

RVH Research Ethics Board (REB)

**GENERAL RESEARCH APPLICATION**

**INSTRUCTIONS**

* This form is used to apply for **initial** REB review of new research projects that involve contact with or observation of human study participants. Please do not use this form for chart reviews
* **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
* A completed application consists of the following documents: 1) General Research Application; 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 the review, approval, and continuing ethics review of research conducted at other sites
* 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 of 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**

**RVH 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”, please 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? [ ]  Yes [ ]  No

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

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

13. Please identify which department(s)/program(s) will be impacted by this study through the use of hospital resources, space, patients, staff, data, or biospecimens (select all the apply):

|  |  |
| --- | --- |
| [ ]  Biomedical Engineering (BIOMED) | [ ]  Maternal, Newborn, Child & Youth Program  |
| [ ]  Cancer Program | [ ]  Medicine Program  |
| [ ]  Cardiovascular Program | [ ]  Mental Health & Addictions  |
| [ ]  Emergency | [ ]  Occupational Health & Wellness, Workplace Safety  |
| [ ]  Facility Support Services | [ ]  Pharmacy Program |
| [ ]  Family Medicine Teaching Unit (FMTU) | [ ]  Professional Practice, Infection Prevention and Control, and Allied Health |
| [ ]  Health Information Management | [ ]  Surgical Services Program  |
| [ ]  Imaging Services | [ ]  Renal Program  |
| [ ]  Intensive Care | [ ]  Surgical Services Program  |
| [ ]  Laboratory Services | [ ]  Other (specify): Click here. |

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. 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. Is the Principal Investigator of this study affiliated with RVH? [ ]  Yes [ ]  No

If “No”, a local Co-Investigator is required to provide institutional oversight of the study at RVH.

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. |

1. Does this study have any Co-Investigators? [ ]  Yes [ ]  No

If “Yes”, please provide the contact information for each Co-Investigator below. Please list additional names and contact information on a separate page.

|  |  |  |
| --- | --- | --- |
| 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 |

|  |  |  |
| --- | --- | --- |
| 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 |

|  |  |  |
| --- | --- | --- |
| 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. Does this study have a Study Coordinator? [ ]  Yes [ ]  No

If “Yes”, please provide the Study Coordinator’s contact information below.

|  |  |  |
| --- | --- | --- |
| 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(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 the Principal Investigator the student’s supervisor? [ ]  Yes [ ]  No

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

|  |  |  |
| --- | --- | --- |
| 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. Please list any additional study team members (e.g., abstractors, statisticians, students) who will have access to identifiable participant information.

|  |  |  |
| --- | --- | --- |
| First Name | Last Name | Primary Institutional Affiliation |
| 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. |
| 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. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

**SECTION C: DESCRIPTION OF RESEARCH**

1. Is this an interventional study? [ ]  Yes [ ]  No

If “No”, proceed directly to **Question 3** directly below.

1. Is this a clinical trial? [ ]  Yes [ ]  No

For the purposes of this application, a clinical trial is defined as any study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

1. Is this an observational study? [ ]  Yes [ ]  No

For the purposes of this application, an observational study monitors changes over time without introducing an intervention.

1. Does this study require human tissue or biological specimen (e.g., cadaver, biological fluids) collection and/or analysis? [ ]  Yes [ ]  No

If “Yes”, please select all that apply:

[ ]  Retrospective collection and/or analysis

[ ]  Prospective collection and/or analysis

[ ]  For banking

[ ]  For biomarker analysis

[ ]  For genetic analysis

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

If “Yes”, please indicate if the material is:

[ ]  **MANDATORY** for participation in themain study *OR* [ ]  **OPTIONAL** to the main study?

1. Does this study include genetic testing? [ ]  Yes [ ]  No

If “Yes”, please attach as a separate Informed Consent for Genetic Testing form with this application.

