Research Ethics Board

Guidelines For Researchers

September 2011

Definitions

		Website
CITI	Collaborative Institutional Training Initiative	https://www.citiprogram.org
ICF	Informed Consent Form	
PHIPA	Personal Health Information Privacy Act	http://www.health.gov.on.ca/english/public/pub/ministry_reports/phipa/bill_159.pdf
PI	Principal Investigator	
PICO	Population Intervention Comparison Outcome	http://www.umdnj.edu/camlbweb/EBM/picomodel.htm
PRE	Panel on Research Ethics	www.pre.ethics.gc.ca
QCIPA	Quality of Care Information Protection Act 2004:	http://www.health.gov.on.ca/english/providers/legislation/priv_legislation/quality_info.html
QI	Qualified Investigator (for clinical trial or medical devices trials only)	
RDC	Research Development Committee	
REB	Research Ethics Board	
REO	Research Ethics Office	
SAE	Serious Adverse Event	
SJCG	St. Joseph's Care Group	www.sjcg.net
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/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

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Application for Ethical Review of a Research Project
Involving Humans, their Information and/or their Biological Materials

St. Joseph's Care Group and Thunder Bay Regional Health Sciences Centre have distinct and independent Research Ethics Boards. While application forms have been standardized between the two organizations, if your project requires **approval from both organizations, ensure application is made to each organization separately**. Please consult the websites for submission and meeting dates as well as the process to apply to each organization.

St. Joseph's Care Group (SJCG) Research Ethics Office Rm Ca134b ~ 1st Floor LPH 580 N. Algoma St. Thunder Bay, ON P7B 5G4 Email: REO@tbh.net Phone: (807) 343-4300 ext. 4298 or 4723 Fax: (807) 343-4376 TBRHSC REB WEBSITE	**Thunder Bay Regional Health Sciences Centre (TBRHSC)** Research Ethics Office Rm 1534 ~ Level 1 980 Oliver Road Thunder Bay, ON P7B 6V4 Email: REO@tbh.net Phone: (807) 684-6422 or 684-6434 Fax: (807) 684-5904 SJCG REB WEBSITE

For assistance with application to the Research Ethics Board for either organization
Contact the Research Ethics Office at REO@tbh.net

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 [TCPS 2: December 2010] and other commonly accepted standards in order to protect patients, investigators, and the institution.

In Thunder Bay, St. Joseph's Care Group (SJCG) and Thunder Bay Regional Health Sciences Centre (TBRHSC) each have their own respective Research Ethics Boards (REB). Research teams may require review and approval from both organizations to complete their work. To facilitate research in Thunder Bay, SJCG and TBRHSC have collaborated on a shared Research Ethics Office (REO) which serves as the administrative gateway for research ethics review for both organizations. REO staff will facilitate REB applications which require submission to both SJCG and TBRHSC REBs.

Research Ethics Applications have been standardized for TBRHSC and SJCG. While the main application is identical, the process to ensure the required resources and cooperation of programs, staff and equipment is unique for each organization. These differences need to be carefully followed depending on which organization you are requesting support from.

- For SJCG, Directors/Managers are required to indicate their support to the research team by signing a **Organizational Impact Form** prepared by the research team outlining the resources required for a successful completion of the research project.

- For TBRHSC, all applications must be reviewed and supported by the **Research Development Committee.**

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

Research Ethics Boards (REB) functions:

- to approve, 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.

Principles of Ethical Review for research involving humans:

As described in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans [TCPS 2: December 2010], 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

Part 1: The Initial Application

Application process for St. Joseph's Care Group (SJCG):

The SJCG Research Ethics Board (REB) meets over an extended lunch hour on the **1st Monday** of each month, September to June (delayed 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 REO@tbh.net 3 weeks before the scheduled REB meeting. The Research Ethics Office (REO) will assign a SJCG 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.

Application process for Thunder Bay Regional Health Sciences Centre (TBRHSC):

The TBRHSC Research Ethics Board (REB) meets over an extended lunch hour on the **4th Monday** of each month, September to June (delayed 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 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.

Note: If a research team requires REB approval from both SJCG and TBRHSC, each organization requires one original signed copy of the full REB application. The Principal Investigator will be assigned a unique SJCG REB # and TBRHSC REB # to facilitate the tracking of the approval process at each organization.

Full REB Review:

Full REB reviews are conducted at the convened monthly meetings. The Principal Investigator (PI) is to 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 contact 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.

