



Thunder Bay Regional Health Sciences Centre

RESEARCH GUIDELINES DIRECTORY

GUIDELINES

Research Ethics Team Terms of Reference.....	1
Research Ethics Team Composition.....	2
Levels of Ethics Review.....	4
• Expedited Review Guidelines.....	5
Decision Making.....	7
• Appeal of Decision	
• Reconsideration of the Negative Decision	
• Appeal of the Negative Decision Following Reconsideration	
Conducting Research at TBRHSC.....	8
• Guidelines for Writing a Proposal.....	9
• Guidelines for Writing an Informed Consent/Information Letter.....	11
• Access to Hospital Information.....	18
• Declaration of Conflict of Interest.....	19
• Source Documentation to be maintained by Researcher.....	20
• Reporting Serious Adverse Events.....	21



Thunder Bay Regional Health Sciences Centre Research Ethics Team

TERMS OF REFERENCE

INTRODUCTION

The Research Ethics Team (RET) of Thunder Bay Regional Health Sciences Centre (TBRHSC) functions to ensure that all research involving human subjects conducted at TBRHSC meets the highest ethical and acceptable scientific standards, in accordance with the spirit of the Tri-Council Policy Statement: Guidelines on Research Involving Human Subjects.

As described in the Tri-Council Policy Statement: Guidelines on Research Involving Human Subjects, the Thunder Bay Regional Health Sciences Centre RET will strive to uphold the following the principles:

- Respect for human dignity
- Respect for free and informed consent
- Respect for vulnerable persons
- Respect for privacy and confidentiality
- Respect for justice and inclusiveness
- Balancing harms and benefits

PURPOSE

The purpose of the Research Ethics Team is:

1. To review and make recommendations for approval of all proposed human subjects research involving Thunder Bay Regional Health Sciences Centre staff, patients, physicians, students, residents and hospital information.
2. To ensure that research involving human subjects within the Thunder Bay Regional Health Sciences Centre meets the highest standards of scientific and ethical conduct.
3. To safeguard the rights, safety, and well-being of participants in clinical research, paying special attention to research involving vulnerable subjects.
4. To ensure that the researcher has evaluated the expected impact of their research on the institutional resources of the Health Sciences Centre and to ensure that this impact does not compromise the overall delivery and access to services within the Health Sciences Centre.
5. To educate, support and mentor researchers in the Health Sciences Centre environment to understand the process of ethical review and to become familiar with the tools and guidelines that ensure the timely and comprehensive review of research projects.

AUTHORITY AND REPORTING STRUCTURE

The Research Ethics Team (RET) is a standing committee of the TBRHSC Medical Advisory Committee (MAC) and by virtue of this relationship, the authority and mandate of the Research Ethics Team is established by the MAC.

The Research Ethics Team makes recommendations which are forwarded via the minutes to the Medical Advisory Team and Senior Management Team.

COMPOSITION

The Thunder Bay Regional Health Sciences Centre Research Ethics Team is comprised of a maximum of 15 members whose skills and experiences offer a diversity of insight and perspectives and who, collectively, have the qualifications to review and evaluate the science, medical aspects, and ethics of proposed research. The Thunder Bay Regional Health Sciences Centre RET will always strive for the following minimum composition:

- 2 physicians (1 family practitioner, 1 specialist)
- 1 external advisor with expertise in methodology/ethics
- 1 member of the Council of Clergy
- 1 lawyer
- 1 consumer advocate
- 1 allied health professional
- 1 member with expertise in clinical epidemiology and biostatistics
- 1 member of the Thunder Bay Regional Health Sciences Centre Senior Management Team (permanent position)
- 1 administrative coordinator from TBRHSC – (permanent position)

Members of the TBRHSC RET will be appointed for 3 years with 1/3 being replaced each year. By mutual consent between the RET member and the Chair of the RET, the RET members may be appointed for additional terms.

If required, a person with expertise in the topic area being researched may be invited as a special guest to participate in the RET discussions.

The RET Chair is appointed by the Research Ethics Team for a term of three (3) years.

The members of the RET play different but complimentary roles, however, all members of the RET should have both the training and the expertise to make sound judgments on the ethics of the research proposal. It is the responsibility of the RET to facilitate initial and continuing education of their members.

As of August 2007, the Research Ethics Team has 10 members (6 female and 4 male) and includes: 2 Physicians, 2 lawyers, 1 academic methodologist, 1 administrator, 1 community person, and 3 professional staff.