1. Does this study require any access to existing records? [ ]  Yes [ ]  No

If “Yes”, please specify source (select all that apply):

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

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

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

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

1. Does this study involve qualitative methods? [ ]  Yes [ ]  No

If “Yes”, please select all that apply:

[ ]  Questionnaire/Survey

[ ]  Focus Group

[ ]  Interview

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

Please attach a copy of all study questions and interview guides as supporting documentation with this application.

1. What is the role of the hospital or healthcare facility in this study (max 200 words)?

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

**SECTION D: CLINICAL TRIALS**

* Please note, if this is **not** a clinical trial, please proceed directly to **Section E: Methodology** below
1. What type of clinical trial is this (select all that apply)?

|  |
| --- |
| [ ]  Investigational Medicinal Product[ ]  Investigational Device[ ]  Natural and Non-prescription Health Product[ ]  Health-related intervention (e.g., surgical procedure, behavioral treatment, dietary intervention) |
| [ ]  Pilot [ ]  Phase 1 [ ]  Phase 2 [ ]  Phase 3 [ ]  Phase 4 [ ]  Unknown  |
| [ ]  Randomized [ ]  Single Blind [ ]  Double Blind [ ]  Open Label  |
| [ ]  Investigational Drug(s) [ ]  Investigational Biologic(s) [ ]  Investigational Natural Health Product(s) [ ]  Investigational Medical Device(s) [ ]  Gene Therapy/Stem Cell/Transplant [ ]  Other (specify): Click here. |

1. Will this trial use an active comparator? [ ]  Yes [ ]  No

If “Yes”, please justify that the comparator is standard care and that clinical equipoise exists (max. 200 words):

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

1. Will this trial use a placebo control? [ ]  Yes [ ]  No

If “Yes”, please justify that the placebo is necessary and that clinical equipoise exists (max. 200 words):

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

If “Yes”, please describe how you will reduce the risks to participants assigned to the placebo (max. 200 words):

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

1. Does this clinical trial require Health Canada approval? [ ]  Yes [ ]  No

If “Yes”, who submitted the Clinical Trial Application to the Office of Clinical Trials of Health Canada?

[ ]  Lead Qualified Investigator

[ ]  Local Qualified Investigator

[ ]  Sponsor

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

1. Have you received a No Objection Letter (NOL) to perform this study from Health Canada?

[ ]  Yes [ ]  No  [ ]  Not applicable

* Please note, REB approval will not be granted until the appropriate regulatory approvals have been received.
1. Do any of the following conditions (*a-d*, directly below) apply to this study? [ ]  Yes [ ]  No

a. At least one study facility is located in the United States (U.S.), a U.S. territory, or other foreign jurisdiction

b. The study is conducted under a U.S. FDA Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) or other foreign jurisdiction equivalent

c. The study involves a drug, biological, or device product that is manufactured in and exported from the U.S., a U.S. territory, or other foreign jurisdiction

d. The study evaluates at least one drug, biological, or device product regulated by the U.S. FDA or foreign jurisdiction equivalent

1. Are there any other agencies providing regulatory approval and/or oversight of this clinical trial (e.g., U.S. Food and Drug Administration, European Medicines Agency)? [ ]  Yes [ ]  No

If “Yes”, please identify these agencies:

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

1. Has the study been registered on a clinical trial registry? [ ]  Yes [ ]  No

If “Yes”, please provide the registry information:

Registry Name: Click here to enter text. Registration Number: Click here to enter text.

If “No”, please explain why the trial is not registered (max. 200 words):

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

* Note, all clinical trials must be registered before patient recruitment can begin.

**SECTION E: METHODOLOGY**

* Note, this section is intended to be a summary only. Please submit a detailed study protocol outlining the research that you plan to conduct with this application.
1. What is the rationale for this study (max. 200 words)?

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

1. What are the objectives of this study (max. 200 words)?

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

1. Please specify your study design (max. 200 words):

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

1. Please provide details about your study population (max. 200 words):

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

1. Please specify your study procedures (max. 200 words):

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

1. What is your primary outcome and how will it be measured (max. 200 words)?

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

1. What is your secondary outcome and how will it be measured (max. 200 words)?

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

1. What is your sample size?

Local: Click here to enter text. Total (for multi-site research): Click here to enter text.

