Thunder Bay Regional Health Sciences Centre

Research Ethics Board

Instructions for Application Form 2019

Acronyms

		Website
CITI	Collaborative Institutional Training Initiative	https://www.citiprogram.org
ICF	Informed Consent Form	
PHIPA	Personal Health Information Privacy Act	https://www.ontario.ca/laws/statute/04p03
PI	Principal Investigator	
PICO	Population Intervention Comparison Outcome	
PRE	Panel on Research Ethics	www.pre.ethics.gc.ca
QI	Qualified Investigator (for clinical trial or medical devices trials only)	
REB	Research Ethics Board	
REO	Research Ethics Office	
RP	Research Program	
SAE	Serious Adverse Event	
SOP	Standard Operating Procedures	
TBRHSC	Thunder Bay Regional Health Sciences Centre	www.tbrhsc.net
TCPS 2	Tri-Council Policy Statement	http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

Table of Contents

Contact Information

Thunder Bay Regional Health Sciences Centre (TBRHSC)

Research Ethics Office
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Phone: (807) 684-6422

Part 1: Introduction

A Research Ethics Board (REB) oversees all research involving humans and their related information to ensure that research meets the highest scientific and ethical standards in accordance with the spirit of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans [TCPS2: December 2014] and other commonly accepted standards in order to protect patients, investigators, and the institution.

All applications must also be reviewed and supported by the **Research Program.**

Details to obtain support for the resources to conduct research within TBHRSC are highlighted later in this document under Supporting Documents for Initial Application.

Research Ethics Boards (REB) functions:

- to approve, disapprove, reject, propose modifications, or terminate any proposed or ongoing research;
- to review and make recommendations for approval of all proposed human participant research involving TBRHSC patients, staff, physicians, students, residents, and hospital information;
- to safeguard the rights, safety, and well-being of participants in clinical research; and,
- to educate, support, and mentor researchers regarding the process of ethical review.

The TBRHSC Research Ethics Board (REB) meets over an extended lunch hour on the **4th Monday** of each month, September to June (moved up one week if meeting date falls on a holiday). All researchers are required to submit an electronic copy of their REB application (including all supporting documents) to TBR_REO@tbh.net by the first Monday of each month.

The Research Ethics Office (REO) will assign a TBRHSC REB # for the application. The REO staff screens all applications for clarity and completeness to ensure an efficient review process. Complete applications are directed to the full REB or delegated review pathway.

The REO staff will communicate by email with the research team regarding the status of the application for the upcoming agenda. At this point, one originally signed paper copy is to be submitted to the Research Ethics Office to finalize the application process. Incomplete applications will not be included on the upcoming agenda**Principles of Ethical Review for research involving humans:**

As described in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans [TCPS2: December 2014], the REB subscribes to the following ethical principles that are commonly held and valued by diverse research disciplines:

- Respect for Persons
- Concern for Welfare
- Justice

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REB Decisions

REB decisions are made either by consensus or a majority vote of the REB members present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict of interest policies.

The REB should reach one of the following decisions as a result of its review of research submitted for initial or for continuing review:

Approval When an acceptable risk/benefit ratio exists and the regulatory criteria required for approval are satisfied, the research may be approved as submitted.

The approval date is defined as the REB meeting date when the application was last reviewed by the full membership. The expiry date of the REB approval is calculated from this date.

Approval with Modifications/ Clarifications: When an acceptable risk/benefit ratio exists, and the regulatory criteria required for approval are satisfied, but the REB members require modification to any aspect of the application or clarification or further information to secure approval.

Deferral: The REB will defer its decision to a subsequent Full Board meeting when significant questions are raised during its review of the research and/or when the criteria required for approval have not been met. Researcher responses must be received and reviewed at a Full Board meeting.

Disapproval: The REB may disapprove the research when it fails to meet the ethical standards for approval and where revision is unlikely to enable the REB to reach a positive determination. Disapproval is not decided through the delegated review mechanism. If the research is disapproved, the reasons for disapproval will be communicated to the Researcher and the Researcher will be given an opportunity to respond in person or in writing.

Full REB Review:

Full REB reviews are conducted at the convened monthly meetings. When requested, the Principal Investigator (PI) or their delegate may attend the REB meeting by appointment for approximately 20 minutes to present their proposed project and address questions from the REB. If required, teleconferencing may be arranged in advance through the Research Ethics Office. The Research Ethics Officer will notify the PI regarding any specific requirements and exact appointment time.

