

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 DATABASES

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

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>	Pending (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:

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 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, 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/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 R249, 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.**