHART REVIEW AND SECONDARY USE OF CLINICAL DATA PROPOSALS</b>			
<p><b>Please provide a brief description of the proposed research (approximately one page), which must include the following information:</b></p> <ol style="list-style-type: none"> <li>1. The data abstraction form or the list of data fields to be collected should be appended to this form. Name, Date of Birth, &amp; Full Postal Code should not be collected.</li> <li>2. Any probable linkage of data (i.e., techniques used to link together records which relate to the same individual in one or more data sets). Why this is necessary and how this will be achieved?</li> <li>3. Rationale and hypotheses.</li> <li>4. Anticipated benefit.</li> <li>5. Anticipated harms and how these will be addressed.</li> </ol> <p><b>Note:</b> 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</p>			

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**RETROSPECTIVE CHART REVIEW AND SECONDARY ANALYSES OF CLINICAL DATA – CONT'D**

**SUMMARY OF CHART REVIEW AND SECONDARY USE OF CLINICAL DATA PROPOSALS (Cont'd):**

Name additional REB's who have reviewed the application and indicate the status of the review.	<u>Approved</u>	<u>Disapproved</u>	<u>Pending</u> (anticipated date of approval)
_____	☐	☐	☐ _____
_____	☐	☐	☐ _____
_____	☐	☐	☐ _____

**FUNDING OR SPONSORING AGENCY:**

**Funded projects**

Please provide name and address of contact person: \_\_\_\_\_

A fee of \$3,000.00 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 delegated 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, CHEO Research Ethics Board.

**My signature confirms that, as Primary CHEO site investigator:**

- I assume full responsibility for the research as outlined in this application.
- I will 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/2329_Admin%20010%20Confidentiality.doc)  
[http://cheonet/data/1/rec\\_docs/3242\\_HREC%20067%20Access%20to%20and%20Disclosure%20of%20Patient%20Health%20Information.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:
  1. Be used only as necessary, to fulfill the specific research objectives and related research questions described in this application and approved by the REB.
  2. Be encoded in a way that would not be identifying of the individual. Codes based on date of birth, ethnicity, and residency will be avoided. Variables that can be identifying of the person either alone or in combination will similarly be avoided.
  3. Be stored in locked areas and access will be restricted to the names listed above. Any personal health information that leaves the site for any reason will be de-identified, password protected and encrypted. Data will be destroyed at the conclusion of the study.
  4. Not be used to contact or attempt to contact the patient whose personal health information is being researched unless CHEO first obtains the patients’ express written consent,
  5. Not be published in a way that could reasonably allow others to identify the patient whose personal health information is being researched,
  6. Immediately notify the REB in writing if the investigator becomes aware of any breach of confidentiality or security.
  7. Be disclosed except as required or permitted by law.

**Signed:**

\_\_\_\_\_  
Primary CHEO Site Investigator

\_\_\_\_\_  
Print Name:

\_\_\_\_\_  
Date:

\_\_\_\_\_  
Research Assistant

\_\_\_\_\_  
Print Name:

\_\_\_\_\_  
Date:

Please forward to:  
**Ms. Natalie Morocz, Administrative Assistant**  
**Research Ethics Board**  
**Children's Hospital of Eastern Ontario**  
**Room 249, 401 Smyth Road, Ottawa, Ontario, K1H 8L1**  
**Telephone: (613) 737-7600, ext. 3350**

**CHEO Research Ethics Board – APPROVAL**

**Chair's Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**RESEARCH ETHICS BOARD APPLICATION FORM FOR  
 DATABASES**

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.