Delegated Review:

Delegated Review occurs for studies presenting less than minimal risk as defined by TCPS2**.** *It is at the discretion of the REB Chair, not the researcher if the study is minimal risk or not.* For delegated review one or more of the REB's members will conduct a review. All delegated reviews are promptly reported to the full REB membership at the next convened meeting.

Communication following REB review:

Communication with the Principal Investigator and/or their best contact, is by email and/or phone with e-copies of documents attached.

Points to Consider:

- The Research Ethics Office will not accept incomplete application packages for review. Although much of the proposal / clinical protocol is included in the REB application, **it is the expectation of the REB that a full separate protocol/proposal be submitted.**

- A complete application includes both an electronic version of all documents, submitted to TBR_REO@tbh.net, and a paper copy, with wet ink signature(s), submitted to the TBRHSC Research Ethics Office
- Ensure that all supplemental forms are handed in at the time of the REB application. An application must be complete to be reviewed.
- Ensure that you submit all documents electronically to TBR_REO@tbh.net. Submission to the REO email account facilitates timely screening of your application, and ensures that you will receive feedback ASAP.
- Avoid compressing the files when sending electronically. Send them as individually labeled word or PDF documents.

  If you have any question regarding the submission requirements, review process or how to answer questions on the form, do not hesitate to contact the Research Ethics Office for a consultation at TBR_REO@tbh.net.

Communication following REB review:

Communication with the Principal Investigator or their best contact, is by email with e-copies of documents attached.

Note: Ensure all contact information supplied in Section A of REB application is accurate and up-to-date.

Revisions/Clarifications Required:

If required, revisions/clarifications requested by the REB are to be submitted to the required Research Ethics Office within the time limit stated. Resubmission directions will be included in the REB response to the Principal Investigator. Applications requiring revisions/clarifications that are not addressed within the required timeframe will be considered withdrawn from the REB review process.

Once REB approval has been granted, the Principal Investigator and/or best contact will be notified by email with an attached pdf copy of the letter of approval. **Original signed hard copies** will be mailed either by inter-hospital mail (where appropriate), or Canada Post.

For Office Use Only:

REB Number:

Submission Date:

Approval Date:

The REO staff will assign your project an REB number.

NOTE: Boxes will expand as needed and headers will repeat if boxes break between pages. If you have any difficulty completing this form contact TBR_REO@tbh.net.

Section A: Description of Research Team

Principal Investigator: The **Principal Investigator (PI)** is the individual responsible for the research project at TBRHSC. This may be someone internal or external to the organization(s).

- The **Principal Investigator (PI)** is the individual responsible for the research project at TBRHSC.
- Ensure that full contact information, including a reliable email address is listed.

Best Contact Person for Project:	☐ same as section	← click if PI is the best contact and do not complete this section

- Complete all contact information for an individual who would be best contacted by the Research Ethics Office regarding this study. This person should be able to answer questions about the status of the protocol/project, and be in direct contact with the PI when needed.

Research Team (list all co-investigators)

- Complete all information for each co-investigator on the study. **FOR CLINICAL OR MEDICAL DEVICE TRIALS:** a qualified investigator must be identified as either the Principal or a Co-Investigator. Add [QI] after their name.
- Each co-investigator is required to sign a Declaration of Conflict of Interest Form and append to this application. Depending on the level of responsibility and access to only de-identifiable information, short term/temporary research assistants are not required to submit a signed form. Reflecting the responsibility of the Principal Investigator's oversight of the entire research program, it is best practice for the Principal Investigator to keep a log and standard operating procedures for access to information. If required, submit an amendment if the research team expands after the initial approval is granted.
- All members of the research team are to be knowledgeable of the TCPS 2 guidelines and other required regulations for the type of research being conducted (e.g., for clinical trials, CITI certification).

- If there is greater than 3 co-investigators, attach a list as an appendix to the application.

Section B: Research Project/Protocol Title	
Full Title:	• Ensure the title entered matches all other documentation regarding this study (e.g., research protocol name, Clinical Trial Registry name).
Short Title:	• As Above, ensure that the Short Title matches all other documentation.

Overall Description of the Research Project/Protocol

Research Question

- State in a question format ~ **one sentence.**
- The research question should indicate who is being studied, what the intervention is (if any), what are the comparison groups (if any), the outcome measures and the methodology to be used. One strategy would be to use the **PICO method** to formulate your research question.
- Qualitative methods may or may not have all of the above components.

