INSTRUCTIONS & GUIDELINES

When do I use this form?

IF RESEARCH, does it involve contacting patients?

YES NO

If YES...complete “Application for REB Review” form

IF QUALITY ASSURANCE...

...complete Q. 1 to 9(a) of “Application for Retrospective Review”

Is this Quality Assurance?

True / False?

1. The study involves the systematic monitoring, assessment or evaluation of the various aspects of an organization (e.g., a service, program, project or facility of the organization, or performance of its employees or students within the mandate of the organization or according to the terms of employment or training) to ensure that standards of quality are being met, or to correct or enhance the various aspects of the organization.

2. The study does not involve a systematic investigation to establish facts, principles or generalizable knowledge.

3. No personal identifying information will be collected.

4. There will be no patient intervention or contact.

If you answered True to all of the above statements, complete Questions 1 through 9 (a) of this Application and submit it directly to the appropriate Health Records Department (see below). Otherwise, please complete the applicable sections of this Application and submit it to the appropriate REB (see below). When in doubt, refer to the REB Website for examples of Quality Assurance activities, or contact the REB Office.

Privacy Tutorial

All Investigators (including students) conducting retrospective review of health records are required to provide evidence of training for privacy protection of human subjects prior to submission of this Application. This requirement for training may be met by completing the brief web-based program at http://ethics.mcmaster.ca/chart/ Upon successful completion of the tutorial, print a certificate for your own record and enter the certificate number in the appropriate place on the Application.

Application Review and Notification

Quality Assurance Studies - submit the Application form to the appropriate Health Records Department (DO NOT FAX).

Research Studies – submit the Application form, together with supporting documentation to the appropriate Research Ethics Board Office (DO NOT FAX). Applications normally undergo an expedited review process. Approved applications requesting access to information through the Health Records Department will be forwarded by the REB Office directly to Health Records for processing. The Local Principal Investigator will receive an email confirming REB approval.
RESEARCH ETHICS BOARD (REB) / HEALTH RECORDS
APPLICATION FOR RETROSPECTIVE REVIEW OF MEDICAL CHARTS/HEALTH RECORDS

1. (a) Is this a student project? ☐ Yes ☐ No
   (b) Is this a ☐ Quality Assurance study OR a ☐ Research study? (see Instruction page for criteria)

2. (a) Title of Study:
   (b) List up to 5 keywords that describe this project:

3. (a) Local Principal Investigator: (Only one person can be designated as the LPI. If more than one name is listed, the first name will be assigned the role of Local Principal Investigator. The Local Principal Investigator must have an appointment at the institution where this application is being submitted for review) 

<table>
<thead>
<tr>
<th>Name &amp; Degree(s)</th>
<th>Univ. Title or Position</th>
<th>Clinical Program</th>
<th>Hospital Affiliation</th>
<th>Phone #</th>
<th>Email</th>
<th>* Tutorial Certificate #</th>
</tr>
</thead>
</table>

   * Privacy Tutorial: All Investigators (including students) conducting retrospective review of health records are required to provide evidence of training for privacy protection of human subjects prior to submission of this Application. This requirement for training may be met by completing the brief web-based program at http://ethics.mcmaster.ca/chart/. Upon successful completion of the tutorial, print a certificate for your own record and enter the certificate number in the appropriate place on the Application.

(b) Funding Source (Name of sponsor/funding agency/industry partner – state full name):

(c) Indicate location(s) where the study will be conducted:
   ☐ Hamilton Health Sciences – specify site: ☐ MUMC; ☐ HEND; ☐ HGH; ☐ CHED; ☐ JCC; or
   ☐ Other – specify:
   ☐ St. Joseph’s Healthcare – specify site: ☐ SJH; ☐ CMHS; ☐ CAHS; or ☐ Other – specify:
   ☐ McMaster University ☐ Community – specify:

(d) Will this study be reviewed by another Research Ethics Board or Institution? ☐ YES ☐ NO
   If YES, please attach any other REB or institutional approvals. ☐ Attached ☐ To follow