REB Application Submission Process:

Required Documents for Initial Study Submission:

- Research Ethics Application
- Organization Impact Forms (SJCG) / Research Development Committee Endorsement (TBRHSC)
- Research Proposal / Clinical Protocol
- Detailed Budget Statement

Additional Documents (where applicable):

- Declaration of Conflict of Interest Forms for EACH additional co-investigator
- Information letters and other Recruitment Materials
- Informed Consent Forms
- Data Collection Tools (surveys / data abstraction forms, interview guides)
- Joint Pharmacy and Therapeutics Approval
- Health Canada Regulatory Documents (No Objection Letter, Investigational Testing Authorization)
- Clinical Trial Agreement (Contracts)

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.**
- 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 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 REO@tbh.net

During the REB Meeting:

Principal Investigators are to present a 3 to 5 minute overview of their proposed research study. For out of town research teams, teleconferencing arrangements may be made in advance through the Research Ethics Office. A question and answer period between the REB membership and the research team will follow. The research team will be thanked and depart the meeting to allow for the REB membership to discuss the project and finalize the REB decision.

Decision of the REB:

Whether the REB review was conducted through the delegated review pathway or at the convened meeting by the full membership, the REB may make one of the following decisions:

1. approval, no revisions required;
2. minor clarifications/revisions requested by the REB, to be submitted to and reviewed by the Chair, REB. Final REB approval is delegated to the Chair of the REB pending acceptable revisions;
3. clarifications/revisions required for submission and approval as per directive in the motion of the REB [e.g., review by identified REB member; sub-committee of REB; electronic distribution of revisions to entire REB with timeline for comments]. After revisions are submitted and reviewed according to the REB motion, final REB approval is delegated to the Chair of the REB;
4. major clarifications/revisions are requested. Principal Investigator is requested to resubmit a revised application for full REB review. Principal Investigator may or may not be asked to attend the second REB meeting;
5. not recommended for approval. Principal Investigator may request reconsideration;
6. decision deferred.

Communication following REB review:

Communication with the Principal Investigator 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 Research Ethics Office at REO@tbh.net 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 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.

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 and reported to the Research Ethics Office at REO@tbh.net**

Check the appropriate boxes – one or both

Research Ethics Application for

☐ **St. Joseph's Care Group (SJCG) REB**

☐ **Thunder Bay Regional Health Sciences Centre (TBRHSC) REB**

For Office Use Only:

REB Number:

Submission Date:

Approval Date:

The REO will assign your project a REB number. If applying to both TBRHSC and SJCG, separate REB numbers will be issued for each site.

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

Section A: Description of Research Team

Principal Investigator: The **Principal Investigator (PI)** is the individual responsible for the research project at SJCG or 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 SJCG or TBRHSC. This may be someone internal or external of the organization.
- Ensure that full contact information, including a reliable email address is listed.
- Each investigator is required to sign a Declaration of Conflict of Interest Form and append to the application

Best Contact Person for Project:	☐ same as section	← click if PI is the best contact and do not complete the 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. Any research team member having access to identifiable or personal health information should sign this form. 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 and submit to REO@tbh.net 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 TCPS 2 for the Definition of Minimal Risk
- Reference TCPS 2 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.
- 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'.
- 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?
- 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 2007: recruitment phase, July – Sept 2007: intervention A, Aug – Nov 2007: intervention B, Jan, 2008: 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.**

For SJCG: Organizational Impact Forms will need to be signed by all Directors/Managers impacted by the research activity. The research team should have an initial discussion with the appropriate leaders to discuss how the project can be carried out within the institution. The research team completes the REB Organizational Impact Form available on the website and request all required Directors/Managers signatures. This form is appended to this application form as evidence of agreement to provide the human resources and supplies needed to complete the project.

For TBRHSC: All applications requiring REB review will require approval from the Research Development Committee before REB submission. The purpose of the RDC is to review the quality of research proposals and 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. This process is a required step before REB application, and in fact, makes up a portion of your REB submission. For RDC submission, please contact the Administrative Assistant to the VP, Research at RDC@tbh.net or 1(807) 684-6571 for guidance on the RDC requirements.

Although RDC review and endorsement is required before REB application is considered complete, it is highly recommended that the research team consult these guidelines to ensure the research is proposed has taken into account the ethical considerations to be reviewed by the REB. If you require further guidance, please feel free to consult the REO staff through REO@tbh.net.

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	**S**	**TBRHSC**

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:

- ✓ 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. For projects only involving either of the two organizations, the total number is the total of local participants. **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 TCPS 2 describes the minimum expectations regarding the research consent process.

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).

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.

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. (see Appendix 2 – Consent Forms).

