St. Joseph's Care Group

Research Ethics Board

Guidelines for Researchers Applying to the REB

May 3, 2022

TABLE OF CONTENTS

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

Part I: Research Ethics Board (REB) Application

The REB at St. Joseph's Care Group (SJCG) follows the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS2 (2018). This document is referenced throughout the Guidelines.

APPLICATION REQUIREMENTS

The following documents are required for the initial REB application:

- ✓ Research Ethics Application signed by the Principal Investigator (PI)
- ✓ Organization Impact Form
- ✓ Research Protocol
- ✓ Budget
- ✓ TCPS 2: CORE-2022 (Course on Research Ethics) Tutorial certificate from the PI and each member of the Research Team (please note the certificate must be from the tutorial released in February 2022)

The following additional documents may also be required:

- ✓ Declaration of Conflict of Interest Supplemental Form for each Research Team member
- ✓ Recruitment Materials
- ✓ Information Letter
- ✓ Informed Consent Form
- ✓ Data Collection Tools (e.g., survey, data abstraction form, interview guide)
- ✓ Other documents as appropriate (e.g., Joint Pharmacy and Therapeutics Approval, Health Canada Regulatory Documents)

Incomplete application packages will not be accepted and will be returned to the researcher. Please note that although much of the research protocol is included in the REB application, a separate protocol is required.

APPLICATION FORM

Please see below for assistance with each section of the REB application form.

Section A: Research Project/Protocol Title

- Ensure the title entered matches all documentation regarding the research project/protocol.

Section B: Research Team

- Principal Investigator (PI) is "the researcher who is responsible for the ethics conduct of the research and for the actions of any member of the research team" (TCPS2 Glossary).
- The Best Contact should be able to answer questions about the status of the research project and be in direct contact with the PI as needed.

Section B: Research Team (continued)

- Any Research Team member having access to identifiable or personal health information should listed as a co-investigator and sign the Conflict of Interest Form.

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

- Depending on the level of responsibility and access to only de-identifiable information, short term/temporary research assistants are not required to submit this form.
- Reflecting the responsibility of the PI's oversight of the entire research program, it is best practice for the PI to keep a log and standard operating procedures for access to information.
- Submit an amendment if the Research Team expands or changes after the initial approval is granted.
- All members of the Research Team are to be knowledgeable of the TCPS2 and other required regulations for the type of research being conducted (e.g., Collaborative Institutional Training Initiative certification for clinical trials).
- If there are more than 10 co-investigators, attach a list as an appendix to the application.

Section C: Overall Description of Research Project/Protocol: Research Question

- The research question should indicate the population being studied, the intervention is (if any), the comparison groups (if any), the outcome measures, and the methodology to be used.
- One strategy is to use the PICO Model (i.e., population, intervention, comparison or control, outcome) to formulate the research question.
- Qualitative methods may or may not have all of the above components.

Section C: Overall Description of Research Project/Protocol: Research Summary

- Compose this section as a lay description of the study for the public (e.g., a description of the study that appropriate for a brochure or newspaper article). Remove all jargon and acronyms.
- List the purpose of the research project/protocol. The purpose is the main reason the study is being conducted. Include the direct implications or applications of the study.
- List the aim and/or objectives of the study.
- Provide justification for the study.

Section D: Application Overview

- List all other organizations where REB review is being or has been sought.
- If the proposal has been peer-reviewed for scientific merit, append a copy to the application.
- Please consult the TCPS2 for relevant definitions of terms used in this section.

Section E: Research Project/Protocol Design and Methodology

- Write this section for a broad audience – not all REB members are clinicians. Avoid acronyms and technical terminology or, if such terms are used, provide clear definitions.
- Describe how the research question will be answered. For example, areas to address could include:
    - Statistical measures that will be used
    - How the efficacy of the intervention be measured
    - How data will be organized, coded and evaluated
- This section requests complete details on all procedures (e.g. qualitative and/or quantitative techniques) in which participants take part. Ideally, detail procedures sequentially, as they will occur for the participant, and described in terms that 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 is methodologically sound.
- For particularly technical descriptions, reference the research protocol.

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

Section F: Implementation of the Research Project/Protocol Including Timelines

- Provide an itemized timeline from proposed beginning to completion for the research project submitted for review (e.g., January – February: recruitment phase, March – May: Intervention A, June – August: Intervention B, September - November: data analyses and write up).
- Multi-site protocols may not reflect the local situation. Detail how the protocol will be tailored to ensure standardized data collection amongst sites.
- Include the time required of participants if they choose to participate.
    - ❖ HINT: Include this information in the Consent Form.
- If staff time is required, provide details of resources needed from SJCG.
- Ensure the timeframes are realistic to allow for unforeseen delays. Approval is granted on the timeframe outlined; be generous with time estimates.
- All Directors/Managers impacted by the research must sign and Organization Impact Form agreeing to support the resources and services requested by the Research Team. The Research Team should have an initial discussion with the appropriate leaders to discuss what is required to complete the study.

