Health Sciences North
Horizon Santé-Nord

Research Services Office
705-523-7100, ext. 2409
reb@hsnsudbury.ca

HEALTH SCIENCES NORTH
RESEARCH ETHICS BOARD APPLICATION

Instructions

- All sections of this application **MUST** be completed before it will be considered for REB review.
- All research must be compliant with:
  - The Tri-Council Policy Statement, available at http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/
  - The Ontario Personal Health Information Protection Act (2004), available at https://www.ontario.ca/laws/statute/04p03
  - Any other relevant regulations or guidelines.

Handwritten submissions will not be accepted

SECTION 1: GENERAL INFORMATION

1.1 **Project Title:**

1.2 **Sponsor/Funder (if applicable):**

1.3 **Lay Summary (max: 300 characters)**
Brief Description of project in layman's terms.
A separate detailed protocol **MUST** be included with each application.

1.4 **Principal Investigator at this site** (if a student project, the supervisor should be listed as the Principal Investigator (PI))

Name:	**Telephone**:
Email:	

1.5 **Local collaborator (if different from PI):**
For studies originating from outside of the institution, a staff member must be involved as the institutional liaison who will accept responsibility for the research activities at the institution, as well as serve as the administrative contact with the REB. Must have a @hsnsudbury.ca or @hsnri.ca or @sjsudbury.com email.

Name:	**Telephone**:
Email:	

1.6 **Is this a student or resident project?** ☐ **Yes** ☐ **No**
If YES, name of student:

1.7 **All REB correspondence should be sent to:**

Name:	**Telephone**:

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SECTION 1: GENERAL INFORMATION

Email:

SECTION 2: STUDY DESIGN

2.1 **Where is the research being conducted? (e.g. NECC, outpatient, ICU, community, etc.):**

2.2 **Please specify the nature of the study, check <u>all</u> that apply:**

- ☐ Chart Review (specify): ☐ Retrospective ☐ Prospective
- ☐ Clinical Research (Involving):
  - ☐ Living human participants
  - ☐ Human remains
  - ☐ Cadavers
  - ☐ Embryos
  - ☐ Fetuses
  - ☐ Human tissue and biological specimens (e.g. from cadavers, biological fluids, etc.)
    Indicate if the material is ☐ **INTEGRAL** to the main study or ☐ **OPTIONAL** to the main study.
    - ☐ Banking
    - ☐ Biomarker
    - ☐ Genomic
    - ☐ Genetic
    - ☐ Other (e.g. pharmacokinetic/pharmacodynamics etc.) (Specify):
- ☐ Qualitative (please check all that apply:)
  - ☐ Focus Groups
  - ☐ Interviews
  - ☐ Observational (e.g. naturalistic, field etc.)
  - ☐ Questionnaires/Surveys
  - ☐ Other (Specify):
- ☐ Case Study
- ☐ Epidemiological / Database
- ☐ Institute for Clinical Evaluative Sciences (ICES) data
- ☐ Quality Assurance / Quality Improvement / Educational
- ☐ Sub-study; indicate the Project # of main/related study:
- ☐ Other (Specify):

SECTION 3: REGULATED RESEARCH

3.1 ☐ **If not applicable, please skip to Section 4**

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SECTION 3: REGULATED RESEARCH

3.2 ☐ Health Canada Regulated (i.e. the research involves any drug or natural health product as an intervention and/or an investigational medical device)
(Specify): ☐Phase 1 ☐Phase 2/3 ☐Phase 4 ☐n/a
☐ Investigational drug(s)
☐ Investigational biologic(s)
☐ Investigational natural health product(s)
☐ Investigational medical device(s)

3.3 **Medical Device Class**: ☐Class I ☐Class II ☐Class III ☐Class IV

3.4 **Name(s) of Investigational Product(s) or Device(s)**:

3.5 **Is this research FDA regulated** (e.g. there is an IND/IDE, a FDA Form 1572 was signed, the trial results will be submitted to the FDA, etc.)? *If unknown, please contact the research sponsor.* ☐ **Yes** ☐ **No**

3.6 **Is this research funded or supported by the US government**? *If unknown, please contact the research sponsor.* ☐ **Yes** ☐ **No**

3.7 ***For studies being conducted in compliance with Good Clinical Practice (e.g. drug trials) - please attach a copy of the Investigator's CV or other description of his/her qualifications to conduct this clinical trial***

3.8 **Please confirm the project has a process to monitor the safety of participants outlined in the protocol** (e.g. Data Safety Monitoring Board/Committee (DSMB/C). ☐ **Yes** ☐ **No**
If <u>NO</u>, please provide a description of how participant safety will be monitored.