Section H: Potential Benefits

Please see Chapter 2, section B of TCPS 2 for 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/SJCG 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: 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 O: Clinical Trial/Medical Devices Studies ONLY

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

FOR TBRHSC: Consult the Translational Research Program at Thunder Bay Regional Health Sciences Centre if you are conducting a 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 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
- Identify all documents by title, appendix reference, version number and version date
- Ensure that this list is modified upon subsequent submissions

Section Q: Research Ethics Agreement

As the Principal Investigator:

- 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 re-approval 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, 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 SJCG/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 SJCG/TBRHSC as outlined in this research ethics application until formal notification of approval has been received from all required REBs and, if required, related financial agreements/contracts.

The undersigned hereby agrees to these terms:

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

Signing this document indicates your agreement to oversee the overall conduct of the described research activity, including activities carried out by research team members on your behalf.

When notified by the Research Ethics Office staff, submit one original signed copy of this REB application for each organization for which you are applying for REB approval.

Print Name: _____

Date: [month day, year] _____

I agree to allow SJCG/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 research projects.

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: 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. Any research team member having access to identifiable or personal health information should sign this form. 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 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.
Organization Impact Form(s) (*SJCG ONLY)*	Describe the cooperation and resources necessary from SJCG to ensure completion of the research project (e.g., procedures, time commitment, training, meetings, chart review, space). **Be specific**, and provide details about the resources you are requesting. Discuss thoroughly with Manager of each program/department you are requesting support. A separate detailed form is required of each individual manager affected by the research If a manager/director is a member of the research team, ensure their supervisor approves their involvement in the project as indicated by their signature on the organizational impact statement.
Research Development Committee Approval *(TBRHSC ONLY)*	Approval from the RDC must accompany all applications being submitted to the Research Ethics Office for review by the Research Ethics Board. For information about the Research Development Committee review process, please contact the Office of the Vice President, Research at RDC@tbh.net .
Research Proposal / Clinical Protocol / Thesis	The research protocol is a separate document from the ethics application detailed above. This is the scientific document that details the entire project.
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 TCPS2 requirements for informed consent. All consent forms/ information letters and invitations are required to include the REB Chair Contact information paragraph. Additionally, see Appendix 2 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, Investigational Testing Authorization)	Regulatory documentation from Health Canada is required before REB approval may be finalized. For assistance with these documents, contact the Translational Research Program at Thunder Bay Regional Health Sciences Centre.
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.**	

Part 2: Continuing Ethics Review

Continuing Ethics Review is part of the monitoring requirements of the Research Ethics Board. After initial REB approval has been granted, the REB is responsible to ensure research teams are following their submitted protocols. To this end, **SJCG and TBRHSC will grant REB approval for a period no greater than one year.**

Continuing Ethics Review can be in the form of a **Report** provided to the REB (e.g., Study Completion Report) or an **Application** which requires REB approval before it is implemented (e.g., Re-Approval Application, Amendment Application). All information that is reported to the REB will be acknowledged as received.

Before REB approval expires, the research team is required to submit either a study completion report or apply for renewal of the REB approval. The Principal Investigator will be sent an email 60 days prior to REB expiry, reminding of the need to submit either a study completion report or re-approval application.

Points to Consider: Every research study that is granted REB approval requires at a minimum a study completion report on or before the REB expiry date. If the same project required both SJCG and TBHRSC REB approvals, separate REB # were assigned, and a study completion report is to be submitted to each organization.

Study Completion Report

Researchers must notify the Research Ethics Board when the research project is completed, discontinued or terminated by completing and submitting a Study Completion Report.

- A research study is considered completed when the researcher no longer requires any involvement with the organization. This decision is made by the Principal Investigator and may vary by methodology. For example, for multi-site studies, you may choose to close your research study when local recruitment, intervention and follow-up are complete at the local site, even though other sites might still be active.
  CAUTION: If there may be a need to access records for data verification purposes, (e.g., pharmaceutical sponsored studies, academic projects) it is best to renew the REB application to allow for continued access. Graduate Students may prefer to keep their REB application active until such time as their thesis has been examined and approved by their academic institutions.

Other Continuing Ethics Review Documents

These documents may or may not be required depending on the course of the research project.

Re- Approval Application

Each REB approval granted is for no longer than one year and has a clear expiry date. If the research team wishes to continue research activity beyond the expiry date, the Principal Investigator must complete an REB Re-Approval Application before the REB expiry date. Deadlines for submission of Re-Approval Applications are the same as for new studies.

Research studies that originally outlined activity for greater than one year must submit an annual status report in the form of a REB Re-Approval Application. Research studies that require an extension beyond the original approved research plan and REB expiry date must be submit an REB Re-Approval Application. In the latter case, a revised organizational impact review may be required at the discretion of the Research Ethics Office.

The REB Re-Approval Application form outlines the status and progress of the project. This is consistent with the REB's responsibilities around monitoring ongoing protocols that have received ethics approval.