Section G: Recruitment of Participants Involved in the Research Project/Protocol

- This section is of primary concern during the REB review process. The following must be clearly addressed by the Research Team:
    - Fair/equitable recruitment practices,
    - Voluntary participation,
    - Free and informed consent – an individual who has a position of authority over the potential participant (e.g., physician/patient, teacher/student) cannot obtain consent,
    - No coercion or pressure to participate,
    - Time for participants to consider the research opportunity being proposed,
    - Participating or not participating in the research project will have no impact on care received at SJCG,
    - Research participants do not waive their legal rights,
- Clearly state inclusion and exclusion criteria for potential participants.
- In the event of greater recruitment than stated in the application, submit an amendment form for approval by the REB before increased enrollment may begin.
- If multiple cohorts are sought (e.g., the study involves surveying nurses, clients and family members), detail recruitment plans for each group individually.
- Describe how the confidentiality of participant contact information (e.g., names, telephone numbers, email addresses) will be protected.
- Attach copies of any recruitment materials (e.g., letters, advertisements, emails, flyers, scripts).
- Indicate where participants will be recruited (e.g., specific unit at hospital, clinic).
- State who will make the 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 H: Informed Consent

- Chapter 3 of TCPS2 describes the minimum expectations regarding the research consent process.

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

- Points to consider for the consent process include the:
  - point of contact for the consent process,
  - forms/materials will be used for the consent process,
  - location and timing of the consent process,
  - amount of time participants have to review information about their potential involvement,
  - reporting of incidental findings to the participant.
- If a member checking process 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. Identify whether assent forms will be used. Clearly outline if a participant's ability to consent be monitored over time.
- Describe in detail how participants are 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)
- Points to consider for the withdrawal process include:
  - the point when withdrawal is no longer feasible,
  - how a participant can withdraw and who they must contact (consider each possible stage of withdrawal),
  - the risks associated with withdrawal at certain phases of the study (especially important with clinical trials),
  - what will happen to data collected up to the point of withdrawal,
  - whether the standard of care treatment continue if the participant withdraws,
  - if the data from a withdrawn participant be used.

Section I: Potential Benefits

- See Chapter 2 of TCPS2 for information regarding potential benefits of research.
- 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 or re-imbursement for participation in research are NOT considered benefits to the participant.

Section J: Potential Risks

- See Chapter 2 of TCPS2 for information a regarding the concepts of the risks of research.
- Identify known and anticipated risks to participants for each procedure, test, interview or any other aspect of the study.
- Include all potential physical effects of any procedure that is not part of standard care.
- If the research may cause the participant to become upset, embarrassed or have any other negative psychological effect (short or long term), provide appropriate resources/supports to mitigate this risk.
- Identify any potential for risks to participants' privacy.
- State any potential financial losses that could occur as a result of participation in the research and whether participants be reimbursed. Include how and when this will happen.
- Describe any methods of deception used in the research. Provide justification for the use of deception as well as a detailed debriefing procedure.

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

FOR ALL RISKS:
Researchers must indicate the steps 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 research. 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 K: Confidentiality

- See Chapter 5 in TCPS2.
- Include any circumstances where individual research results could be disclosed to third parties (e.g., participants, parents of child participant, child welfare).
- 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).
- State how confidentiality be maintained in research reports and articles.

Section L: Personal Health Information

- Describe all sources of personal health information (e.g., electronic medical records, paper charts, interviews, identifying surveys, professionals outside the clinical circle of care).
- Attach and reference the data abstraction form used to record the data.
    - ❖ This form is mandatory for research projects that access medical records.
- Requests for personal health information must be done in accordance with Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A.
- Describe the personal health information required and the anticipated sources from which this information will be accessed.
- Make clear who will have access to identifiable and non-identifiable information. Access to identifiable information must be justified. Inform participants who will have access to their data and how they will be used now or in the future.
- Identify any individuals or agencies outside of the Research Team that may have, need, or desire access to the data. Provide details regarding what information will be made accessible, the justification for this access and the risks of allowing this access.

Section M: Data Management and Storage

- Data collected electronically must be stored on a secure, password-protected server or a password protected and encrypted portable device (e.g., thumb drive, laptop). Clearly indicated this in the application.
- If identifiers are required (e.g., medical chart number, name), a separate key should be created to assign identifiable information to a research-specific ID number. This ensures that the data attached to the names are not kept in the same files and if or when data need to be linked back to identifiers, this can be accomplished in a secure manner.
- Describe the short-term storage (i.e., while conducting study) of both electronic data and paper. State where the records will be stored and the security measures in place.

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

- Describe the long-term storage (i.e., post data analysis) of both electronic data and hard copy records. State where the records will be stored, the security measures in place and how long the records will be kept.
- Identify how records will be destroyed in the secure manner.

Section N: Funding Sources

- Indicate which organization administers the funding.
- Include a detailed budget that itemizes all costs associated with each phase of the study.