TEAM PROCESS

The Thunder Bay Regional Health Sciences Centre review process is guided by the Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans (1998) and other commonly accepted standards

1. The Research Ethics Team will accept RET application forms and associated documents from Researchers by the first Monday of the month.
2. The Team will meet monthly, with the exception of the summer (July and August). Meeting agendas and packages are circulated at least one week in advance of scheduled meetings.
3. Face-to-face meetings are required for full board meetings to ensure a thorough discussion by the RET members.
4. For minimal risk studies, annual re-approvals, research involving review of patient records etc. the Chair may authorize an expedited review (see Expedited Review Guidelines). Decisions and outcomes of such reviews and subsequent approvals must be reported to the full RET.
5. Upon receipt of Ontario Cancer Research Ethics Board (OCREB) decision for multi-centre trials at

Regional Cancer Care of TBRHSC, record recommendations in the RET monthly minutes.

6. The researcher/investigator will attend the RET meeting at which their research is being reviewed. Their role is to provide an overview of the research study and to answer questions of the RET members.
7. A quorum of 50% plus 1 is required for voting purposes.
8. Members of the RET will use the "Research Protocol Review Form" (RET C) as a guide for considering proposed research projects.
9. A conflict of interest declaration for RET members will be made at the outset of every RET meeting and/or prior to the presentation of each individual research project. Members must disclose any real or apparent conflict of interest regarding a proposal under review. Members who have a conflict with a proposed research project will abstain from discussions and will not vote.
10. Decisions will be made by consensus: only in exceptional circumstances will decisions be made by majority vote at the discretion of the Chair.
11. The RET will review the budget for the study as well as the Declaration of Conflict of Interest by the researcher.
12. Recommendations are forwarded to MAC and Senior Management via monthly minutes.
13. The RET communicates the outcomes of the RET review to the researcher through an approval form and an excerpt from the minutes that is applicable to their research project. If the RET is considering a negative decision the researcher is informed and then allowed an opportunity to respond before the RET makes a final decision.
14. The minutes of the RET shall clearly document relevant discussions and decisions by the RET. The minutes shall list the members that make up the quorum and detail every motion.
15. On an ongoing basis the RET monitors all open studies, receives and reviews reports of serious adverse events, amendments, new study information, annual reports and summaries of completed research.
16. An annual report of RET activity is submitted to the Quarterly Medical Staff Meeting and Senior Management.
17. All records for submission will be maintained by the RET Secretary.
18. All correspondence with the investigator will go through the RET Secretary and Chair.



Thunder Bay Regional Health Sciences Centre Research Ethics Team

LEVELS OF ETHICS REVIEW

There are two levels of review:

1. Full RET review
2. Expedited review conducted by RET Chair/designate and a minimum of one other RET member (see Expedited Review Guidelines)

Proportionate Approach

The more potentially invasive or harmful the proposed or ongoing research, the greater should be the care in its review. While all research must be reviewed adequately, proportionate review is intended to reserve most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research. The concept of minimal risk provides the foundation for proportionate review.

A research study is initially assessed, primarily from the viewpoint of the potential subjects, of the character, magnitude and the probability of potential harms inherent in research. The categories of risk include but are not limited to physical, psychological, social, and economic.

Clinical studies can be assessed through a harm-benefit analysis, with

- Therapeutic procedures justified by the benefit to the subject and,
- Non-therapeutic procedures by the importance of the knowledge gained.

Therapeutic procedures used in clinical trial research must be assessed for clinical equipoise¹, be consistent with standards of care, and the risks be reasonable in relation to likely benefits to patients.

Non-therapeutic procedures potentially have no benefit to the subject. The two requirements they must possess are they must be 1) minimal risk² and 2) the risks must be reasonable to the knowledge to be gained. Greater care should be exercised to protect subjects from harm in non-therapeutic research. Strong independent justification is required before exposing a health volunteer to substantial risk of harm just to gain scientific information.

The Thunder Bay Regional Health Sciences Centre's, Research Ethics Team, offers two levels of review, each linked to the other through formal authorization by the institution. The levels of review are: full RET review, and expedited review by an individual or subgroup.

¹Clinical Equipoise: Expert disagreement as to the preferred therapy.

²Minimal risk is commonly defined as follows: If potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk.



Thunder Bay Regional Health Sciences Centre Research Ethics Team

EXPEDITED REVIEW GUIDELINES

All submissions are reviewed by the full RET unless they qualify for an expedited review. Submissions are assessed by the RET chair (or designate) and the RET Secretary to determine if they qualify for expedited review. Expedited reviews will be conducted by the RET chair (or designate) and a minimum of one other RET member. Please note that if a submission meets the criteria for an expedited review, the RET cannot guarantee that the review will take place prior to the next scheduled RET meeting.