- The Research Ethics Office emails continuing ethics review reminders 60 days prior to the expiry date.
- In addition to requesting details about numbers of participants enrolled in the project, the form collects details on procedural changes from those originally approved as well as details on the occurrence of any adverse events.

Re-Approval Application Process

- Deadlines for submission of Re-Approval Applications are the same as for new studies.
- Annual Re-approval Applications may be reviewed by delegated or full REB ethics review, as determined by the REB Chair.
- Submit one electronic copy of the REB Re-Approval Application including all supporting documents to REO@tbh.net.
- Submit one originally signed hard copy of the complete package to Research Ethics Office.

Failure to apply for REB Re-Approval will result in suspension of REB approval.

Amendment Application

Researchers must obtain the approval of the REB before amending an REB-approved research project and any of the related research documents.

Examples (not exhaustive) of when REB approval is required include, but are not limited to, amendments relating to the:

- Risks to research participants
- Research design (e.g., sample size, inclusion/exclusion criteria, intervention procedures, etc.)
- Research documentation (e.g., information and consent forms, recruitment letters/scripts, questionnaires, etc.)
- Research title or objectives
- Principal investigator or co-investigators
- Research site location
- Research sponsor
- Researcher contact information
- Extent and duration of the research
- Recruitment Methods, Number of Participants
- Evaluation of clinical efficacy or safety of a research drug or the chemistry and manufacturing information that may affect the safety or quality of the drug (applicable to clinical drug trials)

The Three R's

NOTE: Significant changes to the approved research study may constitute a new research study application.

Consider if there is a change to:

- Research Question
- Recruitment
- Risk

Please consult us at REO@tbh.net

Exception: *Changes to protocols may be required to minimize the immediate risk to research participants*. In these situations where approval for an amendment was not sought from the REB prior to the implementation of the amendment, the researcher must promptly report, in writing, to the Research Ethics Board, the required amendment, as well as a deviation report explaining the reason for the immediate change.

Amendment Application Process

- Deadlines for submission of Amendment Applications are the same as for new studies.
- Amendment Applications may be reviewed by delegated or full REB ethics review, as determined by the REB Chair.
- Submit one electronic copy of the REB Amendment Application including all supporting documents to REO@tbh.net.
- Submit one originally signed hard copy of the complete package to Research Ethics Office.
- Clearly indicate all amendments/changes in all documents. For example, **additions are to be bolded** and **deletions are to be struck out with a single line**. Ensure version dates are incremented appropriately.
- Provide a "clean copy" of all documents. For consent forms, the clean copy provided will be date stamped with the REB approval date and serve as your master copy.

Local Serious Adverse Event (SAE) Report

Local serious adverse events are all adverse drug reactions or adverse events which are **both** serious and unexpected, or all unanticipated medical device SAE's that occur at the TBRHSC /SJCG site for the study, **and** that are related or possibly related to the study drug or treatment. Local serious adverse events should be reported to the REB promptly. Such events should be reported using the Local Serious Adverse Event Report form, and should include:

- The status of the study and summary of participants enrolled.
- A detailed description of the local event including an assessment as to whether the event reaction was mild, moderate or severe.
- An opinion expressed by the local investigator that the event is both serious and unexpected and a justification of that opinion.
- An opinion expressed by the local investigator that the event is related or potentially related to the study drug/procedure/device and an explanation of that opinion.
- An opinion expressed by the local investigator respecting the implications of the SAE on the continuation of the study and any further actions that may be required such as changes to the study procedure, informed consent or protocol.
- A statement of the study team response to the event and the patient outcome of the SAE.

Non-Local Serious Adverse Event (SAE) Report Spreadsheet Submissions

Upon receipt of an External Safety Report from the sponsor, it is the Principal Investigator's responsibility to review each non-local SAE Report.

***See Appendix 1 for specific instruction on how to fill out the Non Local SAE spreadsheet form.**

Protocol Deviations / Violations Report

Protocol deviation/violation is any departure from the defined procedures and/or treatment plans as described in the protocol version submitted and previously approved by the REB. Reports are acknowledged as received and reported at the next convened REB meeting. Further information or explanation may be requested by the Research Ethics Office or the REB.

Protocol deviations/violations must answer the following points:

- Date of Deviation
- Date Principal Investigator was made aware of Deviation/Violation
- Date Sponsor Notified
- Brief Description of the Issue
- Patient Safety Impacted
- Corrective Action Taken Locally to Resolve Issue

Reports & Receivables Form

Any information which is to be reported to the REB but does not require approval must be submitted using the Reports and Receivables Form. All information submitted on this form will be acknowledged as received by the Research Ethics Office and the date it will be reported to the Research Ethics Board.