1. How did you determine your sample size (max. 200 words)?

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

1. How will you analyze your data (max. 200 words)?

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

**SECTION F: STUDY INTERVENTIONS**

1. Does this study involve any of the following interventions? [ ]  Yes [ ]  No

If “No” (e.g., observational study), please proceed directly to **Section G: Safety and Monitoring**

If “Yes”, please select all that apply:

[ ]  Chemotherapy [ ]  Questionnaire and/or survey

[ ]  Drugs [ ]  Interview/Focus Groups

[ ]  Medical Device [ ]  Gene Therapy/Stem Cell/Transplant

[ ]  Exercise [ ]  Surgery

[ ]  Radiotherapy [ ]  Cognitive/Behavioral Therapy

[ ]  Natural Health Product and/or Non-Prescription Drug

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

1. Does this study involve any diagnostic testing? [ ]  Yes [ ]  No

If “Yes”, please specify: [ ]  Imaging [ ]  Laboratory [ ]  Other (specify): Click here to enter text.

1. Does this study require any drugs? [ ]  Yes [ ]  No

If “Yes”, list all drugs identified in the study protocol (add more rows, as needed):

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Investigational | Generic Name | Brand Name | Manufacturer | Dose | Frequency | Route | Duration |
| [ ]  Yes [ ]  No | Click here. | Click here. | Click here. | Click here. | Click here. | Click here. | Click here. |
| [ ]  Yes [ ]  No | Click here. | Click here. | Click here. | Click here. | Click here. | Click here. | Click here. |
| [ ]  Yes [ ]  No | Click here. | Click here. | Click here. | Click here. | Click here. | Click here. | Click here. |
| [ ]  Yes [ ]  No | Click here. | Click here. | Click here. | Click here. | Click here. | Click here. | Click here. |
| [ ]  Yes [ ]  No | Click here. | Click here. | Click here. | Click here. | Click here. | Click here. | Click here. |

1. Describe the usual standard of care for this population (max. 200 words):

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

1. What procedures will be carried out in the study that are not considered part of the diagnostic, therapeutic “routine”, or standard of care (max. 200 words)?

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

1. Indicate the additional risks associated with the study as compared to the usual standard of care. Do not refer to other sections of this form (max. 200 words):

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

**SECTION G: SAFETY AND MONITORING**

* Note: all studies must be monitored to ensure participant safety and confidentiality, and to ensure the integrity of data collection and analysis.
1. How will you monitor the conduct of this study (max. 200 words)?

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

1. Will an interim data analysis be done? [ ]  Yes [ ]  No

If “Yes”, please describe the analysis (max. 200 words):

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

1. Does this study have a steering committee? [ ]  Yes [ ]  No

If “Yes”, please provide a copy of the committee’s Terms of Reference with this application or provide a description of the steering committee below (max. 200 words):

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

1. Does this study use a Data Safety Monitoring Board (DSMB)? [ ]  Yes [ ]  No

If “Yes”, please provide a copy of the DSMB charter with this application or provide a description of the DSMB below (max. 200 words):

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

1. Is the DSMB independent of the sponsor? [ ]  Yes [ ]  No [ ]  Not applicable
If “No”, please identify what alternative arrangements are in place to monitor the safety data and by whom and how the overall risk/benefit information will be communicated to the REB (max. 200 words):

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

**SECTION H: RISKS AND BENEFITS**

1. List the known risks of study intervention(s) including approximate rate of occurrence, severity, and reversibility (max. 200 words): [ ]  Not applicable

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

1. List the risks of any tests, procedures, or other protocol-mandated activities that are conducted for research purposes only, including approximate rates of occurrence, severity, and reversibility (max. 200 words):

[ ]  Not applicable

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

1. For studies involving placebo, washout or withholding treatment, list any risks related to withdrawal or absence of treatment (max. 200 words): [ ]  Not applicable

