

RVH Research Ethics Board (REB)

**APPLICATION FOR MEDICAL CHART REVIEW**

INSTRUCTIONS

* This form is used to apply for **initial** RVH REB review of new research projects involving medical chart review. Please **do not** use this form if the study involves contact with or observation of human study participants
* **All sections** of this form **MUST** be completed before it will be considered for REB review. Incomplete submissions will be returned to the Principal Investigator and/or Study Coordinator for completion.
* A completed application consists of the following documents: 1) Application for Medical Chart Review; 2) study protocol; and 3) supporting documentation. A cover letter is recommended.
* All research must be compliant with:
	+ The Tri-Council Policy Statement, available at

<https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html>;

* + The Ontario Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A, available at

<http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm>; and

* + Any other relevant regulations or guidelines
* The RVH REB may request and share information related to its review of research conducted by external investigators
* Please visit [www.rvhresearchinstitute.ca](http://www.rvhresearchinstitute.ca) for detailed information regarding REB meeting schedules and submission guidance

**SUBMISSION PROCEDURE**

* Please submit three (3) paper copies and one (1) scanned or electronic copy of your completed application to the address below. Do not staple any sections of your submission; use paperclips to keep copies together.

Dr. Jesse McLean

Director, Research

Centre for Education & Research

Royal Victoria Regional Health Centre

201 Georgian Drive, Barrie, ON, L4M 6M2

Email: McLeanJe@rvh.on.ca

Phone: 705-728-9090 Ext. 41350

**SECTION A: GENERAL INFORMATION**

**REB STUDY NUMBER: (Internal Use Only) only)**

1. Please select the organization you are applying from:

[ ]  RVH [ ]  BCFHT [ ]  GBGH [ ]  Hospice Simcoe

[ ]  GBHS [ ]  Other (specify): Click here to enter text.

1. Full Study Title:

|  |
| --- |
| Click here to enter text.  |

1. Abbreviated Study Title (max. 10 words):

|  |
| --- |
| Click here to enter text.  |

1. What is the expected study period?

|  |  |
| --- | --- |
| Estimated start date: Click here to enter a date. | Estimated end date: Click here to enter a date.  |

1. Has this study undergone a formal scientific review? [ ]  Yes [ ]  No

If “Yes”, attach the approval letter with this application.

1. Has this study been submitted to any other REB/IRB/REC? [ ]  Yes [ ]  No

If “Yes”, please attach the approval letter or other relevant correspondence with this application.

1. Has this study been denied approval by any other REB/IRB/REC? [ ]  Yes [ ]  No

If “Yes”, please attach the REB/IRB/REC letter with this application.

1. Is this an investigator-initiated study? [ ]  Yes [ ]  No
2. Is this an industry sponsored study? [ ]  Yes [ ]  No

If “Yes”, please identify the sponsor?

|  |
| --- |
| Click here to enter text.  |

1. Is this a student or fellow/resident project? [ ]  Yes [ ]  No

If “Yes”, please specify the program: [ ]  Fellow/Resident [ ]  MD [ ]  PhD [ ]  Master’s [ ]  Bachelor’s

1. Is this a multi-site study? [ ]  Yes [ ]  No
2. Do you plan on conducting any part of this study at RVH or other local sub-site (e.g., GBGH, BCFHT)? [ ]  Yes [ ]  No

If “No”, specify the location(s) where study procedures will take place (max. 200 words):

|  |
| --- |
| Click here to enter text.  |

1. How will you make the results of this study public (select all that apply)?

[ ]  Peer reviewed publication

[ ]  Thesis or dissertation

[ ]  Study registry

[ ]  Presentation

[ ]  Report to participants (explain): Click here to enter text.

[ ]  Other (explain): Click here to enter text.

1. What is the purpose and objective(s) of this study (max. 200 words)?

|  |
| --- |
| Click here to enter text.  |

1. How would you explain this study to a lay person (max. 200 words)?

|  |
| --- |
| Click here to enter text.  |

**SECTION B: INVESTIGATORS**

* Please attach a signed and dated curriculum vitae and applicable certificates of research ethics training for the Principal Investigator, Co-Investigator(s), and all other study team members identified on this application.
1. Who will serve as the Principal Investigator for this study?