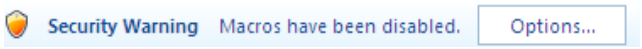
Examples include, but are not limited to:

- Safety letters (provided that they do not meet the criteria for an SAE)
- DSMB reports
- Summary Reports
- New Information
- Suspension of Accrual
- Studies closed to accrual/enrollment

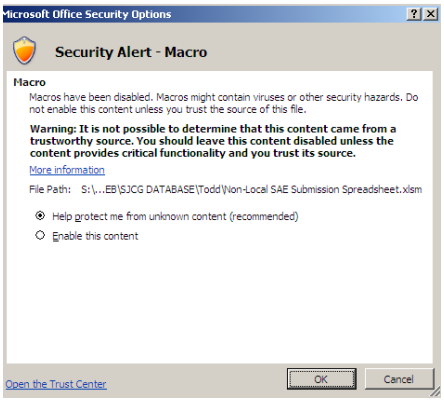
APPENDIX 1
RESEARCH ETHICS BOARD
Non-Local Serious Adverse Event
Spreadsheet Guide (Excel 2007)

1) Open the file "Non-Local SAE Submission Spreadsheet."

a) A Security Warning will pop up just above the spreadsheet with the message "Macros have been disabled." (as shown below)



b) Click "Options" to bring up a Security Alert window. This window will inform you that you should not enable macros unless you trust the source of the file.

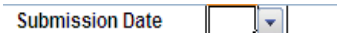


c) In this case we do want to enable macros since the file source is trusted. Click "Enable this content." Finally, click "OK."

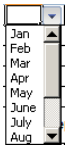
d) The window will disappear and the spreadsheet will be displayed again.

2)

a) With the spreadsheet open, you will notice that you need to fill in several values near the top of the screen: "Submission Date," "REB#," "Study Title," and "Principal Investigator." Click the square immediately to the right of Submission Date to select it. An arrow will appear as shown below:



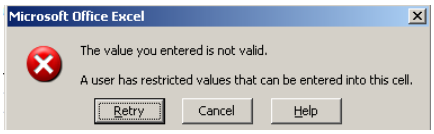
b) Click the arrow to display a drop down list of all possible months. Select the appropriate month from the list.



c) Repeat this process to select a day and a year from the drop down lists.

Submission Date	Jan	1	2010

d) Double-click the box beside "REB#." It will now allow you to type the seven-digit REB number. If you enter a number that is too short or too long an error message will appear as follows:



e) Finally, double-click the box beside "Study Title" to enter the study title, and double-click the box beside "Principal Investigator" to type in the Principal Investigator's title, first and last names. Once you are finished, the spreadsheet should look similar to the example below.

Submission Date	Jan	1	2010
REB #	2010001		
Study Title	Example study		
Principal Investigator	Dr. John Doe		

3) You are now ready to enter SAEs into the spreadsheet.

a) Double-click the box immediately below the Patient ID Number header (this should be row 16 column F). Type in the patient ID number. When you are finished, the spreadsheet should look similar to this picture:

13		Date of SAE						SAE Relationship			Type 3 SAE Changes		
14	Patient ID Number (One patient per row)	Month	Day	Year	Adverse Event (Separate multiple events with a comma)	I = Initial FU = Follow-up	U = Unexpected E = Expected	Reporting Investigator	Sponsor	SAE Type*	Protocol	Consent	Investigator Brochure
15								Use same language as in report					
16	E1X1A1M1P1L1E												

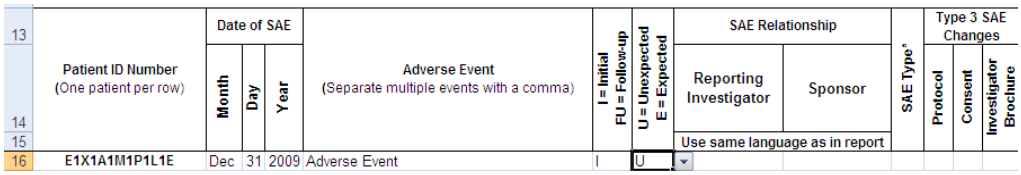
b) Next, fill in the date of the SAE in the following three boxes by using the drop-down lists provided. These drop-down lists work exactly the same as those used for the submission date at the top of the screen.

13		Date of SAE						SAE Relationship			Type 3 SAE Changes		
14	Patient ID Number (One patient per row)	Month	Day	Year	Adverse Event (Separate multiple events with a comma)	I = Initial FU = Follow-up	U = Unexpected E = Expected	Reporting Investigator	Sponsor	SAE Type*	Protocol	Consent	Investigator Brochure
15								Use same language as in report					
16	E1X1A1M1P1L1E	Dec	31	2009									

c) Next double-click the box below "Adverse Event" and type in a description of the adverse event.