Research Summary

- In 300 words or less, in space provided [12 point Font], describe the goals of the overall research project in clear and simple language.
- This section is written for the public. Think of it as a write up to describe your study in a brochure or a newspaper article. Remove all jargon and acronyms.
- List the purpose of the research project. The purpose is the main reason that the study is being conducted and should include the direct implications or applications of the study (e.g., the reason for conducting the study could be to determine safety, effectiveness, dosage level, etc.).
- List the aim and/or objectives of the study
- Provide justification for the study

Section C: Application Overview

- Ensure that all other organizations are listed where REB review is being or has been sought
- If the proposal has been peer-reviewed for scientific merit, ensure that a copy of this is appended to the application. Only 'arms length' reviews will be accepted.
- Reference TCPS2 for the Definition of Minimal Risk
- Reference TCPS2 for the Definition of Vulnerable Population

Section D: Research Design & Methodology (check the appropriate box by location, then provide details)

- Ensure that this section is written for a broad audience. Not all REB members are clinicians, therefore all acronyms and technical terminology should be avoided. If used, clearly define.
- Describe how your research question will be answered: What statistical measures will be used? How will the efficacy of the intervention be measured? How will qualitative data be organized, coded and evaluated?
- This section requests complete details on all procedures (e.g. qualitative and/or quantitative techniques) in which participants will be asked to participate. Ideally, detail procedures sequentially, as they will occur for the participant, and described in terms which can be understood by reviewers without specialized knowledge of the research area.
- For all study types including pilot studies, justify the sample size on scientific grounds.
- If there is a control group, you should determine what number/ratio would be methodologically sound. If there is no control group, indicate 'No control group'.

  For particularly technical descriptions, the research protocol can be referenced

Section E: Local Implementation of Project Including Project Time lines (indicate for each organization)

Detail what aspects of the overall project are to be accomplished within the organization

- Provide an itemized timeline from proposed beginning to completion for the research project submitted for review. (e.g., May – June 2016: recruitment phase, July – Sept 2016: intervention A, Aug – Nov 2016: intervention B, Jan, 2017: data analyses and write up)
- Detail how the project will be customized/implemented **for each site**. Be specific. Multi-site protocols may not reflect the local situation. Detail how the protocol will be tailored to ensure standardized data collection amongst sites. It is the PI's responsibility to ensure any modifications are acceptable with the sponsor, if applicable.
- How much time will be spent by participants if they choose to participate?
    - HINT: Ensure this information is also stated in the Informed Consent Process.
- Will staff time be required? If so, detail all resources required.
- Ensure the timeframes are realistic, allowing for unforeseen delays. Approval will be granted on the timeframe outlined; be generous with time estimates.

NOTE: This section will be supported by each organization's process for review of resources required to conduct research.

All applications requiring REB review will require registration with the Research Program.

The purpose of the Research Program is to review the impact the research will have on TBRHSC's resources and services, as well as to ensure that processes are in place for cost recovery of resources and services used. For Research Program submission, please contact Research Program at researchprogram@tbh.net for their requirements.

Section F: Recruitment of Participants Involved in the Research		
	Yes	**No**
Does this research project involve direct participation of human participants?	☐	☐
Does this research project involve the review of health records (EMR & paper charts)?	☐	☐
Recruitment numbers		

Answer these checkboxes based on each phase of involvement. Many studies require access to both persons and their Health Records.

This section is of primary concern during the REB review process. The REB needs to be assured of the following principles: section is of primary concern during the REB review process. The REB needs to be assured of the following principles:

- ✓ Fairness/equity in the recruitment practices
- ✓ Voluntary participation
- ✓ Free and informed consent. Consent should not be obtained by an individual who have a position of authority with the potential participant. (e.g., physician/patient, teacher/student). Coercion and pressure to participate must be avoided.
- ✓ Time for participant to consider the research opportunities being proposed
- ✓ Participating or not participating in the research activity will have no impact on your overall care.
- ✓ You do not waive your legal rights as a research participant.

Points to Consider:

- All initial questions listed in Section F are completed.
- Full inclusion and exclusion criteria for potential participants **by each site needs to be detailed.** For multi-site projects, list the maximum number of participants locally by site, and then the total number per study

NOTE: in the event of greater recruitment than is stated, an amendment application will require approval by the REB before increased enrollment may begin.