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

1. Include a summary of the data regarding reproductive risks, such as teratogenicity or embryotoxicity, risk to breastfeeding, or risk to conception (max. 200 words): [ ]  Not applicable

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

1. Does participation in this study affect alternatives for future care? [ ]  Yes [ ]  No [ ]  Not applicable

If “Yes”, please explain (max. 200 words):

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

1. How will you minimize and manage risks to study participants (max. 200 words)?

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

1. Will participants receive any benefits from participating in this study (e.g., continued access to new drug, travel reimbursement)? [ ]  Yes [ ]  No

If “Yes”, please explain: Click here to enter text.

1. Will participants or substitute decision makers receive any compensation? [ ]  Yes [ ]  No

If “Yes”, please select all that apply:

|  |
| --- |
| [ ]  Reimbursement for expenses incurred as a result of research participationAmount: Click here to enter text. Specify (e.g., travel, meals, parking): Click here to enter text. |
| [ ]  Payment for timeAmount: Click here to enter text. Justification for compensation (max. 200 words): Click here to enter text.  |
| [ ]  Gifts for participationValue: Click here to enter text. |
| [ ]  Other (please specify): Click here to enter text. |

1. How will the scientific community benefit from this study (max. 200 words):

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

1. How will society benefit from this study (max. 200 words):

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

**SECTION I: PARTICIPANTS**

1. Does this study affect any of the potentially vulnerable groups listed below? [ ]  Yes [ ]  No

If “Yes”, please select all that apply:

[ ]  People with cancer [ ]  Children

[ ]  People with incurable disease [ ]  Elderly people

[ ]  People in medical emergencies [ ]  Aboriginal Peoples (see TCPS2, Chapter 9)

[ ]  People in long-term care [ ]  People in poverty

[ ]  People with mental health issues [ ]  People in prison

[ ]  People who are unable to consent [ ]  Other (specify): Click here.

1. Does your research involve any of the following special considerations listed below? [ ]  Yes [ ]  No

If “Yes”, please select all that apply:

[ ]  Women of childbearing potential [ ]  Tissue samples

[ ]  Pregnant women [ ]  Fetal tissue or placenta

[ ]  Healthy volunteers [ ]  Prisoners

[ ]  Students [ ]  Participants unable communicate

[ ]  Staff [ ]  None of the above

[ ]  Genetic research [ ]  Other (specify): Click here.

1. Do you have any age, sex, gender, language, ethnic-specific, or race-specific inclusion or exclusion criteria?

[ ]  Yes [ ]  No

If “Yes”, please explain (max. 200 words):

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

**SECTION J: RECRUITMENT**

* Please note, any document to be viewed by a study participant (e.g., recruitment posters, letters, consent/assent forms, information sheets) must be included with your application
1. How do you plan to recruit participants (select all that apply)?

[ ]  Investigators or members of the study team will approach their own participants

[ ]  Investigators will receive referrals from other health care providers (i.e., non-study personnel)

[ ]  Decision Support Unit will prepare a list of potential participants based on inclusion/exclusion criteria

[ ]  Advertising (e.g., poster, pamphlet, email)

[ ]  Database of people who consented to future contact; please explain (max. 200 words): Click here.

[ ]  Direct approach (e.g., random digit dialing); please explain (max. 200 words): Click here.

[ ]  Educational records (e.g., information from a registrar); please explain (max. 200 words): Click here.

[ ]  Other (specify; max. 200 words): Click here.

1. Do you need to screen Personal Health Information (PHI) to identify potential study participants?

[ ]  Yes [ ]  No

If “Yes”, please describe your screening/identification process (max. 200 words):

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

* Please note, investigators must destroy all information collected during screening/identification in a secure manner, as soon as screening is complete.