3.9 **If using a placebo, please provide justification.**

SECTION 4: RESEARCH PARTICIPANTS

4.1 **Brief description of participants** (e.g. *Emergency Department patients over the age of 55*):
Please refer to TCPS 2 Chapter 2 for considerations for special populations.

4.2 **Based on the description in the protocol, are there any age, ethnicity, language, gender or race-related inclusion or exclusion criteria?** ☐ **Yes** ☐ **No**

4.3 **Number of local participants you plan to enroll or records you plan to review:**

SECTION 4: RESEARCH PARTICIPANTS

4.4 **Will the participants be compensated in any way?** ☐ **Yes** ☐ **No**
If YES, please provide details:

SECTION 5: RISKS, BENEFITS AND SAFETY

5.1 **List the risks of any study intervention(s), tests, procedures or other protocol-mandated activities** that are conducted for research purposes only, including approximate rates of occurrence, severity and reversibility.

OR

As described in the:
☐ Protocol
☐ Product Monograph
☐ Investigator Brochure
☐ Instructions for Use

5.2 For studies involving placebo, washout, or withholding treatment, **list any risks related to withdrawal or absence of treatment.**
☐ Not Applicable

OR

As described in the:
☐ Protocol
☐ Product Monograph
☐ Investigator Brochure
☐ Instructions for Use

5.3 **Include a summary of the data regarding reproductive risks** such as teratogenicity or embryotoxicity of the study drug, any risk with breastfeeding, or risk to men regarding conception.
☐ Risks unknown
☐ Not Applicable

OR

As described in the:
☐ Protocol
☐ Product Monograph
☐ Investigator Brochure
☐ Instructions for Use

5.4 **Does participation in this study affect alternatives for future care?** ☐ **Yes** ☐ **No**
If YES, explain.

5.5 **List anticipated benefits to the participant, if any.**

5.6 **List potential benefits to society and the research community, if any.**

5.7 **If applicable, please describe the plan to identify and to disclose incidental findings to the participants.**
For more information about incidental findings, please refer to TCPS 2 Article 3.3.

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SECTION 5: RISKS, BENEFITS AND SAFETY

SECTION 6: RECRUITMENT AND CONSENT

6.1 **Identify the Recruitment Methods:**

☐ **Researcher's Patients**: If the patient is under the care of the Researcher, the Researcher may approach the patient directly, but in such a manner that the patient does not feel pressured or obligated in any way.

☐ **Referrals**: Researcher may provide colleagues with an REB approved consent form or research information sheet to give to their patients. The patient will then be asked to contact the Researcher directly, or, with documented permission from the patient, the Researcher may initiate the call.

☐ **Health Records Department/Decision Support**: The Researcher may ask the Health Records Department or Decision Support, after REB approval, to identify patients who appear to meet the research's eligibility criteria. It is NOT acceptable for the Researcher or his/her staff to contact patients identified through hospital records, clinic charts or other databases independently, unless the patient has previously agreed, or is already under the medical care of the Researcher.

☐ **Registries**: If the REB has previously approved a patient research registry and the patient has provided permission to be contacted for potential research, the Researcher or his/her research team may contact these patients directly. The person contacting the patient should identify him/herself as associated with the patient's clinical caregiver, and remind the patient that they have agreed to be contacted. The patient must be offered the option of having his/her name removed the database.

☐ **Advertising**: The REB must first review and approve the text and the use of any advertisements, notices or media messages.

☐ **Other (Specify):**

If no consent is to be obtained please skip to section 6.17

6.2 **Who will introduce the study to potential participants? How will contact be made** (e.g., in person, phone, letter, e-mail, website)**?**
Attach a copy of the script or any written materials if applicable.

6.3 **Describe the consent process** (e.g. how will consent be obtained, where will the consent process take place, how long will participants have to review the consent form, etc.). If the study population requires special consent considerations (e.g. child, incapacitated adult, unable to communicate, etc.), refer to Section 6.8.

SECTION 6: RECRUITMENT AND CONSENT

6.4 **Who will obtain consent?** Please provide their job title and role in the study.
Note: This person may be different than the person who introduced the study.