- If multiple cohorts are sought within each organization, ensure that recruitment is detailed for each group individually (e.g., survey of nurses, patients and family members).
- Describe how the confidentiality of contact information (names, addresses, telephone numbers, or email addresses of potential participants) will be protected.
- Attach copies of any recruitment materials (e.g., letters, advertisements, flyers, media scripts, and/or websites/internet messages).
- Indicate where participants will be recruited (e.g., specific unit at hospital, clinic, school).
- Who will make initial contact, and how will this be done (e.g., phone call/ email).
- Describe the relationship between the investigator(s), the person obtaining consent, and the participant(s).

Section G: Informed Consent

Chapter 3 of TCPS2 describes the minimum expectations regarding the research consent process.
Refer to the TBRHSC's REB Infromed Consent Form (ICF) Checklist.

Points to Consider:

Consent Process:

- Who will be the point of contact for the consent process?
- What forms/materials will be used for the consent process?
- Where will the consent process take place?
- When will the consent process take place? And how much time are participants given to review the information about their potential involvement?
- Will incidental findings be reported back to the participant?
- If a member checking process (qualitative designs) will be used, ensure this is detailed in the consent process
- If the participant is not able to consent on their own behalf, ensure that a detailed process is outlined regarding who will be approached for consent. Will assent forms be used? Will a participant's ability to consent be monitored over time?
- Provide a copy of all documentation to be used in the recruitment process. (e.g., information letters, consent forms, assent forms, promotional flyers).
- Consent forms must include complete contact information for the Research Team and the REB Chair. The presentation styles of this information should be similar for both.

Withdrawal Process:

- Describe in detail how participants will be informed of their right to withdraw from the study. Consider withdrawal at all phases of involvement (e.g., after consent but before beginning research activity, during research activity, after completion of direct involvement; when withdrawal of information is no longer feasible?).
- How does a participant withdraw? Who do they contact? Again, take into account each possible stage of withdrawal.
- Are there risks associated with withdrawal at certain phases of the study? This is especially important with clinical trials.
- What will happen to data collected up to the point of withdrawal?
- Will standard of care treatment continue if the participant withdraws?
- If the data from a withdrawn participant be used in any way, explain why and how.

Section H: Potential Benefits

Chapter 2, section B of TCPS2 provides further details regarding the description of benefits in the REB application.

Points to Consider:

- Describe the proposed benefits to the participants, the scientific community and/or society that would justify asking participants to participate;
- If there are no direct benefits to participants, state this explicitly. If specific benefits cannot be assured, but may be hoped for by participants, state explicitly that the participant may or may not benefit from participation in the study;Incentives / re-imbursement for participation in research are NOT considered benefits to the participant.

Section I: Potential Risks

Known and anticipated risks to participants must be identified for each procedure, test, interview or any other aspect of the study:

- Physical risks: include all potential physical effects of any procedure that is not standard of care.
- Psychological Risks: Is there any chance that the research may cause the participant to become upset, embarrassed or have any other negative psychological effect (short or long term)? If so, ensure that appropriate resources are available to mitigate this risk.
- Social Risks: Any access to identifiable personal information has the potential for risk to an individual's privacy.
- Financial Risks: What potential financial losses could be caused by participation? Will participants be reimbursed? How and when?
- Deception and Debriefing: Describe any methods of deception used in the research. Ensure that a justification is provided for the use of deception as well as a detailed debriefing procedure.

FOR ALL RISKS:

Researchers must indicate the steps to be taken to ensure that risks are minimized to the extent reasonably possible. In the case of procedures involving greater than minimal risk (e.g. psychological or physiological), researchers must outline their appropriate credentials to deal with any negative impact on the participants which may be attributed to participation in the study. Researchers who do not have this expertise must have arrangements in place for provision of referral services and/or intervention for dealing with any negative impact on participants. Describe any strategies that are in place to minimize or manage the risks for participants and other affected individuals.

Section J: Confidentiality

See Article 5.2 in TCPS 2 for reference:

Points to Consider:

- Are there any circumstances where individual research results will be disclosed to third parties? (e.g., participants, parents of child participant, child welfare, etc).
- Describe the steps that will be taken to ensure confidentiality of the data. If confidentiality cannot be maintained, explain why not.
- Describe steps for confidentiality within the research team. (e.g., procedures to minimize access to identifiable information).
- How will confidentiality be maintained in research reports and articles?