1. Does your recruitment plan require you to contact potential participants by:

Telephone [ ]  Yes [ ]  No

Email [ ]  Yes [ ]  No

Letter [ ]  Yes [ ]  No

If “Yes” to any of the above, please include all recruitment material (e.g., pamphlets, posters, telephone scripts, emails) to this application

**SECTION K: CONSENT**

1. Do you need to request a waiver of consent for this study? [ ]  Yes [ ]  No

If “Yes”, please provide justification for a waiver of consent in your study protocol or supporting documentation.

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

If “Yes”, please proceed directly to **Section L: Collection, Storage, & Protection of Personal Information**

1. Will you be seeking written consent from adult participants (i.e., age ≥16)? [ ]  Yes [ ]  No

If “Yes”, please attach the consent form(s) for participants with this application

If “No”, please explain why (max. 200 words):

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

1. Will any participants be minors (i.e., age 0-15)? [ ]  Yes [ ]  No

If “Yes”, please attach the consent form(s) for parents (or legal guardian) and a separate, age-appropriate, assent form, if applicable

1. Will all participants be competent to consent? [ ]  Yes [ ]  No

If “Yes”, what conditions must be met to be considered competent to consent (max. 200 words):

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

If “No”, can the Substitute Decision Maker(s) provide consent on behalf of the participant: [ ]  Yes [ ]  No

If applicable, please ensure the consent form(s) include relevant sections for the Substitute Decision Maker(s)

1. Describe the consent process (max. 200 words):

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

1. Who will obtain consent to participate (max. 200 words)?

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

1. Is there a relationship between the participants and any of the following persons?

Person obtaining consent: [ ]  Yes [ ]  No

Investigator: [ ]  Yes [ ]  No

Study team: [ ]  Yes [ ]  No

If “Yes” to any of the above, explain the nature of the relationship (e.g., physician, employer) and what steps will be taken to avoid the perception of undue influence (max. 200 words):

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

1. How much time will be given to the participants to review the information before being asked to give consent (max. 200 words)?

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

1. Will participants have the option to withdraw from this study? [ ]  Yes [ ]  No

If “Yes”, what do they have to do to withdraw (max. 200 words):

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

 If “No”, please explain:

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

**SECTION L: COLLECTION, STORAGE, & PROTECTION**

**OF PERSONAL INFORMATION**

**Types of information:**

* **Identifiers:**
	+ **Identifying information:** identifies a participant through direct identifiers (e.g., full name, medical record number)
	+ **Identifiable information:** participants could be identified through a combination of indirect identifiers (e.g., date of birth, diagnosis, and postal code)
* **De-identified and/or coded information:** identifiers are removed and replaced with a code (e.g., alphanumeric characters), which can be used to re-identify patients
* **Anonymized information:** all identifiers are removed and no code is kept so that participants cannot be identified by the recipient of the information
* **Anonymous information:** no identifiers were collected

**Personal Health Information:**

* Investigators must comply with the duties set out in the Ontario Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A with respect to the collection, use, and disclosure of Personal Health Information (PHI);
* Investigators must comply with the privacy, confidentiality, and consent guidelines outlined in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans and other requirements and guidelines as set by the Royal Victoria Regional Research Centre’s Standard Operating Procedures for research;
* Collection of a participant’s Social Insurance Number (SIN) is prohibited;
* PHI should be collected at the lowest level of identifiability possible (e.g., initials instead of full name; age instead of date of birth)

|  |
| --- |
| **PHIPA Storage requirements:*** Paper files with identifiable information must be kept in a locked cabinet with a locked office (but not in a personal residence)
* Electronic files with identifiable information may be stored on password protected computer on a secure network (i.e., antivirus software, data backup, firewall) or they must be encrypted
* Electronic filed with identifiable information may be stored on mobile devices (e.g., laptop, compact disc, flash drive, memory card)

**Coding requirements:*** Identifying and/or identifiable PHI should be protected by a coding system
* The code (Study ID and identifiable PHI) must be isolated from study data and stored in a secure manner
 |

1. Do you need to record any identifiers for this study? [ ]  Yes [ ]  No

If “Yes”, please select all that apply:

[ ]  Full name [ ]  Telephone number

[ ]  Initials [ ]  Email

[ ]  Health card number [ ]  Images (e.g., photograph, x-ray, MRI scan)

[ ]  Medical record number [ ]  Date of birth

[ ]  Address [ ]  Age

[ ]  Full Postal Code [ ]  Other (please specify): Click here to enter text.