Please note, the Principal Investigator cannot be an undergraduate or graduate student.

|  |  |  |
| --- | --- | --- |
| First: Click here. | Last: Click here. | Degree(s): Click here. |
| Institution: Click here. | Program: Click here. | Department: Click here. |
| Street Address: Click here. | Room/Suite #: Click here.  | City: Click here. |
| Province: Click here. | Postal Code: Click here. | Email: Click here. |
| Telephone: Click here. | Fax: Click here. | RVH Affiliated? [ ]  Yes [ ]  No |
|  |

1. Is this study part of a student’s academic training program? [ ]  Yes [ ]  No
If “Yes”, please provide the student’s contact information below.

|  |  |  |
| --- | --- | --- |
| First: Click here. | Last: Click here. | Degree: Click here. |
| Institution: Click here. | Program: Click here. | Department: Click here. |
| Street Address: Click here. | Room/Suite #: Click here. | City: Click here. |
| Province: Click here. | Postal Code: Click here. | Email: Click here. |
| Telephone: Click here. | Fax: Click here. | RVH Affiliated? ☐ Yes ☐ No |

1. Is the Principal Investigator the student’s supervisor? [ ]  Yes [ ]  No [ ]  Not applicable

If “No”, please provide the supervisor’s contact information below.

|  |  |  |
| --- | --- | --- |
| First: Click here. | Last: Click here. | Degree: Click here. |
| Institution: Click here. | Program: Click here. | Department: Click here. |
| Street Address: Click here. | Room/Suite #: Click here. | City: Click here. |
| Province: Click here. | Postal Code: Click here. | Email: Click here. |
| Telephone: Click here. | Fax: Click here. | RVH Affiliated? ☐ Yes ☐ No |

1. Please list any additional study team members who will have access to information obtained from patient medical records, including abstractors, co-investigators, students, statisticians, and collaborators (leave blank if no additional study team members):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name and Degree(s) | Primary Institutional Affiliation | Profession | Role on Project | Email |
| Click here. | Click here. | Click here. | Click here. | Click here. |
| Click here. | Click here. | Click here. | Click here. | Click here. |
| Click here. | Click here. | Click here. | Click here. | Click here. |
| Click here. | Click here. | Click here. | Click here. | Click here. |

**SECTION C: COLLECTION, STORAGE, & USE**

**OF PERSONAL INFORMATION**

1. Indicate the location(s) where the collection/abstraction of patient health information will occur:

|  |
| --- |
| Click here to enter text.  |

1. What is the source of the patient health information you are accessing?

[ ] Health Records or Decision Support Unit

[ ]  Electronic Medical Record (specify):Click here to enter text.

[ ] Clinic/Office Records (specify):Click here to enter text.

[ ] Outside Institution (specify):Click here to enter text.

[ ] Other (specify): Click here to enter text.

1. Identify if you require any resources (e.g., database training, health record retrieval, pre-screening eligible populations) from the following: [ ] Not applicable

[ ] Health Records (specify): Click here to enter text.

[ ] Decision Support Services (specify): Click here to enter text.

[ ] Other (specify):Click here to enter text.

1. What type of data will you require?
2. [ ] Aggregate data(i.e., you do not need to collect and/or use personal health information from individual medical charts). Data is considered to be aggregated when groups of observations are replaced with summary statistics based on those observations.
3. If you only require aggregate data for your study, indicate your search criteria (e.g., diagnoses, procedure, time period, other):

|  |
| --- |
| Click here to enter text.  |

(b)[ ] Identifiable data(i.e., you need to view individual medical charts)

If you require identifiable data, please provide justification for a waiver of consent in your study protocol or supporting documentation. The REB may approve research that involves an alteration to the requirements for consent if the investigator meets the criteria set out in the following documents:

* PHIPA, 2004, c. 3, Sched A, s.44 (3) (<https://www.ontario.ca/laws/statute/04p03>); and
* TCSP2 – 2018, Article 3.7A (<http://www.pre.ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html#a>)

If you require identifiable date, please check the following relevant boxes to identify what type of data you are collecting. If you do not require identifiable data, please proceed directly to **Question 6** below.

Investigators should plan to collect personal data at the lowest level of identifiability necessary to achieve the study objectives. For example, investigators should collect age (years) instead of date of birth (dd/mm/yyyy), if possible. Investigators should be aware that even a dataset without direct identifiers may present a risk of indirectly identifying subjects if the data contains sufficient information about the individuals concerned.

For additional guidance, please consult the CIHR Best Practices for Protecting Privacy in Health Research: <http://www.cihr-irsc.gc.ca/e/29072.html>