(e) Conflict of Interest: Will any investigators, members of the research team, and/or their partners or immediate family members:
   (i) Receive any personal benefit (for example, a financial benefit such as remunerations, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of, or connected to this study? ☐ YES ☐ NO
   (ii) If YES, please describe the benefits and explain how they will be managed to ensure that participant rights and welfare are not affected. (Do not include conference and travel expense coverage, possible academic promotion, or other benefits which are integral to the conduct of research generally). ☐ Attached

4. Individual(s) who will be reviewing/abstracting medical records/charts:

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<thead>
<tr>
<th>Name and Degree(s)</th>
<th>Staff Affiliation? (Specify SJH, HHS, MAC or None)</th>
<th>Profession</th>
<th>Precise Role on Project</th>
<th>Email</th>
<th>* Tutorial Certificate#</th>
</tr>
</thead>
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RETROSPECTIVE REVIEW OF MEDICAL CHARTS/HEALTH RECORDS
Version May 2007
5. Additional individuals on the study team who will be given access to the collected data:

<table>
<thead>
<tr>
<th>Name and Degree(s)</th>
<th>Staff Affiliation? (Specify SJH, HHS, MAC, or None)</th>
<th>Profession</th>
<th>Precise Role on Project</th>
<th>Tutorial Certificate Number *</th>
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* Refer to Instructions. This field must be completed for all individuals. For tutorial: http://ethics.mcmaster.ca/chart/

6. What is the purpose of the study, the objectives and the question(s) this study will answer? (Describe briefly)

7. Risks and Benefits of the Proposed Study.
   (a) What are the anticipated public and scientific benefits of the study? (Describe briefly)
   
   (b) What are the possible harms/risks to patients and how will you manage the risks? (Describe briefly)

8. What patient information source are you accessing?
   - Health Records/Clinic/Office Files? (Specify which)
   - Electronic Database (Specify which)
   - Outside Institution (Specify which)
   - Other (Specify which)

9. What type of data do you need?
   (a) Aggregate (i.e. you do not need to collect and use personal health information from individual medical charts/health records, e.g. you want to determine how many post-op wound infections occurred in patients with hip replacement surgery?)

   If you require only aggregate data, indicate your search criteria (e.g. diagnosis, procedure, time period, other):

   COMPLETE FOR AGGREGATE DATA ONLY:
   There is no further information required at this time if you require only aggregate data. Sign as indicated below:
   1. Please sign below to verify that you will not be abstracting personally identifiable information from patient charts, otherwise continue completing the Application.
   2. Sign the Confidentiality Agreement at the end of the Application.

   Local Principal Investigator
   Date

   (b) Person level data (i.e. you need to view individual medical charts/health records)?

   If you require person level data, are you planning to obtain consent from each patient for access to and use of their personal health information?
   - YES – If YES, this is the wrong form – refer to the Instructions on page 1.
☐ NO – If NO, provide justification for a waiver of consent (Note: The REB may waive the requirement for subject consent and authorization if these criteria are met: a) the research purposes cannot be achieved without the information; b) it is impracticable to obtain consent; c) the information is used in a manner that will ensure its confidentiality; and d) the public interest in conducting the research exceeds the public interest in protecting the privacy of the individuals.)

(c) If you require person level data, are you collecting any of the following personal identifiers? (Please check all applicable): Investigators should plan to collect personal data at the lowest level of identifiability necessary to achieve the study objectives. We recommend using only initials, and first 3 digits of postal code. Even a dataset without direct identifiers may present a risk of indirectly identifying data subjects if the dataset contains sufficient information about the individuals concerned. For advice, consult the CIHR Best Practice Guidelines for Protecting Privacy and Confidentiality:
http://www.cihr-irsc.gc.ca/e/29072.html