[ ]  Partial Postal Code

1. How will you record study data?

[ ]  Case Report Form (CRF). If selected please attach the CRF(s) with this application.

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

1. Will REDCapTM be used to collect and manage study 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.

1. Will you use a coding system to protect participant information? [ ]  Yes [ ]  No

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

1. Indicate how and where you will store and protect the study code (or other participant data with identifiers)?

|  |  |  |
| --- | --- | --- |
| Type of Record | Required Protection | Specific Location (i.e., building, room number) |
| Paper file | [ ]  Locked cabinet in a locked institutional office | Click here to enter text. |
| Electronic file | [ ]  Password protected computer on a secure network | Click here to enter text. |
| [ ]  Encryption (specify software used): Click here. | Click here to enter text. |
| Audiovisual | [ ]  Locked cabinet in a locked institutional office | Click here to enter text. |

1. Describe the security measures that will be taken to protect the confidentiality of participant information (max. 200 words):

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

1. Do you plan to anonymize the study data? [ ]  Yes [ ]  No

If “Yes”, when (max. 200 words)? Click here to enter text.

* Please note, investigators are required to destroy identifiers or links at the earliest possible time
1. How long will you keep the study data? Click here to enter text.
* Please note, if this study requires Health Canada approval, all records must be retained for 15 years. For all other studies, the REB recommends a retention period of 10 years. Sponsors and external investigators may set other requirements.
1. What will you do with the study data after the retention period (max. 200 words)?

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

**SECTION M: TRANSMISSION OF DATA**

1. Does this study require you to send data outside of the institution where it was collected? [ ]  Yes [ ]  No

If “No”, please proceed directly to **Section N: Secondary Use of Data**

If “Yes, a Data Transfer Agreement or other relevant agreement may be required; please contact the RVH Research Institute at research@rvh.on.ca or 705-728-9090 Ext. 41350 to inquire.

1. Where will the data be sent (max. 200 words)?

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

* Please note, any data sent to the U.S. will afford the U.S. government undue and unfettered access to this data; as such, investigators must inform study participants of this possibility.
1. Please list the names and institutional affiliations of persons not identified in **Section B: Investigators** who will have access to study identifiers: [ ]  Not applicable

|  |  |  |
| --- | --- | --- |
| Name | Primary Institutional Affiliation | Role on Project |
| 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. |
| 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. |

1. How will the data be transmitted (select all that apply)?

[ ]  Fax

[ ]  Email (Note: transmission of data via personal email is not permitted)

[ ]  Canada Post (Note: study data must be delivered by Registered Mail)

[ ]  Private courier (Note: study data must be tracked and signature provided upon delivery)

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

**SECTION N: SECONDARY USE OF DATA**

1. Will you link the collected data with any other data set (e.g., Statistics Canada; ICES): [ ]  Yes [ ]  No

If “Yes”, please specify:

Identify the data set(s): Click here to enter text.

Identify specific data that will be linked to the data set: Click here to enter text.

Explain how the linkage(s) will be made (max. 200 words): Click here to enter text.

Explain why the linkage(s) is/are required (max. 200 words): 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, even if unknown at this time, any secondary analysis of the data must be approved by the RVH REB

**SECTION O: FUNDING**

1. Does this study require any financial or in-kind support? [ ]  Yes [ ]  No

If “No”, please proceed directly to **Section P: Contracts and Agreements**

1. Please indicate the source of funding for this study (select all that apply):

|  |  |
| --- | --- |
| Funding Category | Funding Source(s) |
| [ ]  Industry (e.g., pharmaceutical company, contract research organization) | Click here to enter text. |
| [ ]  Government (e.g., Canadian Institutes for Health Research; Ontario Ministry of Health and Long-Term Care; Cancer Care Ontario) | Click here to enter text. |
| [ ]  Charitable Foundation (e.g., The Heart and Stroke Foundation) or Non-Profit Organization | Click here to enter text. |
| [ ]  Internal (e.g., foundation, department, program) | Click here to enter text. |
| [ ]  Other | Click here to enter text. |

1. What is the current status of funding?

[ ]  Funding obtained

[ ]  Funding applied for/pending; expected decision date: Click or tap to enter a date.