6.5 **Please describe the process for providing research participants with new information and the process for obtaining ongoing consent.** *Please see TCPS 2 Article 3.3 for additional information.*

6.6 **Is there is a relationship (e.g., patient, employee, etc.) between the participants and either of the following:**

Person obtaining consent	☐ **Yes**	☐ **No**
Principal Investigator	☐ **Yes**	☐ **No**

If YES, explain the nature of the relationship and what steps will be taken to avoid the perception of undue influence.

6.7 **Please describe the process whereby a participant can withdraw consent. Include any associated documentation with the submission.**

6.8 **Are you enrolling any of the following participants? (check all that apply):**

☐ Children (anyone aged 16 or below)
☐ Individuals temporarily unable to consent
☐ Individuals who lack the capacity to consent
☐ Patients in emergency situations who are unable to consent
Contact reb@hsnsudbury.ca if completing an emergency research study
☐ None of the above **(Please skip to Section 6.15)**

6.9 **Describe by whom and how capacity will be assessed for any individuals listed above.**
NOTE: children, by default of their age, do not lack the capacity to consent e.g. some adolescents

6.10 **Provide information on how the welfare of these participants will be protected.**

6.11 **If assent will be obtained (e.g. for children to be enrolled in the study), describe the assent process.** *TCPS 2 Chapter 4*

6.12 **How will you ensure the child or incapacitated adult agrees to participate?**
TCPS 2 Article 3.10

SECTION 6: RECRUITMENT AND CONSENT

6.13 **If participants are incapable of providing consent, how will substitute decision-makers be identified?**

6.14 **When inability to provide an informed consent is expected to be temporary (e.g. children aging, adults regaining cognitive abilities), describe what procedures will be used to regularly assess capacity and to obtain consent if the individual later becomes capable of providing consent.**

6.15 **Communication Difficulties (check all that apply):**

☐ Individuals who may require translation
☐ Individuals who are illiterate
☐ Participants who have trouble understanding and/or producing speech (and require special support including the use of assistive devices)
☐ None of the above (**Please skip to Section 6.17**)

6.16 **Provide an explanation of what procedures will be used to address any communication difficulties** (e.g., the use of translated forms, translator, and impartial witness).

6.17 **Is a waiver of the requirement to obtain informed consent being requested for this study?** ☐ **Yes** ☐ **No**

NOTE: Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable information.

If YES, please provide justification (see TCPS 2 sections 3.7 and 5.5 for the required information)

SECTION 7: PRIVACY & CONFIDENTIALITY

7.1 The Research Ethics Board considers the following information to be sensitive personal health information, collection of which could result in identification of and/or harm to the participant (e.g. cause embarrassment, refusal of employment or insurance coverage, stigmatization). The collection of this information must be explicitly stated in the consent form.

Indicate the sensitive personal health information you will be collecting for your study. Please note this is not an all-inclusive list:

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SECTION 7: PRIVACY & CONFIDENTIALITY

- ☐ No sensitive personal health information will be collected
- ☐ Biometric identifiers (e.g. fingerprint, retina scans)
- ☐ Date of birth
- ☐ Email address
- ☐ Family history
- ☐ Health card number
- ☐ Initials
- ☐ Name
- ☐ Medical record number
- ☐ Unusual diagnosis
- ☐ Confidential legal information
- ☐ Date of death
- ☐ Ethnicity
- ☐ Genetic information
- ☐ HIV status
- ☐ Local references (e.g. Address, postal code, etc.)
- ☐ Race
- ☐ Social insurance number
- ☐ Data with research participant identifiers
- ☐ Dates of treatment, where treatment is rare or unique
- ☐ Family Income
- ☐ Gender
- ☐ Identifiable images
- ☐ Mental health status
- ☐ Religious affiliation
- ☐ Telephone or fax number
- ☐ Other: [ ]

7.2 **If you have checked any of the sensitive information fields above, describe why the collection of each field is necessary to achieve the scientific objective of your study.**

7.3 **Describe the procedures to be used for preserving the confidentiality of data during the lifecycle of the project (i.e. during data collection, analysis, and storage and in the release of findings).**

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SECTION 7: PRIVACY & CONFIDENTIALITY

7.4 **Are participant data being stored on a portable IT (electronic) device (e.g. laptop, USB, etc.) or taken off-site?** ☐ **Yes** ☐ **No**
If NO please skip to section 7.7

7.5 Provide rationale for why the data must be stored on a portable IT device or taken off-site.
Note: All data that includes identifiable personal health information MUST be encrypted at all times. Additionally, master lists allowing for re-identification of data must be stored separately from the data.