<table>
<thead>
<tr>
<th>DIRECT IDENTIFIERS</th>
<th>✓</th>
<th>INDIRECT IDENTIFIERS</th>
<th>✓</th>
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<tbody>
<tr>
<td>Full Name (Recommend initials)</td>
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<td>Initials</td>
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<tr>
<td>Address</td>
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<td>Full Date of Birth (day/month/year)</td>
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<td>Telephone Number</td>
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<td>Age at time of data collection or year of birth</td>
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<td>OHIP #</td>
<td></td>
<td>Full Postal Code (recommend first 3 digits only)</td>
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<tr>
<td>Social Insurance Number</td>
<td></td>
<td>First 3 digits of Postal Code</td>
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<tr>
<td>Email address</td>
<td></td>
<td>Healthcare Provider (recommend type of provider, eg. Family Physician, VON)</td>
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<tr>
<td>Medical Record Number</td>
<td></td>
<td>Discharge Date</td>
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<tr>
<td>Full Face Photograph</td>
<td></td>
<td>Other date (e.g. date of service)</td>
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<td>OTHER -</td>
<td></td>
<td>Fax Number</td>
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<td></td>
<td></td>
<td>Medical Device Identifier</td>
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<td></td>
<td>Certificate/License number</td>
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<td>Vehicle Identification1</td>
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<td>OTHER -</td>
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1 Vehicle identification numbers (VIN) and serial numbers including license plates.

(d) If you are collecting any of the above personal identifiers, justify why each item is required:

(e) A description of the reasonably foreseeable harms and benefits that may arise from the use of the personal health information and how you intend to address those harms. e.g., if PHI is inappropriately released consequences could include embarrassment, refusal of employment or insurance coverage, stigmatization of individuals/groups.

10. What is the minimum number of records required to achieve your study?

11. Data to be abstracted for the time period of (from when to when?):

12. Attach data collection form or list of fields to be abstracted. (Mandatory: Application will be returned if this information has not been included.)

13. Are any sensitive issues raised in this study which may require subject consent? (e.g. HIV status, mental health problem or diagnosis, subjects identifiable, e.g. pedigrees, other)
☐ YES If yes, justify not getting patient consent and specify additional safeguards for confidentiality:
☐ NO

14. Do you plan to link the locally collected data with any other data set(s) (e.g. OHIP data, census tract data)?
☐ YES If yes, indicate (i) why it is being linked; (ii) identify the data set; (iii) identify how the linkage will occur; and (iv) provide a list of data items contained in it.

☐ NO
15. Indicate the steps to be taken to ensure security of data with personal identifiers. Please check all that apply.

NOTE: If direct identifiers must be retained they should be isolated on a separate dedicated server/network without external access (i.e. research databases with patient information should not be housed on portable devices such as laptops or flashcards).

<table>
<thead>
<tr>
<th>PROCEDURAL MEASURES</th>
<th>✓</th>
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<tbody>
<tr>
<td>▪ Data access to the segregated/identified data will be limited to a “need to know” basis</td>
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<tr>
<td>▪ There will be an audit trail of access to electronic records</td>
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<tr>
<th>PHYSICAL</th>
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<tbody>
<tr>
<td>▪ Completed data abstraction forms will be stored in locked filing cabinets in secure location – Specify:</td>
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<tr>
<td>▪ Computers will be housed in a locked secure location – Specify:</td>
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<tr>
<td>▪ Data file backup will be stored in a separate, locked secure location – Specify:</td>
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<tr>
<td>▪ Other – Specify:</td>
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<th>TECHNICAL</th>
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<tr>
<td>▪ Data will be stored on a computer which is password protected</td>
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<tr>
<td>▪ Data will be stored in a computer file which is password protected</td>
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<tr>
<td>▪ Frequent backups of data will occur</td>
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<td>▪ Data will be stored on computer systems with virus protection</td>
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<td>▪ Data will be stored on computer systems with uninterrupted power source</td>
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2 Reminder: All changes to previously approved research plans require approval, including any change in persons given access to the data.

16. (a) Will data be sent outside of the institution where it was collected and/or will you be receiving data from other sites (for example, in the case of a multi-site study where you are the coordinating site receiving data)?

☐ YES If YES, explain why it is necessary to send/receive data outside of the institution where it was collected.

☐ NO

(b) Transmission of data via:

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<thead>
<tr>
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<th>Sent?</th>
<th>Rec’d?</th>
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<tr>
<td>Fax - Security at the receptor site MUST be described:</td>
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<td>Email (Encryption protocol MUST be attached)</td>
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<td>Private Courier (Must be able to trace delivery)</td>
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<td>Canada Post Xpresspost or Priority Courier (Regular mail may NOT be used)</td>
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<td>Other – Specify:</td>
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(c) Where will data be sent?