Expedited reviews may be possible for the following situations:

1. Research protocols involving no more than minimal risk*. (TCPS 1.6)
2. Annual renewals/closure of approved projects in which there has been little or no change in the ongoing research. (TCPS 1.6)
3. Research involving review of patient records by hospital personnel (TCPS 1.6) in which evidence of research compliance with TBRHSC Policy HIS-08 (Privacy of Personal Health Information) is evident. Research must show compliance with de-identification of personal information* as outlined in policy.
4. Affirmations that conditions laid down by the RET as a condition of approval have been met (TCPS 1.6) as stated in the motion from the RET meeting.
5. Promotional brochures on previously RET approved studies that do not contain new or misleading information.
6. The study involves non-invasive product testing or quality assurance* activities where publication is planned.
7. New business items such as amendments, consent changes, and investigational brochure revisions, in which the integrity of the original study is not substantially changed, or the reported degree of risk does not necessitate a change in protocol or consent.
8. Serious adverse events, safety reports, and data safety monitoring reports will be reviewed by the RET secretary and an RET physician or RET member designated by the full REB, and any concerns will be reported to the full RET.

Please note that if the study meets the above criteria, but is being funded by a commercial sponsor, full RET may be required.

In keeping with the Article 1.6 of the TCPS, the RET Chair, with the assistance of the RET secretary, shall report to the full RET of all decisions made through an expedited review process and information will appear in the RET minutes.

***Minimal Risk is defined as follows:** if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research (TCPS, 1.5).

In some areas of treatment (example surgery, chemotherapy, or radiation therapy) the treatments themselves are known to pose considerable risks of harm. Such therapeutic risks may be regarded as within the range of minimal risks for patient subjects, since they are inherent in the treatment that patient will be undergoing as part of his or her current everyday life. The idea that considerable anticipated therapeutic risks might also be within the range of minimal risks extends to the therapies in a trial (TCPS, 1.5).

Quality assurance studies should not be subject to REB review (TCPS, 1.1).

***Quality Assurance Measures are defined as:**

- Evaluation and review of the quality of a service or a product.
- Identifying problems or deficiencies in delivery
- Defining activities and procedures to overcome deficiencies
- Monitoring the effectiveness of corrective measures

Quality Assurance does not require REB approval when it:

- Is intended solely for internal use
- Only measures the integrity of the functions delivered by the organization or performance of staff internal to the institution while carrying out their duties and responsibilities
- Is not intended through publishing, to continue to generalize scientific knowledge about treatments and procedures.

***De-identification of personal health information as defined in TBRHSC Policy HIS-08:**

- De-identity in relation to the personal health information of an individual, means to remove any information that identifies the individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify the individual, and “de-identification” has a corresponding meaning. Name removal may not be sufficient to de-identity personal health information in cases with unique factors.



Thunder Bay Regional Health Sciences Centre Research Ethics Team

DECISION MAKING

Every effort will be made among the RET members to achieve consensus on decisions about research. To facilitate consensus decision making the RET may have consultation with the researcher, invite external advice and have further reflection by the RET. If disagreement persists a decision will be made under the procedural rules of the institution.

The RET Chair will monitor the RET's decisions for consistency, ensure that these decisions are recorded properly, and ensure that researchers are given written communication of the RET's decisions (with reasons for negative decisions) as soon as possible following the RET meeting.

APPEAL OF DECISION

The following sets out an appeal procedure that can be exercised by the Principal Investigator (PI) in the event of a negative review by the TBRHSC RET or the imposition of conditions that the PI disagrees with. It is intended to ensure the utmost fairness in the RET's procedures.

Reconsideration of the Negative Decision

In accordance with Article 1.10 of the Tri-Council Policy Statement (TCPS), if a negative decision has been received for the Research Ethics Board (REB), researchers have the right to request, and the REB has an obligation to provide reconsideration of decisions affecting the research project.

Any PI, who disagrees with the results of an ethical review by the RET, must provide a clear, detailed basis for the disagreement and relevant documentation that will support his/her request for reconsideration by the RET. This information must be sent by letter or by email to the RET Chair and/or RET Secretary. The letter will be forwarded to the RET.

A meeting between the RET and the PI will be scheduled at the earliest possible RET monthly meeting. The PI will be invited to further discuss the project with the RET in order to reach a final consensus on the issues that are still subject to disagreement. The PI may not be present for the final deliberations of the REB. The PI will receive a letter from the RET Chair outlining the results of the reconsideration as soon as possible following the RET meeting.