<b>PROTOCOL TITLE:</b>			<b>PROTOCOL #</b>
			<i>For office use only</i>
<b>Indicate nature of project</b> <input type="checkbox"/> New database <input type="checkbox"/> Ongoing, existing database <input type="checkbox"/> Clinical Database			
<b>PRIMARY CHEO SITE INVESTIGATOR:</b>			
<b>NAME</b>	<b>DIVISION OR PSU</b>	<b>PHONE #</b>	<b>SIGNATURE</b>
<b>SECONDARY CHEO CO-INVESTIGATORS</b> <i>(use supplementary pages as required.)</i>			
<b>NAME</b>	<b>DIVISION OR PSU</b>	<b>PHONE #</b>	<b>SIGNATURE</b>
<b>MEMBERS OF THE RESEARCH TEAM WHO WILL HAVE ACCESS TO THE INFORMATION</b> <i>(Other than those named above)</i>			
<b>NAME</b>	<b>ROLE ON THE RESEARCH TEAM</b>	<b>PHONE #</b>	<b>SIGNATURE</b>

**SUMMARY OF CHART REVIEW AND SECONDARY USE OF CLINICAL DATA PROPOSALS**

**Please provide a brief description of the proposed research, which must include the following information:**

1. What is the scope and purpose of the database?
2. What are the expected types of studies that will use information from this database?
3. Anticipated benefits.
4. Anticipated harms and how these will be minimized.
5. What patient information source will be accessed, e.g., Health Records, Electronic Database, Outside Institution, etc...
6. The data abstraction form or list of data fields included in the database.
7. Any probable linkage of data (i.e., techniques used to link together records which relate to the same individual in one or more data sets, OHIP data, censuses tract data). Why this is necessary and how this will be achieved?
8. What measures that will be taken to ensure security of the data with personal identifiers, e.g., physical, technical, procedural.
9. Will data be sent outside of the institution? Why is this necessary? How will the data be sent? The site where the data will be housed?

**Note:** Clinical databases often require that certain personal identifying information be retained, in which case 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

**SUMMARY OF CHART REVIEW AND SECONDARY USE OF CLINICAL DATA PROPOSALS (Cont'd):**

Name additional REB's who have reviewed the application and indicate the status of the review.	<u>Approved</u>	<u>Disapproved</u>	<b>Pending</b> (anticipated date of approval)
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____

**FUNDING OR SPONSORING AGENCY:**

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Please provide name and address of contact person: \_\_\_\_\_

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**My signature confirms that, as Primary CHEO site investigator:**

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- I will 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”.  
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[http://cheonet/data/1/rec\\_docs/3242\\_HREC%20067%20Access%20to%20and%20Disclosure%20of%20Patient%20Health%20Information.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:
  1. Be used only as necessary, to fulfill the specific research objectives and related research questions described in this application and approved by the REB.
  2. Be encoded in a way that would not be identifying of the individual. Codes based on date of birth, ethnicity, and residency will be avoided. Variables that can be identifying of the person either alone or in combination will similarly be avoided.
  3. Be stored in locked areas and access will be restricted to the names listed above. Any personal health information that leaves the site for any reason will be de-identified, password protected and encrypted. Data will be destroyed at the conclusion of the study.
  4. Not be used to contact or attempt to contact the patient whose personal health information is being researched unless CHEO first obtains the patients’ express written consent,
  5. Not be published in a way that could reasonably allow others to identify the patient whose personal health information is being researched,
  6. Immediately notify the REB in writing if the investigator becomes aware of any breach of confidentiality or security.
  7. Be disclosed except as required or permitted by law.

**Signed:**

\_\_\_\_\_  
*Primary CHEO Site Investigator*

\_\_\_\_\_  
*Print Name:*

\_\_\_\_\_  
*Date:*

\_\_\_\_\_  
*Research Assistant*

\_\_\_\_\_  
*Print Name:*

\_\_\_\_\_  
*Date:*

**Please forward to:**  
**Ms. Natalie Morocz, Administrative Assistant**  
**Research Ethics Board**  
**Children’s Hospital of Eastern Ontario**  
**Room 249, 401 Smyth Road, Ottawa, Ontario, K1H 8L1**  
**Telephone: (613) 737-7600, ext. 3350**

**CHEO Research Ethics Board – APPROVAL**  
**Chair's Signature:** \_\_\_\_\_  
**Date:** \_\_\_\_\_

**Please note that the REB approval is valid for one year from the date of approval.**  
**An annual renewal must be submitted to maintain the approval.**