Section K: Personal Health Information

Describe all sources of personal health information: electronic medical records, paper charts, interviews, identifying surveys, professionals outside the clinical circle of care, etc. Ensure that you attach and reference the data abstraction form which will be used to record the data. This is a required part of the REB submission for studies that are requesting access to patient medical records of any kind.

Points to Consider:

- Principal Investigators are to ensure request for personal health information in accordance with the Personal Health Information Privacy Act [2004].
- Provide a description of the personal health information required from each site and the anticipated sources from which this information will be accessed.
- Attach survey and/or data abstraction/case report forms for chart reviews studies.
- Researchers should make clear who will have access to identifiable and non-identifiable information. Access to identifiable information must be justified. Participants must also be informed 'who' will have access to his/her data and what use will be made of it, either now or in the future.
- Identify any individuals or agencies outside of the research group that may have, need, or desire access to the data. Provide details regarding what information will be made accessible, what is the justification for this access and what the risks of allowing this access are.

Section L: Data Management and Storage

Describe data management, storage and security regarding information collected from either organization.

Points to Consider:

- Ensure that any identifiable data that is collected electronically is on a secure password protected server OR if stored on a portable device (USB thumb drive, laptop, etc.) that it is both password protected and encrypted.
- If identifiers are required (e.g., medical chart number, name, addresses) a separate key should be created to assign indefinable information to a research specific ID number. This ensures that the data attached to the names are not kept in the same files (electronic or paper) and that if and when data needs to be linked back to identifiers, this will be accomplished in a secure manner.
- Describe the **SHORT** term storage (while conducting study) of both electronic data and paper: Where will the data be stored? What security measures are in place?
- Describe the **LONG** term storage (post data analysis) of both electronic data and hard copy records: Where will the records be stored? What security measures are in place? How long will it be stored for?

Section M: Funding Sources

Please acknowledge all sources of funding/support to complete the project:

Points to Consider:

- Internal TBRHSC support, academic support, including student support, grants and industry-sponsored initiatives or contracts.
- Indicate which organization administers the grant or contract funding.
- Include a detailed budget that itemizes all costs associated with each phase of the study.

Section N: Clinical Trial/Medical Devices Studies ONLY

Skip This Section if this study is not a Clinical Trial/Medical Device study

Consult the Research Program at Thunder Bay Regional Health Sciences Centre if you are conducting clinical trial with this organization.

Points to Consider:

- Ensure all supporting documentation is appended to the REB application.
- List all supporting documentation in Section P
- Take the time to review all documentation. Ensure that it is consistent with all other documents.

Section O: Declaration of Conflict of Interest for Principal Investigator		
Note: Each additional project investigator is required to complete and sign a Declaration of Conflict of Interest Form to append to this application.	**Yes**	**No**
If the answer is **"Yes" to <u>any</u> of the questions in Section N,** describe the relationships and the implications of the potential conflict of interest, including the additional protections which have been put into place to protect study participants and/or information accessed.		

Section P: List of Documentation for this Application

The list of documents supporting this REB application will be referenced in the approval letter, as such this list needs to accurate.

Points to Consider:

- Ensure all documents submitted are listed on this form.
- The titles of the electronically submitted documents should match the titles of the REB forms.
- Supplementary documentation should be numbered and named in a way that is easy to sort and understand.

For example:

1. Application Form.
2. Research Proposal/Clinical Protocol.
3. Consent Form(s).
4. Information Letter(s)/Recruitment Materials (on letterhead, and specific for TBRHSC).
5. Data Collection Tool(s) (e.g., Surveys/Data Abstraction Forms/Focus Group Guides).
6. Joint Pharmacy & Therapeutics approval.
7. Health Canada/other regulatory documents (e.g., REBA, No Objection Letter, Investigation Testing Authorization).
8. Budget Statement (including institution responsible for administration of grant/contract.
9. Declaration of Conflict of Interest Form for each additional team member.