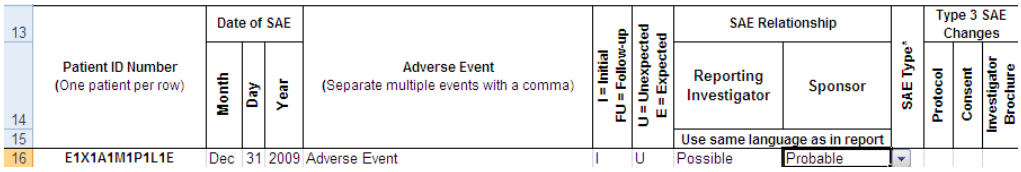
d) After you have typed in the description, double-click the next box and click the arrow to display a drop down list of the event status. You can either enter "I" for "Initial" or the follow-up number.

e) Next click the following box and select either “U” or “E” from the drop down list for unexpected or expected, respectively. By now your spreadsheet should look similar to the following picture:



13		Date of SAE						SAE Relationship			Type 3 SAE Changes		
14	Patient ID Number (One patient per row)	Month	Day	Year	Adverse Event (Separate multiple events with a comma)	I = Initial FU = Follow-up	U = Unexpected E = Expected	Reporting Investigator	Sponsor	SAE Type*	Protocol	Consent	Investigator Brochure
15								Use same language as in report					
16	E1X1A1M1P1L1E	Dec	31	2009	Adverse Event	I	U						

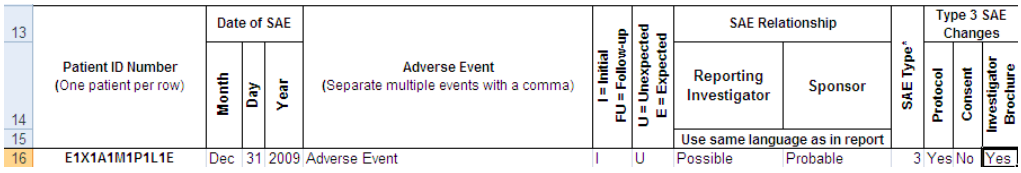
f) Now double-click the next two boxes separately to specify the SAE relationship for reporting investigator and sponsor. Use the drop-down lists to select a word. If the word you are looking for isn’t listed, simply double-click the box and type it in manually. When you are done the spreadsheet should look similar to this picture:



13		Date of SAE						SAE Relationship			Type 3 SAE Changes		
14	Patient ID Number (One patient per row)	Month	Day	Year	Adverse Event (Separate multiple events with a comma)	I = Initial FU = Follow-up	U = Unexpected E = Expected	Reporting Investigator	Sponsor	SAE Type*	Protocol	Consent	Investigator Brochure
15								Use same language as in report					
16	E1X1A1M1P1L1E	Dec	31	2009	Adverse Event	I	U	Possible	Probable				

g) Next, double-click the box below SAE Type and specify the SAE type as 1, 2, or 3 from the drop-down list. The meaning of these values is listed at the top of the spreadsheet with a corresponding asterisk. If you choose SAE Type 1 or 2, you are finished entering the first SAE record (disregard **point h** below). If you choose SAE Type 3, you must specify the Type 3 SAE Changes in the last three columns as explained next.

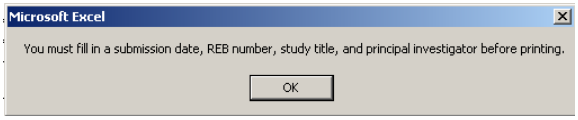
h) If the SAE is of type 3, double-click the box below Protocol to specify if changes should be made to the protocol. The only options in the drop-down list are “Yes” or “No.” Repeat this process to specify “Yes” or “No” for changes to the consent and investigator brochure. When you are finished, the spreadsheet should look similar to the picture below:



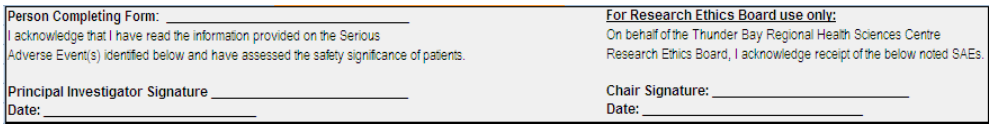
13		Date of SAE						SAE Relationship			Type 3 SAE Changes		
14	Patient ID Number (One patient per row)	Month	Day	Year	Adverse Event (Separate multiple events with a comma)	I = Initial FU = Follow-up	U = Unexpected E = Expected	Reporting Investigator	Sponsor	SAE Type*	Protocol	Consent	Investigator Brochure
15								Use same language as in report					
16	E1X1A1M1P1L1E	Dec	31	2009	Adverse Event	I	U	Possible	Probable	3	Yes	No	Yes