Appeal of a Negative Decision Following Reconsideration

Article 1.11 of the Tri-Council Policy Statement (TCPS) provides that, in cases where researchers and the Research Ethics Board (REB) cannot reach agreement through discussion and reconsideration, an institution should permit review of a REB decision by an appeal board, provided that the board's membership and procedures meet the requirements of the TCPS.

Before any appeal is made, it is expected that both parties will have abided by the iterative reconsideration process. When a final decision has been made following reconsideration, and a project is rejected, appeals will be considered on procedural grounds only, or when there is a significant disagreement over interpretation of the Tri-Council Policy Statement.

_____ REB will serve as an appeals board for TBRHSC RET. The decision of the appeals board shall be final.



Thunder Bay Regional Health Sciences Centre Research Ethics Team

CONDUCTING RESEARCH AT TBRHSC

1. All proposed human subjects research involving the hospital's staff, patients, hospital information, physicians, and students/residents must be submitted to the hospital's Research Ethics Team (RET) for approval.
2. For studies involving pharmaceuticals, Pharmacy & Therapeutics Committee approval of the study drug is required prior to study submission to the Research Ethics Team. The P&T approval date is recorded on the organizational impact form (Form B) and signed by the department head.
3. Prior to submitting a proposal to the RET, an [Organizational Impact Form-Form B](#) be completed by the researcher and signed by the manager and/or chief of the department(s) that are affected. The support of the manager and/or chief of the department is generally based on the resources, human and/or material, required of the department(s). The Organization Impact review also acts as a source of communication with the manager or department.
4. RET review of the proposal is guided by the policies and ethical standards put forth by the Tri-Council Policy Statement (TCPS) and ICH Good Clinical Practice (GCP) Guidelines. Following the noted standards, the RET will review proposal for scientific merit, ethical validity, organizational impact and terms of agreement.
*Refer to [Research Protocol Review Form - RET C](#) for details of RET review guidelines.
5. RET meeting dates and deadlines for submissions are outlined in meeting dates section. [Click here](#) for a listing of meeting dates and the deadlines for submissions.
6. Please note that all industry sponsored research that is reviewed and approved by the RET will be subject to a Research Ethics Review Fee of \$1500 + tax.
7. The researcher is obliged to submit and receive approval for:
 - a. Initial Submissions:
 - Refer to downloadable [Research Submission Checklist-Form I](#) for required documents to be submitted
 - Following submission of a new research proposal, the researcher/investigator will be scheduled to attend an RET meeting to provide a brief overview of the research study and answer any questions.
 - b. Ongoing and Timely Submissions:
 - Amendments to Protocol, Consent, Investigator Brochure (download [Amendment Summary Report-Form F](#))
 - Non-local Serious Adverse Events (download [Non-Local SAE Report Summary-Form D](#))
 - Local Serious Adverse Events (download [Local SAE Report Summary-Form E](#))
 - New Information (i.e. recruitment posters, advertisements, patient education materials)
 - c. Annual Submissions:
 - Complete downloadable [Annual Re-approval Status Form-Form G](#)
 - d. Upon Completion of Study:
 - Complete downloadable [Study Completion Report-Form H](#)
 - Overview of study proceedings and results (if available)



Thunder Bay Regional Health Sciences Centre Research Ethics Team

GUIDELINES FOR WRITING A PROPOSAL

The following are some points which may be helpful in preparing a proposal and consent form. While all points will not be applicable for every study they represent some of the areas considered when reviewing a proposal.

1. Identification: -Title of project, principal investigator(s) and department
2. Background: -Brief review of current, relevant scientific data and literature
 -Reasons for study – current treatments commonly used, pros and cons of present standard treatment
3. Purpose: -Hypothesis, objectives, research problems/questions
4. Population: -Description and reason for interest
 -Study location
 -Inclusion/Exclusion Criteria
 -Study Design (i.e. placebo, control groups)
 -Method of sample selection
 -Sample size and calculation
5. Procedure: -Description of procedures and information to be collected
 -Description of how participants will be contacted
 -Procedures specifically for research purposes
 -Study time
 -Data sources
6. Intervention/Treatment: -Dosages and treatment schedule
 -Alternative treatment or procedures available in place of study procedure
 -Study interventions including interventions which depart from usual treatment
 -Conditions for withdrawal
 -Experimental aspects of treatment
7. Risks and Benefits: -Potential harms, discomforts, inconveniences to participants
 -Description of how potential harm will be minimized
 -Side effects and risks (high, medium, low/minimal)
 *Note: Any risks from the treatment, study design and tests must be clearly stated without minimizing effect and benefits should not be exaggerated
 -Describe benefits the researcher will receive
8. Proposed Data Analysis: -Statistical methods for assessing results
 -Plans for secondary data analysis
9. Process for Obtaining Consent/Assent
10. Confidentiality: -Process for obtaining informed, voluntary, consent and assent
 -Procedures to ensure confidentiality and anonymity during conduct of the study and in the release of findings
 -Identifying agencies/individuals who will have access to confidential data