|  |  |  |
| --- | --- | --- |
| IDENTIFIERS(check all that apply) | How will this item be stored? | Please justify why this information is required |
| Paper | Electronically |
| Full Name  | [ ]  | [ ]  | Click here to enter text. |
| Address | [ ]  | [ ]  | Click here to enter text. |
| Telephone Number | [ ]  | [ ]  | Click here to enter text. |
| Ontario Health Card Number | [ ]  | [ ]  | Click here to enter text. |
| Sex and/or Gender | [ ]  | [ ]  | Click here to enter text. |
| Initials | [ ]  | [ ]  | Click here to enter text. |
| Date of Birth | [ ]  | [ ]  | Click here to enter text. |
| Age or Year of Birth | [ ]  | [ ]  | Click here to enter text. |
| Full Postal Code  | [ ]  | [ ]  | Click here to enter text. |
| First Three (3) Digits of Postal Code | [ ]  | [ ]  | Click here to enter text. |
| Email address | [ ]  | [ ]  | Click here to enter text. |
| Fax number | [ ]  | [ ]  | Click here to enter text. |
| Healthcare Provider  | [ ]  | [ ]  | Click here to enter text. |
| Admission Date | [ ]  | [ ]  | Click here to enter text. |
| Discharge Date | [ ]  | [ ]  | Click here to enter text. |
| Service Date | [ ]  | [ ]  | Click here to enter text. |
| Medical Device Identifier | [ ]  | [ ]  | Click here to enter text. |
| Certificate/License Number | [ ]  | [ ]  | Click here to enter text. |
| Vehicle Identification | [ ]  | [ ]  | Click here to enter text. |
| Medical Record Number | [ ]  | [ ]  | Click here to enter text. |
| Account Number | [ ]  | [ ]  | Click here to enter text. |
| Full Face Photograph | [ ]  | [ ]  | Click here to enter text. |
| Other (specify): Click here to enter text. | [ ]  | [ ]  | Click here to enter text. |

1. What is the minimum number of records required to achieve your study? Click here to enter text.
2. How did you determine the minimum number of records required to achieve your study?

|  |
| --- |
| Click here to enter text.  |

1. What is the time period of the health information that you will abstract from your source?

From: Click or tap to enter a date. To: Click or tap to enter a date.

1. Have you attached a data collection form that includes a list of variables to be abstracted? [ ]  Yes [ ]  No

If “No”, the application will be returned to the Principal Investigator for completion

1. Do you plan to link the locally collected data with any other dataset(s) [e.g., Institute for Clinical Evaluative Sciences (ICES), Canadian Institute for Health Information (CIHI), Statistics Canada)]?

[ ]  Yes [ ]  No

If “Yes”, please provide additional information:

1. Why is the data being linked: Click here to enter text.
2. Identify the linked dataset(s): Click here to enter text.
3. Identify how the linkage will occur: Click here to enter text.
4. Provide a list of data items contained in it: Click here to enter text.
5. Please provide below details of how physical/paper and/or digital/electronic collection tools will protect the information being collected.
* Note: If direct identifiers must be retained, they should be isolated on a separate dedicated server and/or network without external access. Research databases with patient information should not be housed on portable devices, such as laptops or flashcards.

|  |
| --- |
| **PHYSICAL / PAPER (check all that apply)** |
| * Completed data forms will be stored in a locked filing cabinet in a secure location
 | [ ]  |
| * Premises will be locked except when one or more of the individuals named under Section B are present:
 | [ ]  |
| * Access to premises will be controlled (e.g., security clearances, pass cards)
 | [ ]  |
| * Other (please specify): Click here to enter text.
 | [ ]  |
| Provide the name of the organization, building, and room number where the information will be kept (e.g. Royal Victoria Regional Health Centre, 4SC, Room 4501): Click here to enter text. |

|  |
| --- |
| **DIGITAL / ELECTRONIC (check all that apply)** |
| * Computer security methods to prevent unauthorized access will be: De-identified
 | [ ]  |
| Password Protected | [ ]  |
| Encrypted | [ ]  |
| Virus protected | [ ]  |
| Firewalled | [ ]  |
|  Other (specify): Click here to enter text. | [ ]  |
| * Will REDCapTM be used to collect and manage data? [ ]  Yes [ ]  No

Note: REDCapTM is a secure web application designed to support PHIPA-compliant data capture and management. All RVH investigator-led research must be performed using REDCapTM, unless an equivalent, PHIPA-compliant data capture and management tool is available from sponsor or collaborator\*\*  |
| * If data will be de-identified, indicate when this will occur (e.g., as soon as data collection is complete) and how (e.g. use of study ID and master key): Click here to enter text.
 | [ ]  |
| * If using encryption software, please identify the name of the software: Click here to enter text.
 |
| * Provide the name of the organization, building, and room number where the computing equipment storing data with identifiers will be housed (e.g., Royal Victoria Regional Health Centre, 4SC, Room 4501): Click here to enter text.
 |
| * Identify the owner of the computing equipment being used for storage of data with identifiers: Click here to enter text.
 |

\*\*For more information about REDCapTM, please contact the RVH Research Institute at research@rvh.on.ca

**SECTION D: DATA TRANSFER**

1. Will data be transferred outside of the institution where it was collected and/or will you be receiving data from other sites? [ ]  Yes [ ]  No