[ ]  No funding required; please explain (max. 200 words): Click here to enter text.

1. If funding is not awarded, do you plan to proceed with the study? [ ]  Yes [ ]  No [ ]  Not applicable

If “Yes”, are there sufficient resources to cover all study expenses? [ ]  Yes [ ]  No

1. Attach an **itemized study budget** (applies to all full board and delegated review studies) with this application. The budget should reflect all costs to complete the study, including non-monetary compensation (e.g., hours of in-kind support)

**SECTION P: CONTRACTS AND AGREEMENTS**

1. Is there any party external to the institution involved with the research that will be entering into a contract or agreement (e.g., Data Sharing Agreement; Clinical Trial Agreement; Material Transfer Agreement; Collaboration Agreement) with the institution? [ ]  Yes [ ]  No

If “No”, please proceed directly to **Section Q: Conflicts of Interest**

If “Yes”, please identify the other parties involved in the agreement (max. 200 words): Click here to enter text.

* Please note, to identify if a contract or agreement is required for your study, please contact the RVH Research Institute at research@rvh.on.ca
1. Will the contract or agreement limit your access to the research data or your right to publish the study results?

[ ]  Yes [ ]  No

If “Yes”, please explain (max. 200 words): Click here to enter text.

1. Has the contract or agreement been submitted to your organizations relevant contracts or legal team for review?

 [ ]  Yes [ ]  No

If “No”, please explain (max. 200 words): Click here to enter text.

* Please note, all contracts or agreements must be reviewed and signed by authorized institutional officials before research can be conducted

**SECTION Q: CONFLICTS OF INTEREST**

* Please note, conflicts of interest do not imply wrong-doing

It is the responsibility of the Principal Investigator to determine if any of the conflicts listed below apply to any persons involved in the research study or any member of their immediate family. Disclose all contracts, budgets, and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project. Conflicts of interest may also arise with regard to disclosure of personal health information.

1. Will any investigators, members of the research team, and/or their partners or immediate family members:

|  |  |  |
| --- | --- | --- |
| Function as an advisor, employee, officer, director, or consultant for the study sponsor or funding source? | [ ]  Yes | [ ]  No |
| Have direct or indirect interest in the drug, device, or technology employed in this research study (including inventorship, patents, or stocks)? | [ ]  Yes | [ ]  No |
| Receive any honorarium or other personal benefits from the sponsor (apart from fees for service)? | [ ]  Yes | [ ]  No |
| Use services of a family member or a company in which you or a family member has a direct interest? | [ ]  Yes | [ ]  No |
| Receive direct or indirect financial benefit from the disclosure of personal health information | [ ]  Yes | [ ]  No |
| Have a competing interest (situations in which the researcher may be influenced to draw conclusions against the interest of the sponsor or another interested party to the study because the researcher or a family member has an opposing interest related to the research, including a legal suit against a company or sponsor or a financial interest in a competing company or product) | [ ]  Yes | [ ]  No |
| Other (please describe; max. 200 words): Click here to enter text. |

If you have selected “No” for all of the above, please proceed directly to **Section R: Supporting Documents**

1. Please provide more information about each of the conflicts of interest identified above (max. 200 words):

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

1. Please explain how you will manage each of the conflicts of interest identified above (max. 200 words):

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

**SECTION R: SUPPORTING DOCUMENTS**

* Please identify each of the relevant supporting documentation that will accompany this application below;
* Please indicate or assign a version number or date for ***all*** supporting documents in the header or footer of each document (e.g., Version# / Date: 1.0 / DD-MMM-YYYY). Documents without a version number or date will be returned to the Principal Investigator for completion.