11. Data Security: -Storage of data (i.e. stored in a secure location, locked file)
-Length of time data will be stored
-Statement that data will only be used for the proposed study and will be destroyed upon completion of study
12. Ethical Issues/Concerns: -Special population issues – competency, age
-Risks vs. benefits
-Method of sample collection (free of coercion, written and verbal explanations, time to consider)
-Confidentiality safeguards
-Data Security
13. Organizational Impact: -Budget and Available Resources
-How will the costs of services, medications or tests be met when these are in addition to the usual patient practices
-Indication that impact to the organization has been explored



Thunder Bay Regional Health Sciences Centre Research Ethics Team

GUIDELINES FOR WRITING AN INFORMED CONSENT/INFORMATION LETTER

A consent form should provide, to the extent that it is possible, all the information needed for an individual to make an informed decision. Although written information is provided a verbal explanation should also be given as well as the time to consider and ask questions. The invitation to participate in a research study should be presented in a way that avoids coercion or undue influence. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language" (i.e. at a grade 8 reading level). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

The consent form should:

- Be submitted in its final form including letterhead (i.e. as it will be seen by the research participant)
- Be in a language the subject understands
- Use simple, clear language for technical and medical terms
- Define short forms and abbreviations
- Use meaningful comparisons to describe amounts of risks
- The information should be worded in second person
- Number the pages (i.e. 1 or 5, 2 of 5, etc.)
- Consent should be identified by version number and date

The guidelines below outline points that may be considered when drafting a consent form.

1. Introduction:
 - An introductory statement regarding the consent process is recommended
 - Describe study and purpose
 - An explanation of the medical and/or social condition that makes the individual a candidate for this study
 - Number of participants
 - Duration of study, including expected duration of participant's participation in study
 - Study location
 - Current experience with experimental drug or treatment
2. Identification:
 - Title of study
 - Name of Investigator, what their status is and who they represent (i.e. Medical Staff or Medical Student). Important: Clearly state if the Investigator/assistant is not an employee of the hospital or has hospital privileges.
 - Sponsor name, address, phone, website (if applicable)

3. Rights as a Volunteer:
 - Participation is voluntary
 - Refusal to participate does not affect care
 - Right to withdraw from the research, at any time, without penalty, effect on quality of care or loss of benefits to which the participant is otherwise is otherwise entitled.

4. Procedures:
 - The detailed research procedures to be followed (invasive and non invasive)
 - The details of the research activity, describing those aspects of treatment that are experimental and those that are standard treatment(s)
 - Describe study groups (i.e. experimental group and control group and the probability for random assignment to each treatment group)

5. Treatment/Tests:
 - Describe intervention, treatment, drugs, etc.
 - Dosage, frequency, number
 - Number of visits and time commitment
 - Implications for current treatment (i.e. restricted drugs)
 - Availability of treatment following study

6. Eligibility:
 - Inclusion/exclusion criteria (specific exclusion criteria should be addressed)

7. Risks/Participant Inconveniences:
 - Describe clearly and fully any foreseeable risks or inconveniences to the
 - Provide an estimate of probability and frequency of occurrences and seriousness of side effects
 - List who to call if an adverse event occurs

8. Risks to Fetus/ Infant:
 - Women who are of childbearing potential should be warned if there are potential to the fetus/ infant. If so, they should be advised not to become pregnant or breast feed during the study. They or their partner should use a medically acceptable form of contraception. The acceptable forms of contraception should be described and the length of time following the trial that they should continue with birth control.
 - A pregnancy test before entering the study will be necessary and possibly repeated during the study.
 - Similar warnings may be required for male subjects for them or their partner to use effective birth control during the study period.