4) You have now entered a record into the spreadsheet in row 16. Each row in the spreadsheet should correspond to ONE patient. **The exception would be if a single patient had multiple events on the same day with different relationships and SAE type**. In this case, use a new row to enter additional event and related information but **do not** repeat the patient ID number or date of SAE (leave blank). If you would like to enter a new patient, double-click the first box in the next available row and repeat the instructions listed above from **Step 3.** If you enter a lot of records into the spreadsheet, you will notice that the column headers (rows 13, 14, and 15) will stay frozen in place even if you scroll up and down. This will help you remember what values to place in each column.

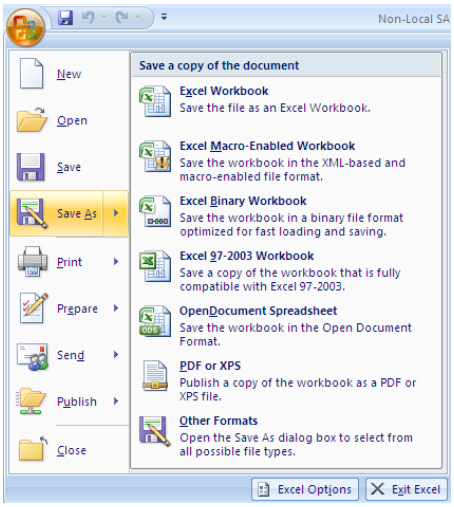
5) When you are ready, print out the spreadsheet. If the error message shown below appears, this means you haven't finished entering values in the box at the top of the screen. Follow the instructions in **Step 2** to fill in these values.



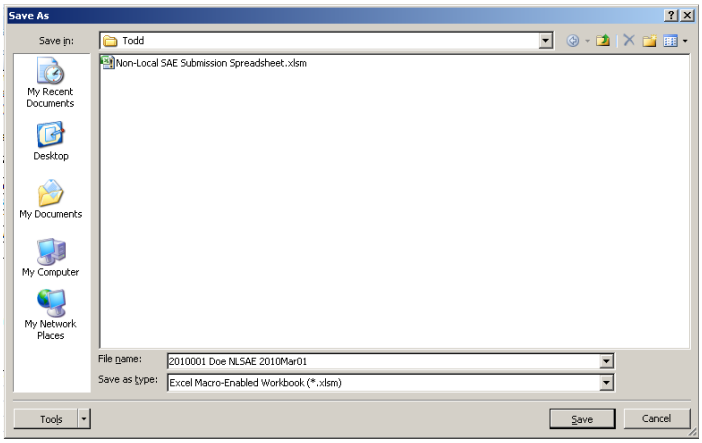
6) Once you are able to print successfully, you will notice that a few extra rows will pop up near the top of the screen as shown below. These rows will appear on the first page of your print-out for the principal investigator and research ethics board chair to sign. When you are ready, print out the document.



7) Now you must save the electronic version of the spreadsheet. Click the Office Button at the top left corner of the screen to display the menu, and hover your mouse over "Save As." As you can see below, a list of different file formats will appear. Simply click the "Save As" button or click "Excel Macro-Enabled Workbook."



8) The screen shown below will appear. Change the file name to the format "REB#" "PI Last Name" "NLSAE" "Date." For example, "2010001 Doe NLSAE 2010Mar01". When you are finished, make sure you are saving the file somewhere you will remember and click "Save."



9) Email the Excel Macro-Enabled Workbook file that you just created to REO@tbh.net. Mail one hard copy with Principal Investigator's signature to the Research Ethics Office

Notes

1) It is recommended that you save your work often to prevent any data loss.
2) If any difficult results during data entry, save what you have completed and contact the Research Ethics Office for assistance. Often we can resolve issues without loss of work.
   Email: REO@tbh.net **Work Phone: (**807) 684-6422

Appendix 2: Research Study Information Letter/ Consent Form

Consent Shall Be Informed: As outlined in the TCPS 2 Article 3.2, researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.