If there is more than one document for any of the above mentioned sections, please name the documents in the following format:

1. Application Form
2. Research Proposal/Clinical Protocol
3. Consent Form A
   - 3.a Consent Form B
   - 3.b Consent Form C

Section Q: Research Ethics Agreement

As the Principal Investigator I agree to the following terms:

- I agree to assume full responsibility for this study.
- I understand that any approval granted by the REB is limited to the information, activities and conditions as outlined within this application including all supporting documents (e.g., Information letters, consent forms). Any amendments and Continuing Review Form requirements will be submitted for approval by the REB prior to implementation.
- I agree to ensure compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014, Personal Health Information Privacy Act [2004] and any other regulations required by this specific protocol and, if applicable, the related funding agreement/contract.
- I have read and will conduct my research in accordance with the research policies and procedures specific for each organization to which I am applying, including all required notifications and renewals.
- I am aware of my responsibility to be familiar with and adhere to the standards outlined by my professional College and academic institution.
- I agree that all information received or exchanged as approved in the REB application will be held in strict confidence. Information disclosed will not be linked to other sources unless specified and approved by the REB.
- I will ensure all co-investigators and research personnel are provided training and demonstrate adequate understanding in the above referenced guidelines and regulations. I will ensure all co-investigators and research personnel have reviewed and demonstrate an understanding of the protocol and are in agreement with the implementation of the protocol at TBHRSC as submitted to this Research Ethics Board (REB).
- I agree to provide access to all required documents for the purpose of monitoring and auditing by the REB, the sponsor and/or other appropriate regulatory authorities.
- I will not initiate research activities within TBRHSC as outlined in this research ethics application until formal notification of approval has been received from the appropriate REB(s) and the Research Program.

Principal Investigator's Signature:
(sign final hard copy after printing)

_____

Print Name: _____

Date: [month day, year] _____

I agree to allow TBRHSC to post my name, the full research title and the effective dates of the active study on their internal website for communication purposes. *Please initial the appropriate box after printing final application.* If you do not agree, consult the Research Ethics Office at time of application.	Yes	No
	☐	☐

This information is posted on the internal website listing REB approved

Supporting Documents for Initial Application

All supporting documentation must be submitted at the time of the initial application. Contact the Research Ethics Office if you have any questions: TBR_REO@tbh.net	
Declaration of Conflict of Interest - Supplemental	Each co-investigator is required to sign a Declaration of Conflict of Interest Form and append to this application. It is the responsibility of the Principal Investigator to educate co-investigators of their responsibilities and obtain signed forms. Reflecting the responsibility of the Principal Investigator's oversight of the entire research program, it is best practice to keep a log and standard operating procedures for access to information. If required, submit an amendment if the team expands after the initial approval is granted.
Research Program Authorization	For information about the Research Program review process, please contact the Research Program at researchprogram@tbh.net. For more information on the Research Program, follow the following link:http://tbrhsc.net/research/research-program/
Protocol	The research protocol is a separate document from the ethics application detailed above. A protocol is document that describes the objective(s), design, methodology, statistical considerations, andorganization of a trial. The protocol usually also gives the background and rationale for the trial,but these could be provided in other protocol referenced documents. (Source: GCP ICH)
Detailed Budget Statement	For all studies, submit a detailed budget. For some 'small' studies such as surveys or chart reviews, a budget is still required based on the estimated costs of paper, copies etc.
Informed Consent Forms / Information Letters and other Recruitment Materials	All consent forms, information letters and invitations to participate in research must meet the requirements listed in the REB's Informed Consent Checklist. All consent forms/ information letters and invitations are required to include the REB Chair Contact information paragraph. Additionally, see the Informed Consent Checklist for a detailed checklist outlining the consent requirements.
Data Collection Tools (surveys / data abstraction forms, interview guides)	Ensure that ALL data collection tools are submitted and LABELED by appendix numbers, and version dates. For copyrighted or proprietary surveys or other tools, provide proof of permission/purchase to use assessment.
Joint Pharmacy and Therapeutics Approval	For all medical device and pharmaceutical products, review and approval from Joint Pharmacy and Therapeutics (JP&T) Committee is required. JP&T forward approval notices directly to the REO.
Regulatory Documents (e.g., Health Canada No Objection Letter,	Regulatory documentation from Health Canada is required before REB approval may be finalized.

Investigational Testing Authorization)	For assistance with these documents, contact the Research Program at Thunder Bay Regional Health Sciences Centre. (researchprogram@tbh.net)
Clinical Trial/Researcher Agreement /Contract	A complete copy of the contract or researchers agreement must be submitted to the REB for review. If there are changes to the contact between REB review, and finalization (execution) of the contact, the REB may be consulted to ensure changes reflect the approval granted.
Note: **If other approvals are required (e.g. Joint Pharmacy and Therapeutics, industry-sponsored contracts, signed research agreements) research may not begin until all approvals/documentation is completed.**	