9. Benefits:
 - Describe the reasonably expected benefits for participant (when there is not intended benefit to the participant, the participant should be made aware of this)
 - Describe expected benefits of research study to society

10. Alternative Treatment:
 - Describe treatment options if subject chooses not to participate in study

11. Withdrawal:
 - Right to withdraw at any time
 - Guidelines for subject being withdrawn from study and implications for treatment/care
 - Rules for stopping study
 - The investigator, in his/her discretion, may terminate participant's involvement if further participation is not in his/her best interest

12. Confidentiality:
- Describe how data will be treated (i.e. de-identified, securely stored, destroyed upon completion of study)
 - The records identifying the participant identity will be kept confidential (and how) and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the research are published, the participant's identity will remain confidential. Any release of information will require the individual's consent.
 - That the monitor(s), the REB and the regulatory authority (ies) will be granted direct access to the participant's original clinical records for verification of clinical research procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing the written informed consent form, the participant's legally acceptable representative is authorized such access.
13. Compensation To Participant:
- The compensation and/or treatment available to the participant in the event of a research related injury. The following standard clause is recommended. "If you become ill or are physically injured as a result of participation in this study, medical treatment will be provided. The reasonable costs of such treatment beyond that provided by your insurance will be covered by the sponsor, _____, for injury or illness that is directly a result of participation in this trial. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities."
 - The anticipated prorated payment, if any, to the participant for participating in the research
 - The anticipated expenses, if any, to the participant for participating in the research.
14. Compensation To Researcher:
- The compensation and/or recognition the researcher receives from conducting the study
 - Disclosure of researcher reimbursement and/or any conflict of interest
15. Notification of Findings:
- Outline if the research results will be published
 - Indicate how the data is to be used and how participants may access a copy of the final results.
16. New Findings:
- Participant will be informed of any new findings which develop during the course of the study which may relate to their willingness to continue in the study
17. Questions/Concerns:
- Names of contacts and phone numbers.
 - Contact information of RET for any questions about rights as a research participant statement
18. Consent:
- The consent section should repeat some of the key points that the subject should understand to participate
 - Statement should include that participation is voluntary and that they will receive a copy of the signed informed consent

19. Signatures:

- The consent should be signed and dated by the subject and by the person who has explained the study and obtained the consent
- The person containing consent should (a) be knowledgeable about the study protocol in order to answer questions that the prospective participant may have, (b) be able to obtain information from the investigators to address issues raised by the prospective participant, and (c) ideally not be in a treating relationship with the prospective participant

20. Date of Consent:

- The consent should have a version number and version date (on each page) for easier tracking of consent versions in the future

PREFERRED WORDING FOR CONSENT

PREFERRED WORDING	REPLACING/RATIONALE
You are being asked to volunteer in a research study.	-it should be clear this is a research study and they are voluntarily participating
This study is being conducted by Dr. Don Smart, a medical student from XYZ Research Laboratory	-the participants needs to know who is responsible for the study, in what capacity they are working, and who they are affiliated with
<p>You may choose not to participate or you may withdraw from the study at any time without affecting your regular treatment.</p> <p>Before you agree to take part in this study, it is important that you understand what the study is about. Please read this information carefully and ask any questions that you may have.</p> <p>You will be selected by random choice (like flipping a coin) to receive either treatment A, B, C.</p>	<p>Rather than: “You may refuse to participate”.</p> <p>Rationale: Trying to achieve informed consent with no coercion.</p> <p>Indicate: an explanation of what “random” means.</p>
The sponsor this study is <u>(name)</u>	Rationale: This should be very clear in the consent.
You will receive either the drug or a placebo, a medication that looks like the real medication but does not contain any medication.	Rationale: describe what “placebo” is. Similarly double-blind explanation- neither you nor your study doctor will know which treatment you are taking, except in an emergency.
<p>Take your time to make your decision about participating in this clinical trial. You may discuss it with your doctor before you make your decision.</p> <p>If you do not want to take part in this study you will be treated with standard care treatments. Your study Dr. will explain the treatments that are available if you choose not to take part.</p> <p>A total of 180 participants from 6 national sites will participate in this study.</p>	<p>Rather than: “...you may discuss it with your family and friends...”</p> <p>Rationale: this would help in the informed process.</p> <p>Rationale: Participant must be informed of all options</p> <p>Rationale: the participant must be able to put these numbers into some perspective</p>
<p>All medical records and research materials, which would identify you, will be confidential, and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.</p> <p>By signing this consent, you hereby grant permission for your original medical records to be made available to authorized representatives of the institutional review board that reviewed the ethical aspects of this study.</p>	<p>Rationale: individuals need to understand that the courts institutional review board, etc may require information.</p> <p>They should be aware of the possibilities of where their information is shared.</p>