|  |  |
| --- | --- |
| Document Type | Version# / Date |
| [ ]  Cover Letter | Click here to enter text. |
| [ ]  Study Protocol (required) | Click here to enter text. |
| Consent Forms |
| [ ]  Participant  | Click here to enter text. |
| [ ]  Assent | Click here to enter text. |
| [ ]  Other (e.g., genetic, pregnant partner) | Click here to enter text. |
| Clinical Trial Documents |
| [ ]  Investigator’s Brochure | Click here to enter text. |
| [ ]  Product Monograph | Click here to enter text. |
| [ ]  Health Canada No Objection Letter (NOL) or other regulatory authorization | Date: Click or tap to enter a date.Control Number: Click here to enter text. |
| General Documents |
| [ ]  TCPS 2 CORE Certificate(s) - Principal Investigator, Co-Investigators, and other study personnel |
| [ ]  CITI GCP - Basic Certificate(s) - Principal Investigator, Co-Investigators, and other study personnel |
| [ ]  Health Canada Division 5 Certificate(s) - Principal Investigator, Co-Investigators, and other study personnel |
| [ ]  REB correspondence(s) | Click here to enter text. |
| [ ]  Advertisement(s) | Click here to enter text. |
| [ ]  Telephone script(s) | Click here to enter text. |
| [ ]  Email template(s) | Click here to enter text. |
| [ ]  Interview guide(s) | Click here to enter text. |
| [ ]  Questionnaire(s) | Click here to enter text. |
| [ ]  Case Report Form(s) | Click here to enter text. |
| [ ]  Pamphlet(s)/Brochure(s) | Click here to enter text. |
| Participant Material |
| [ ]  Journal/Diary/Memoir | Click here to enter text. |
| [ ]  Wallet Card | Click here to enter text. |
| [ ]  Information Sheet | Click here to enter text. |
| [ ]  Other (specify): Click here to enter text. | Click here to enter text. |
| Other documents (please specify; add additional as needed):  |
| [ ]  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 S: SIGNATURES AND IMPACT**

1. **PRINCIPAL INVESTIGATOR AGREEMENT**
* I assume full responsibility for the scientific and ethical conduct of the study as described in this application and submitted protocol;
* I agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects, the Ontario Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A, and any other relevant laws, regulations, or guidelines;
* I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified or will undergo appropriate training to fulfill their role in this project;
* I certify that any and all conflicts of interest have been declared;
* I have declared all costs associated with this project and have obtained the necessary approvals from each impacted department; and
* On behalf of my research team, I recognize the importance of maintaining the confidentiality of all personal information, including personal health information, and the privacy of individuals with respect to that information. I agree that if I receive any personal information, I will only use or disclose this information in accordance with the study protocol and the research participant’s informed consent form (unless a waiver of consent is granted) as approved by the REB, or as required by law. I agree to take any further steps required by the REB and/or the institution to ensure that the confidentiality and security of the personal information is maintained in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects, the Ontario Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A, and any other relevant laws, regulations, or guidelines

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

1. Has evidence of research ethics training (e.g., TCSP2 CORE certificate and/or CITI Program certificates) for the Principal Investigator, Co-Investigator(s), and all other study team members been attached with this application? [ ]  Yes [ ]  No

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

1. Has signed and dated curriculum vitae for the Principal Investigator, Co-Investigator(s), and all other study team member been attached with this application? [ ]  Yes [ ]  No

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

1. Has the study received approval from the directors of each impacted department and has the completed “Research Impact Form” been submitted with this application? [ ]  Yes [ ]  No

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

\*Please note, the Research Impact Form may be obtained from [www.rvhresearchinstitute.ca](http://www.rvhresearchinstitute.ca)

\*\*The Research Office is available to assist with completing the Research Impact Form

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| **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 |