7.6 **Indicate which security measures will be undertaken to protect the data and records.** Note: use of portable IT storage devices must be performed in compliance with the HSN policy 'Use of Information Technology Resources'. Please review for required security measures.

7.7 **Will anyone other than employees, clinical staff or students of HSN / HSNRI / St. Joseph's Health Centre (SJHC) affiliates, where the patients' original records are located, approach participants or have direct access to a research participant or their records for purposes of collecting data or conducting this research?** ☐ **Yes** ☐ **No**

If YES how will you protect participant data?

7.8 **If personal health information is to be linked to other databases (e.g. health registries, Statistics Canada information, ICES, etc.) provide the following details:**
☐ Not Applicable **(Skip to Section 7.13)**

7.9 **Describe the data to which the personal health information will be linked.**

7.10 **Explain how the linkages will be made.**

7.11 **Explain why these linkages are required.**

7.12 **Describe the likelihood that identifiable data will be created through the linkage.**

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SECTION 7: PRIVACY & CONFIDENTIALITY

7.13 **Describe any harms or benefits that could arise if personal health information was inappropriately released (e.g. embarrassment, refusal of employment or insurance coverage, stigmatization of individuals/groups) and how any consequences would be addressed.**

SECTION 8: DATA STORAGE, DESTRUCTION & DISSEMINATION

8.1 **Indicate which of the following security measures will be/has been undertaken to protect the data and records (Check all that apply):**

☐ Data will be encrypted

☐ Master list linking data with identifiers stored separately from data

☐ Data will be password protected

☐ All identifiers to be removed once data collected/verified

☐ Records will be stored in a locked cabinet in a secure location

☐ Access to records and data limited to authorized persons

☐ Data will be stored on a hospital or other institutional network drive that has firewalls in place

☐ As described in the Data Management Plan (DMP)

8.2 **How long will data be stored:**

☐ 10 years from the end of study (*HSNRI Policy #030 Stewardship of Research Records, HSN Policy Retention and Destruction of Records*)

☐ 25 years from end of study (if drug, biologic, device or natural health product trial)

☐ Other (If data is to be kept longer, please provide rationale):

8.3 **Indicate the methods that will be used to destroy the data:**

☐ Paper records will be disposed in Health Sciences North confidential disposal bins

☐ Electronic records will be destroyed by contacting Health Sciences North IT help desk

☐ Old CDs, DVDs, videos, USB keys, external hard drives and other technology will be destroyed

☐ Other (Specify): _____

8.4 **Provide details about the planned dissemination of research results (i.e. publications, posters, presentations, report, etc.)**

STATEMENT OF PRINCIPAL INVESTIGATOR (PI)

Statement of Principal Investigator (PI)

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STATEMENT OF PRINCIPAL INVESTIGATOR (PI)

1. I attest that the information in this application is complete and accurate to the best of my knowledge.
2. I assume full responsibility for the scientific and ethical conduct of this study.
3. I agree to conduct this study in compliance with the:
    a. Tri-Council Policy Statement
    b. The provisions of the Ontario Personal Health Information Protection Act (PHIPA) and its applicable regulations
    c. The applicable laws and regulations of Ontario
    d. If applicable, Health Canada Regulatory requirements
    e. If applicable, ICH Good Clinical Practices: Consolidated Guidelines
4. I agree to abide by the HSN/RI Policies, Procedures and Standard Operating Procedures applicable to the research being conducted. There may be additional requirements for research conducted at St. Joseph's Health Centre affiliates.
5. I certify that all sub-investigators, researchers and other personnel (Research Team) involved in this study at this institution are appropriately qualified and experienced, or will undergo appropriate training to fulfill their role in this study.
6. I certify that the Research Team will adhere to the protocol and consent form as given clearance by the REB and in accordance with any conditions placed on the REB decision and agree to comply with all REB decisions.
7. I agree that the REB may request, receive and share any information involving the research that the REB considers necessary to fulfil its mandate, while maintaining confidentiality and respecting privacy.

Privacy and Security Acknowledgement:

1. On behalf of all members of my research team, I recognize the importance of maintaining the confidentiality of personal health information (PHI) and the privacy of individuals with respect to that information.
2. I will ensure that the PHI is used only as necessary to fulfill the specific research objectives and related research questions described in the application approved by the REB. This includes all conditions and restrictions imposed by the REB or HSN/RI, governing the use, security, disclosure, return or disposal of the research participants' PHI and
3. I agree to take any further steps required by the REB or HSN/RI to ensure that the confidentiality and security of the PHI is maintained in accordance with PHIPA, its accompanying regulations and Tri-Council Policy Statement.