PREFERRED WORDING	REPLACING/RATIONALE
<p>You will be informed by the investigator of significant new findings from the study, which may influence your decision to continue your participation in the study. You doctor may have you withdraw from the study. In this case he/she will explain the reasons and arrange for your continuing care.</p>	<p>Rationale: if the study shows very bad results or side effects participants must be informed so they can make informed choices (and vice versa).</p> <p>Rationale: the participant must know they will not be abandoned if the terms of the study changes.</p>
<p>If the study doctor is not your family doctor, she/he will be told about your participation in this study, unless you do not give permission.</p>	<p>Rationale: If this is the case participant must be informed.</p>
<p>The sponsor will store and process your data with electronic data processing systems and will keep the data as long as the investigational product is marketed or under investigation.</p>	<p>Rationale: make clear, who has data, how it is processed, how this is done, how long data is kept.</p>
<p>Study medication will be provided free of charge for the duration of the study.</p>	<p>Rationale: Participant must be informed of the terms.</p>
<p>The sponsor of this research <u>name</u> will pay the study doctor and research staff for the expense, time and effort to conduct this study.</p>	<p>Rationale: participants must be made aware of this arrangement.</p>
<p>You will receive no payment for participating in this study. You are able to claim expenses for parking and travel from your home in Thunder Bay to the clinical appointment provided you submit your receipt of such expenses.</p>	<p>Rationale: be very specific what your intent is.</p>
<p>If you become ill or injured as a result of participation in the study you will receive appropriate medical care. The sponsor will cover necessary medical costs not covered by the provincial health plan or your private insurance.</p>	<p>Rationale: Statements should reflect the system that applies to the Canadian situation.</p>
<p>If you have any questions about the research or develop a research related problem you should contact Dr. X.</p> <p>If you have any questions about your rights as a research participant, you may call Heather Poulter, Thunder Bay Regional Health Sciences Centre Research Ethics Team (RET) at 807-684-6422. The RET is not affiliated with the study.</p>	<p>Rationale: Protecting patients who have clinical issues and concerns with their rights.</p>
<p>The results of the study may be published in the medical literature, but your identity will not be revealed.</p>	<p>Rationale: Indicate possibility of publishing. Assure anonymity.</p>
<p>I will receive a signed and dated copy of this Informed Consent.</p>	<p>Rationale: a copy of the consent should be given to the participant.</p>



CONFIRMATION OF INFORMED CONSENT PROCESS EXAMPLE

Research Title: _____

Protocol number: _____

Participant's statement

- I have been informed by _____ in detail about the aims, conditions, nature, procedure and duration of the study. In particular, the advantages and disadvantages have been explained to me in detail.
- I have had enough time to ask questions and they have been answered in detail and in full.
- I have read and understood the participant information sheet and have received a copy.
- I am aware that I can at any time reverse my decision to participate in this study without giving any reasons and without incurring any disadvantage.
- I understand that all data will be held strictly confidential and I give my permission for my clinical records to be inspected by representatives of _____ (including its affiliated companies) or the regulatory authorities. (if applicable)
- I have been given a copy of the signed consent form.
- **I agree to participate in this study**

Signed (Participant): _____ Signed (Investigator): _____

Participant's name: _____ Date: _____
(PRINT)

Date: _____

I certify that I have explained the purposes of this project to _____ and he/she signed the consent form in my presence.

Signature of Investigator

Date

Signature of Person Conducting the

Date



THUNDER BAY REGIONAL HEALTH SCIENCES CENTRE RESEARCH ETHICS TEAM

ACCESS TO HOSPITAL INFORMATION

Thunder Bay Regional Health Sciences Centre Research Ethics Team supports the following guideline:

- Researchers and research assistants do not have the right to access the electronic or print medical record of any patient for the purpose of research except in circumstances where, within the protocol for a study, access to the electronic/print record **without the patient's consent** is defined and approved.

This guideline is based on the researcher's "right to know" "need to know" and one's "professional relationship to the patient." Researchers shall always secure a research ethics board approval for obtaining identifiable personal information about subjects. This guideline does not apply to a practitioner's clinical authority to access a patient record.

Completion of the Access to Information Form (Form RET B) will define the personnel that have the authority to access the records of consenting patients for defined studies. This information will be sent to both Health Record and the EMR Clinical Application Support Specialist prior to the researcher accessing the information. Approval for accessing non-identifiable retrospective chart information may not require a patient consent. This type of data must be aggregated so that patient, physician, and facility anonymity is maintained.

