



SJHC Research Ethics Board Chart Review Application Form Guidelines

The request for health records information for research purposes can arise as a retrospective study of information previously collected, as part of an ongoing prospective clinical trial, or as part of an audit function carried out by study sponsors or regulatory agencies related to a clinical trial.

In accordance with the Tri-Council Policy Statement, research studies requiring access to information with identifying information must be reviewed and approved by the Research Ethics Board (REB) at SJHC.

This type of REB application is often expedited (ie. reviewed by REB Chair and designees only) yet is occasionally referred to the REB for a full review. Once approved, an REB approval letter and study number will be issued. The turn-around time for an expedited submission can take a minimum of three weeks.

The REB approval for access to health records only entitles investigators (or sponsors and regulators accompanied by SJHC investigators) access to health records under the normal security conditions imposed by the Health Records Department. Costs for photocopying may be charged to investigators. No identifying information may be photocopied and details regarding how copies will be disposed of will be required.

Investigators must sign the application form. In signing the application form, the Investigator agrees to comply with the SJHC Confidentiality Policy and acknowledges that the person who will be gaining direct access to the medical information (ex. research coordinator, fellow, student, research assistant, monitor) is acting as an agent or delegate of the Investigator. The Investigator accepts full responsibility for the protection of the information.

The Investigator is responsible for contacting the Health Records Manager for further procedures and requirements for accessing the paper chart.

Instructions:

- 1) Please type your responses. Submit one copy of the Health Records Application Form and REB Chart Review Application Form to Thereza Dos Santos, REB Coordinator, St. Joseph's Health Centre, 30 The Queensway, Room 7S712, Toronto, ON, M6R 1B5. You may fax the application but **original signatures must be submitted** (fax: (416) 530-6054). If you have any questions, please contact Thereza at santost@stjoe.on.ca.
- 2) If you are submitting a cover letter, you may address it to the REB Chair: Hazel Markwell, PhD.

- 3) Please provide a signature for SJHC Departmental approval – this may be from a Department head for charts belonging to specific departments or if appropriate, from RoseAnn Pacheco, Director of Health Records (pacher@stjoe.on.ca).
- 4) Forms that are incomplete will not be processed and the researcher will be notified.
- 5) The SJHC Health Records Department will request verification of REB approval (copy of REB approval letter), the Chart Review Application Form, and individual identification prior to granting access to records.

Note: Current costs associated with chart retrieval are \$10 per chart for those currently in-house and \$20 per chart for those which must be retrieved from off-site storage. Charges for photocopies may also be added.

REB Study #: _____ (office use only)

**Research Ethics Board
CHART REVIEW APPLICATION FORM**

TITLE OF STUDY:

INVESTIGATOR(S):

Name	Title/Department	Program
Complete Address	Telephone#	Email Address

Names of those who will carry out the Chart Review:

(Note: You may provide a list of additional people that will carry out the chart review on the next page):

Name	Title/Department	Program
Complete Address	Telephone #	Email Address

Expected Study Duration: Start Date _____ End Date _____

FUNDING: Is the project funded by a sponsor or organization? NO YES

If yes, name the funding agency:

Internal Research Funded Externally Internal Research Not Funded Externally
 External Research

SJHC DEPARTMENTAL APPROVAL:

I have reviewed this Chart Review Application Form and any associated documents, and approve this request for chart access.

Print Department Head Name Department Head signature Date

Print Department Head Name Department Head signature Date

SJHC Confidentiality Agreement

Investigator:

I, the undersigned, agree to adhere to the **SJHC Policy on Information Security and Confidentiality (SE 10-1-1) and Policy on Release and Confidentiality (SJ 04-04-01)** and understand that a breach of either or both of these policies may be just cause for termination of my employment and/or affiliation with the hospital. I agree that all health information, which I may have access to, is to be dealt with in keeping with the policies and procedures of St. Joseph's Health Centre with respect to confidentiality. If identifying information is collected, the information will be kept secure and identifiers removed at the completion of collection. I also accept full responsibility for protection of information that has been collected by a delegate on my behalf.

Print Investigator Name Investigator Signature Date

Print Investigator Name Investigator Signature Date

(Note: additional persons conducting the chart review may be listed below. Investigators below attest to the above Confidentiality Agreement. Investigators accept responsibility for delegates, as noted above, and delegates are not required to sign. If delegate names are known, their names and contact information should be included below.)

Additional Investigators or Persons carrying out Chart Review (if applicable):

1. Study role (Ex. Investigator, Chart Abstractor):

Note: Response to the questions below should be detailed enough for the REB to determine the merit of the study and that sufficient protection is in place to guard the confidentiality and security of patient information.

Study Details:

1. Primary objective for the study (include the study rationale):

2. Specific hypothesis or research question to be addressed:

3. Describe or specify the data to be collected. Attach all data collection forms:

4 Please identify all sources of data:

Inpatient: Day Surgery: Emergency:

Other:

5. Proposed number of research subjects/charts:

6. Target time period of charts required for study (ex. May 2005 – present):

7. Do you require Health Records to produce a list/report?

YES NO

8. How will relevant patient charts be identified?

9. Will any identifying information be recorded?

YES NO

If YES, please respond to the following:

i) List all subject identifiers to be recorded on data collection forms (ie. names, initials,

DOB, OHIP, Hospital ID number).

ii) Please justify the collection of subject identifiers:

iii) Will individual identifiers be removed once the relevant data is collected?

YES NO

If no, please justify.

iv) Is there any anticipated linkage of the data to be collected with other data? If so, how will the linked information be treated?

10. Are photocopies of chart contents requested? YES NO

If YES, how will photocopies be disposed of?

11. **Security & Confidentiality:**

i. Please indicate how data will be stored:

- Computerized files
- Hard copy
- Other (Please specify):

ii. Where will hard copy data be physically stored?(Ex. filing cabinets. Please specify department name, room number, address, etc.)?

N/A

Also, who will have access to this area above?

iii. If storing study data in computerized files please specify where the database is located and who has access. (Address may be required here)

N/A

Is the computer password-protected?

iv. Will data be transferred electronically?

YES NO

If YES, by what medium? (Ex. e-mail, CD, memory stick)

v. Describe any security measures in place to protect confidentiality.

vi. What will happen to the data at the end of the study (ex. anonymized, destroyed)?

vii. Who will have access to data in the future?

viii. How will confidentiality be maintained during long term storage of study records?

N/A

12. Will these data be available or distributed to others? If so, specify how confidentiality will be protected.