In general, information required for informed consent includes:

(a) information that the individual is being invited to participate in a research project;

(b) a statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;

(c) a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;

(d) an assurance that prospective participants:
- are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
- will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and
- will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;

(e) information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;

(f) the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;

(g) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;

(h) the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;

Suggested language for the Chair, Research Ethics Board (use one or the other, or both if appropriate)

If you have any concerns regarding your rights as a research participant, or wish to speak to someone other than a research team member about this research project, you are welcome to contact the:

Chair, Research Ethics Board
Thunder Bay Regional Health Sciences Centre
980 Oliver Road, Thunder Bay, Ontario P7B 6V4
phone: 807-684-6422 fax: 807 684-5904
email contact for REB Chair: ResearchEthics_Chair@tbh.net

or

Chair, Research Ethics Board
St. Joseph's Care Group
580 N. Algoma St., Thunder Bay, Ontario P7B 5G4
phone: 807-343-4300 ext. 4723 fax: 807-343-4376
email contact for REB Chair: REB_Chair@tbh.net

(i) an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected (see Article 5.2), a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;
(j) information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
(k) a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and
(l) in clinical trials, information on stopping rules and when researchers may remove participants from trial.

For consent to be informed, prospective participants shall be given adequate time and opportunity to assimilate the information provided, pose any questions they may have, and discuss and consider whether they will participate. The time required for this initial phase of the consent process will depend on such factors as the

Appendix 3: Items to considered when developing an Informed Consent Form for Clinical Trials

1. What is the purpose of this study and what is being tested?
2. Why am I being asked to join this Study? (inclusion criteria)
3. Are there any reasons I should not consider this study? (exclusion criteria)
4. What benefit can I expect?
5. How long will I be in the study?
6. Where is this study taking place?
7. How many people will take part in this study?
8. What is involved in taking part in this study?
9. Are there any risks associated with study procedures?
10. What about unexpected risks?
11. What about birth control and pregnancy?
12. What other treatment is available if I don't want to be in the study?
13. What happens at the end of the study?
14. What are my responsibilities as a study participant?
15. Can I be taken out of the study without my consent?
16. What if I decide I no longer want to participate after signing this consent form?
17. What about new information?
18. Will it cost me anything?
19. What happens in the case of a research related injury?
20. What about my privacy and confidentiality?
21. Do the researchers have any conflicts of interest?
22. What if I have any questions or problems?
23. What about ethical and regulatory considerations?
24. What are my Rights?
25. What does my signature on this consent mean?

Points to consider:

- All consent forms need to be submitted as the final version, as the paper copy will be date stamped as approved by the REB, and this serve as the master copy for your use.
- All consent forms must be submitted on letterhead.
- All consent forms need to include a version date and page number in a footer.

Resource:

University of Western Ontario's Alternate Word Glossary:
http://www.uwo.ca/research/ethics/guidelines%20for%20all/HSREB/2g009-guideline-alternative-wording-glossary-aug-2001.pdf

** *Thank you to Katherine Andriash, Clinical Research Process Coordinator for sharing her compiled list of questions and resources that she considers when developing an informed consent form.*

Appendix 4: Checklist for Submission of an REB application

Checklist			
I am applying to SJCG REB because:		I am applying to TBRHSC REB because:	
	I am an employee of SJCG		I am an employee of TBRHSC/TBRRI
	I require access to information and/or potential participants at SJCG.		I require access to information and/or potential participants at TBRHSC.

Below is a list of required and supplemental information, if applicable, to complete a research ethics review application. In the first column, indicate if the information is attached. If a standardized form is available from the respective websites, a form identifier is indicated following the description.

Initial Application (required documentation)	
	Research Ethics Application
	SJCG: Organizational Impact Statement TBRHSC: Research Development Committee documentation
	Research Proposal/Clinical Protocol
	Budget Statement (including institution responsible for administration of grant/contract)
Additional Information (if applicable)	
	Declaration of Conflict of Interest Form for each addition team member (see instructions on form)
	Information Letter(s)/Recruitment Materials (on letterhead, and specific for SJCG/TBRHSC)
	Consent Form(s)
	Data Collection Tool(s) (e.g., Surveys/Data Abstraction Forms/Focus Group Guides)
	Joint Pharmacy & Therapeutics approval
	Health Canada/other regulatory documents (e.g., REBA, No Objection Letter, Investigation Testing Authorization)
	Clinical Trial Agreement/Researcher Agreement if to be signed by SJCG or TBRHSC
Continuous Ethics Review (ongoing documentation) The list of ongoing documentation is not submitted at initial application, but is listed to highlight that continuous ethics review is the responsibility of the Principal Investigator.	
	Study Completion Report Form (requires signature)
	Re-Approval Application Form (requires signature)
	Amendment/Change Application (requires signature)
	Protocol Deviation/Protocol Violation Report
	Local Serious Adverse Event Report (requires signature)
	Non-Local Serious Adverse Event Reports [Excel spreadsheet] (printed version required PI's signature)
	Reports & Receivables Form (documentation which is for REPORT ONLY to the REB)
All documentation is to be submitted to the appropriate Research Ethics Office (REO@tbh.net) in a timely manner. Research projects lacking appropriate documentation will be administratively closed by the Research Ethics Office.	