Any inquiries on required access to the electronic record can be directed to the Electronic Medical Record (EMR) Clinical Application Support Specialist.



THUNDER BAY REGIONAL HEALTH SCIENCES CENTRE RESEARCH ETHICS TEAM

Declaration of Conflict of Interest

The term Conflict of Interest in science refers to situations in which financial considerations may compromise, or have the appearance of compromising an investigator's professional judgment in conducting or reporting research.

Conflict of Interest may arise with the researcher, the organization where research is being conducted and the RET.

Conflicts of Interest that arise between a researcher's responsibilities related to his/her arrangements with the granting agency must be revealed. It is important from an ethical standpoint that the Research Ethics Team is aware of the nature of any such arrangements in order to ensure that there are no conflicts which could be perceived to adversely affect participants enrolled in research studies. RETs are obliged to ask what arrangements have been made. Not all conflicting interests are necessarily impermissible. The principal investigator should arrange for someone (who is protected from the pressures of financial incentives) and is other than the treating physician to obtain the participants informed consent to participate.

It is ethically unacceptable for investigators to receive significant personal or family financial benefits (either direct or indirect) for participation in approved studies. "Financial Benefits" may include contractual agreements, stock or share holdings or future options with the sponsoring company, computing equipment, travel benefits, etc. "Significant" is defined as any benefit equal to or exceeding \$10,000. TBREB considers the payment of any fee or cash gifts directly to an individual for soliciting the enrollment of subjects into a clinical trial to be unacceptable and such payments will not be allowed.

If there is a conflict identified the RET may recommend the research to be abandoned, the researcher to withdraw from the study or decide a more stringent/ongoing review is required.

If there is any doubt as the possibility of there being a conflict of interest, the onus is on the investigator to discuss the situation with the Chair of the RET.

Institutional Conflict of Interest is curbed by the institution respecting the autonomy of the RET and ensuring the RET has financial and administrative independence.

RET members must declare Conflict of Interest and decline from the discussions and subsequent approval decisions made for the identified study.

Guidelines

1. Each participating investigator and sub-investigator must complete a [Declaration of Conflict of Interest \(Form C\)](#) outlining financial disclosure or similar industry generated form and submit it to the Secretary of the RET by the time of the RET protocol review meeting.
2. Sub-investigators who join the study after the site initiation date must complete this form before they perform any study-related activities.
3. The RET must be provided with details of the budget.



Thunder Bay Regional Health Sciences Centre Research Ethics Team

SOURCE DOCUMENTATION (To Be Maintained By Researcher)

Investigators are required to prepare and maintain adequate and accurate records of all observations and other data pertinent to the study for each subject. Source documentation is where the information is first recorded, specifically original documents, data, and medical records.

The investigator must maintain primary source documents supporting significant data for each subject in the case history records. These documents, which are considered 'source data', should include documentation of the following:

- Demographic information
- Evidence supporting the diagnostic/condition for which the subject is being studied
- General information or medical history demonstrating that the subject meets the inclusion and exclusion criteria
- Physical findings
- Hospital records (if appropriate)
- Each study visit by date
- Relevant findings/notes by the investigator
- Occurrence serious adverse events
- Any relevant telephone conversations with the subject
- Documentation that informed consent was obtained for each subject prior to participation in the study

The investigator must also retain all printouts/test reports/procedures/forms for each subject. Examples include:

- Original, signed consent forms.
- Diagnostic test results, X-rays and laboratory test results
- Subject diaries or evaluation checklists
- Consultations
- Drug and device receipt, accountability and return records
- Case report forms
- Test instruments

Investigators also need to maintain the following:

- Copies of all correspondence sent to or received by the study sponsor and the monitor
- Research Protocol
- Data monitoring
- Protocol amendments
- Records of Investigational Review Boards communication and study approval
- Materials used in recruiting subjects (i.e. flyers)
- Materials used in obtaining informed consent
- Investigator brochure



Thunder Bay Regional Health Sciences Centre Research Ethics Team

GUIDELINES FOR REPORTING SERIOUS ADVERSE EVENTS

A researcher is obliged to report serious adverse events (SAEs) related to the study as well as SAEs involving the study drug that is being trialed in other studies. The appropriate Serious Adverse Events Report Form (FORM D for Non-Local SAE Report Summary or FORM E for Local SAE Report Summary) is completed and submitted with the SAE Report (provide 1 original and 1 copy)

Should there be an alarming serious adverse event occur locally this event is to be reported to the RET Chair within 48 hours of occurrence.