_____ _____

Signature of the Principal Investigator **Date**

PRINCIPAL INVESTIGATOR CONFLICT OF INTEREST DECLARATION

a)	Do you function as an advisor, employee, officer, director or consultant for the sponsor?	☐ **Yes**	☐ **No**
b)	Do you have direct or indirect financial interest in the drug, device or technology employed (including patents or stocks) in this research study?	☐ **Yes**	☐ **No**

PRINCIPAL INVESTIGATOR CONFLICT OF INTEREST DECLARATION			
c)	Do you receive an honorarium or other benefits from the sponsor (apart from fees for service)?	☐ **Yes**	☐ **No**
d)	Will your department or institution receive or has it received financial benefit (e.g., direct funding, gifts, general use or discretionary funds or any other payment above the institution's standard administrative overhead rate) from the study funder(s)?	☐ **Yes**	☐ **No**
e)	Does this study provide you with salary support?	☐ **Yes**	☐ **No**
f)	If you answered yes to item **e**, what percentage of your annual salary do you estimate will be obtained from the funder(s)?		
g)	Do any of your immediate family members (spouse or spouse equivalent, dependent child) currently have or expect to have any financial interests related to the study funder(s)?	☐ **Yes**	☐ **No**
h)	Do any of the Co/Sub Investigators, research staff or their immediate families (spouse, domestic partners, dependent child) currently have or expect to have any financial interests related to the study funder(s)?	☐ **Yes**	☐ **No**
i)	Do you have any other potential conflicts of interest not specified above?	☐ **Yes**	☐ **No**
If the answer is YES to any of the above, please describe and explain how that conflict is being managed to ensure that participant rights and welfare are not affected.			

REB SUBMISSION CHECKLIST:			
a)	**Anticipated start date:**	**Anticipated completion date:**	
b)	**Is this a multi-centered study?**	☐ Yes	☐ No
c)	**Has or will the application be reviewed by other Research Ethics Boards (REB) outside of HSN?**	☐ Yes	☐ No
	If it has been reviewed, please attach any REB decisions from other jurisdictions.	☐ Attached	
	If the application is still currently under review by another REB, please specify the REB(s) name and contact information.		
d)	**Research Protocol - Required** Either provided by the sponsor or must be created. Templates available: email reb@hsnsudbury.ca	☐ Attached	
e)	**TCPS 2 Certificate - Required** All PI's (or in the case of a student project, the student) must complete the Tri-Council Policy Statement (TCPS 2) online tutorial: https://tcps2core.ca/	☐ Attached	

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REB SUBMISSION CHECKLIST:			
f)	**Budget – Required** REBs ensure that budgets are reviewed to ensure that conflicts of interest are identified and minimized, or otherwise managed.	☐ Attached	
g)	**If this a student project being completed to fulfil academic requirements, please provide the institution's REB approval letter.**	☐ Attached	☐ N/A
h)	**Informed Consent Form(s) or Letter of Information** If provided by the sponsor – must be updated with HSN or SJHC information and have a version number and date. If it needs to be created – templates available: email reb@hsnsudbury.ca Note: if there is a genetic component to the research a separate consent form may be required.	☐ Attached	☐ N/A
i)	**Participant recruitment material** (e.g. advertisements)	☐ Attached	☐ N/A
j)	**Written information to be provided to participants** (such as diaries, contact cards, study brochures, etc.)	☐ Attached	☐ N/A
k)	If research is being conducted off-site or at an SJHC affiliate, provide a **letter of support** from the off-site program	☐ Attached	☐ N/A
l)	**Investigator's Brochure (IB), Product Monograph, Device manual**	☐ Attached	☐ N/A
m)	Available **safety information**	☐ Attached	☐ N/A
n)	**Request for Program Approval Forms** *Required to demonstrate support from the hospital program*	☐ Attached	☐ N/A
o)	For research involving **First Nations, Inuit or Métis peoples** (including data and / or biological materials) please consult TCPS 2 Chapters 8 and 9 for additional requirements.	☐ Attached	☐ N/A
p)	Provide **additional documentation about provisions for access to the drug/natural health product/device once the participant has completed the research.** Note: this is a requirement for phase II/III clinical trials.	☐ Attached	☐ N/A

Please note all submitted applications will be reviewed through a pre-review process prior to submitting to the HSN REB for review.