 If “No”, skip this section and proceed to Section E: Risks and Benefits

 If “Yes”, explain why it is necessary to transfer and/or receive data outside of the institution where it was

 collected (max. 200 words):

|  |
| --- |
| Click here to enter text.  |

1. Where will data be sent (please provide receiving institutions details)?

|  |
| --- |
| Click here to enter text.  |

1. Who will be receiving the data (please provide receiving investigator’s details)?

Note: data may only be disclosed to individuals identified in Section B: Investigators

|  |
| --- |
| Click here to enter text.  |

1. Please provide additional information on how data will be transferred between sites:

|  |  |  |
| --- | --- | --- |
| **Transmission Mode** | **Sending** | **Receiving** |
| Fax (please describe security at the receiving site: Click here to enter text.) | [ ]  | [ ]  |
| Email (encryption protocol must be attached) | [ ]  | [ ]  |
| Private Courier (sender must be able to trace delivery) | [ ]  | [ ]  |
| Canada Post Xpress-post or Priority Courier (regular mail may NOT be used) | [ ]  | [ ]  |
| Other (please specify: Click here to enter text.) | [ ]  | [ ]  |

1. Will there be a Data Transfer Agreement (or equivalent agreement) put in place for the transfer of data?

[ ]  Yes [ ]  No

If “No”, please explain why: Click here to enter text.

1. Will the data be entered into a data set for future use? [ ]  Yes [ ]  No [ ]  Unknown

If “Yes”, please specify:

Where will the data be stored (max. 200 words)? Click here to enter text.

Who will be the data custodian (max. 200 words)? Click here to enter text.

Who will have access to the database (max. 200 words)? Click here to enter text.

What security measures will be in place to protect the data? Click here to enter text.

* Please note, any secondary analysis of the data must be approved by the RVH REB

1. Specify how long you plan to keep the data (note: you are required to destroy identifiers or links at the earliest possible time):

|  |
| --- |
| Click here to enter text.  |

1. Will data be [ ]  destroyed or [ ]  irreversibly anonymized (i.e., the key identifying the link between data and the individual’s identity is deleted)?
* Please note, any mishandling or unauthorized use of study data may lead to cancellation of REB approval and referred to the Privacy Office of the impacted organization(s).

**SECTION E: RISKS AND BENEFITS**

1. What are the anticipated public and scientific benefits of the study (max. 200 words)?

|  |
| --- |
| Click here to enter text.  |

1. Please describe any foreseeable risks and/or harms that may arise from the collection, use, and storage of personal health informationfor this study (max. 200 words):

|  |
| --- |
| Click here to enter text.  |

SECTION F: INVESTIGATOR AGREEMENT

The following represents the terms and conditions under which the handling of confidential information for this research shall proceed. These terms and conditions below have been drafted in compliance with the Ontario Personal Health Information Protection Act, 2004, S.O. 2004, c.3, Sched. A, 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 application, 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 application;
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 study identifier 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 Ontario Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A (<http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm>)
10. Publication of confidential information requires adherence to the following principles:
11. 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;
12. 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;
13. The Royal Victoria Regional Health Centre will be acknowledged within any publication as providing the source information in the following fashion
14. A copy of the accepted manuscript will be given to the institution at the time of its publication
15. Information which is lost or stolen must be immediately reported to the RVH REB at reb@rvh.on.ca and the RVH Privacy Coordinator at privacy@rvh.on.ca
16. 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,

1. Any changes to this research plan will be submitted to the RVH REB for approval prior to proceeding, including any change in persons given access to the data.

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

|  |  |  |
| --- | --- | --- |
|   |  |  |
| Principal Investigator | Signature | Date |

-AND-

Signatures of **all** study team members and individuals reviewing medical records/charts:

|  |  |  |
| --- | --- | --- |
| Print Name | Signature | Date Signed |
| Click here to enter text. |  |  |
| Click here to enter text. |  |  |
| Click here to enter text. |  |  |
| Click here to enter text. |  |  |
| Click here to enter text. |  |  |
| Click here to enter text. |  |  |

**SECTION G: RESEARCH IMPACT SIGNATURES**

1. This completed RVH REB Application for Medical Chart Review, and all supporting documentation (e.g., study protocol, list of abstracted variables), has been reviewed and approved by:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| RVH Privacy Coordinator (required for RVH) or other institutional approver | Signature | Date |

|  |  |  |
| --- | --- | --- |
|   |  |  |
| Clinical Director, FMTU (if applicable) | Signature | Date |

|  |
| --- |
| **RVH REB Internal Use Only** |

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| --- | --- | --- |
|   |  |  |
| Chair, RVH REB | Signature | Date |

|  |  |  |
| --- | --- | --- |
|   |  |  |
| Chair, RVH Medical Advisor Committee | Signature | Date |

|  |  |  |
| --- | --- | --- |
|   |  |  |
| Secretary, RVH Board of Directors | Signature | Date |