(d) Specify the names and affiliations of persons outside of your study team (e.g. technical service providers, other researchers) who will have access to the data

Data sent or received by the institution will require that the parties enter into an information transfer agreement before the data transfer takes place.

17. Will this chart review be entered into an ongoing electronic database for future use in another study?

☐ YES. If yes, specify where it will be stored, who will be the custodian (i.e. the person responsible for data storage and integrity), who will have access to it, and security measures:

☐ NO

18. (a) Specify how long you plan to keep the data. (Please note: You are required to destroy identifiers [or links] at the earliest possible time.)

(b) Will data be ☐ destroyed or ☐ irreversibly anonymized (i.e. the key identifying the link between data and the individual’s identity is deleted)?

NOTE: any mishandling or unauthorized use of study data will lead to cancellation of REB approval for the study -
For REB/Health Records Use only (when patient record source is Health Records Dept)

[ ] Quality Assurance Study – forward directly to Health Records

[ ] Approved by Health Records

REB Chair/Vice Chair Date

[ ] Research Study

[ ] Requires further review by Research Ethics Board:

REB Chair/Vice Chair Date

[ ] Approved by REB – forward to Health Records

REB Chair/Vice Chair Date

[ ] Approved by Health Records

Manager, Health Records Date

Comments:
Confidentiality Agreement

THE FOLLOWING REPRESENTS THE TERMS AND CONDITIONS UNDER WHICH THE HANDLING OF CONFIDENTIAL INFORMATION FOR THE PROJECT SHALL PROCEED. THESE TERMS AND CONDITIONS HAVE BEEN DRAFTED IN COMPLIANCE WITH THE PERSONAL HEALTH INFORMATION PROTECTION ACT AND OTHER PRIVACY LEGISLATION.

1. All information received or exchanged will be held in strict confidence.
2. Information will not be used for any purpose other than for the project for which it was provided. The information will be shared only with those individuals listed on this form, who are working directly on the project, except for authorized oversight of the study.
3. No attempt will be made to contact any individual to whom the information relates, directly or indirectly.
4. Information will be kept in a location that is physically secure and to which access is given only to the individual(s) listed on this form.
5. All direct identifiers will be segregated/stripped from clinical data; a unique study identifier (i.e. a randomly generated or meaningless ID number) will be assigned to each patient record; the Master list linking the ID with identifiable material will be stored in a separate computer file and/or physical location; and the Master list will be locked and password protected.
6. No information will be released outside the province of Ontario.
7. Data sent or received by the institution will require that the parties enter into an information transfer agreement before the data transfer takes place.
8. Policies and procedures on the retention and destruction of information must be in place by the party undertaking the project.
9. It is strongly recommended that members of the research team and any individual(s) listed below read the Personal Health Information Protection Act, Part IV, Sec 44.
10. Publication of confidential information requires adherence to the following principles:
   - The institution agrees to allow the publication of the information as it pertains to the project providing that the institution or its practices are not the main focus of the publication.
   - In cases where the publication focuses on the institution, the institution reserves the right to review and approve the use of this information prior to publication.
   - The institution will be acknowledged within any publication as providing the source information in the following fashion: “e.g. Hamilton Health Sciences Corporation . . . specify year”.
     A copy of the publication will be given to the institution (e.g. Hamilton Health Sciences Corporation, Health Information Services Portfolio).
11. Information which is lost or stolen must be reported to the Chief Privacy Officer of the appropriate institution (i.e. St. Joseph’s Healthcare Hamilton, Hamilton Health Sciences, or McMaster University).
12. A breach of institutional policy regarding access to information and protection of privacy may have serious consequences or be just cause for termination of my employment and/or affiliation with the institution.

NOTE: any mishandling or unauthorized use of study data will lead to cancellation of REB approval for the study.

The undersigned hereby agree to these terms and conditions governing the handling of confidential information, and commits him/herself to these terms and conditions:

Signature of the Local Principal Investigator  Date

Signatures of all Study Team members:

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<tr>
<th>Print Name</th>
<th>Signature</th>
<th>Date Signed</th>
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