Section O: Declaration of Conflict of Interest for Principal Investigator

- If the answer is "Yes" to any of the questions in Section N, describe the relationships and the implications of the potential conflict of interest, including the protections into place to protect study participants and/or information accessed.

Section P: Clinical Trial/Medical Devices Studies

- Skip this section if the research is not a Clinical Trial or Medical Device Study.
- Append all supporting documentation to the REB application and list in Section Q.
- Take the time to review all documentation. Ensure that it is consistent across documents.

Section Q: List of Documents for this Application

- List all documents submitted.
- Identify all documents by title, appendix reference, version number and version date.
- Modify the list upon subsequent submissions.

SUPPORTING DOCUMENTS

Submit the following supporting documentation with the initial application as appropriate.

Declaration of Conflict of Interest Supplemental Form

- Each co-investigator is required to sign a Declaration of Conflict of Interest Supplemental Form.
- It is the responsibility of the PI 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-identified information, short term/temporary research assistants are not required to submit a signed form.
- Submit an amendment if the Research Team changes after the initial approval is granted.

Organization Impact Form

- 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 requested. Discuss thoroughly with Manager of each program/department you are requesting support.
- A separate form is required of each individual manager affected by the research.
- If a manager/director is a member of the Research Team, their supervisor must sign an Organization Impact Form indicating approval for their involvement.

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

Research Protocol

- The research protocol is a separate document from the REB application detailed above.
- This is the scientific document details the entire project.

Detailed Budget

- A budget must be provided for all research projects regardless of size.

Information Letter and Informed Consent Form

- All consent forms, information letters and invitations to participate in research must meet TCPS2 requirements for informed consent (see Chapter 3 of the TCPS2).
- Include the contact information for the REB Chair. The suggested language is:

> 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
> St. Joseph's Care Group
> 580 N. Algoma St., Thunder Bay, Ontario P7B 5G4
> phone: 807-346-3697
> Toll Free within Ontario and Manitoba: 1-855-239-807
> email: REB_Chair@tbh.net

Data Collection Tools and Recruitment Materials

- Submit and clearly label all data collection tools.
- For copyrighted or proprietary surveys or other tools, provide proof of permission/purchase.
- Submit all recruitment materials (e.g., emails, scripts, flyers, posters)

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

Part II: REB Review

The SJCG REB meets on the first Monday of each month from September to June. All researchers are required to submit an electronic copy of their REB application (including all supporting documents) to SJCG_REO@tbh.net three weeks before the scheduled REB meeting. The application is screened for clarity and completeness to ensure an efficient review process. Complete applications are directed to the full REB or delegated review pathway.

FULL-BOARD REVIEW

Full-board reviews are conducted at the monthly REB meetings. The PIs must attend the meeting and present a three to five minute overview of their proposed research study. A question and answer period between the REB members and the PI follows. The entire process usually takes 20-30 minutes. Once the questions are complete, the PI leaves the meeting and the REB members begin discussion.

DELEGATED REVIEW

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

DECISION OF THE REB

Whether the REB review is conducted through the delegated review pathway or at a meeting by the full membership, the REB will make one of the following decisions:

1. Approval with no revisions required;
2. Minor clarifications/revisions requested by the REB – once the revised application package is submitted by the PI, review and approval is delegated to the Chair pending acceptable revisions;
3. Major clarifications/revisions are requested – the revised application is reviewed by the full REB and the PI may be asked to attend an additional REB meeting;
4. Not recommended for approval – the PI may request reconsideration (please consult the Standard Operating Procedures and Terms of Reference of the REB for further details on the appeal process);
6. Decision deferred.

Applications requiring revisions/clarifications that are not addressed within the required timeframe will be considered withdrawn from the REB review process.

Once REB approval is granted the PI will be notified by email with copy of the letter of approval.

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

Part III: Continuing Ethics Review

Continuing Ethics Review is part of the monitoring requirements of the REB. After initial REB approval is granted, the REB is responsible to ensure Research Teams are following their submitted protocols. To this end, the REB will grant 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., a Completion Report) or an application which requires REB approval before it is implemented (e.g., Re-Approval Application or Amendment Application). All information reported to the REB will be acknowledged as received.

Before REB approval expires, the Research Team is required to submit a Completion Report or apply for renewal of the REB approval. The PI will be notified prior to the expiry date, reminding of the need to submit either a Completion report or Re-Approval Application.

COMPLETION REPORT

The PI must submit a Completion Report to the Research Ethics Board when the research is completed, discontinued, or terminated.

A research study is considered complete when the researcher no longer requires any involvement with SJCG. This decision is made by the PI and may vary by methodology. For example, for multi-site studies, the PI may choose to close the research study when local recruitment, intervention and follow-up are complete at the local site, even though other sites might still be active.

If there is 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 their thesis has been examined and approved by their academic institution.

RE-APPROVAL APPLICATION

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 PI must submit a Re-Approval Application before the REB expiry date.

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

The Re-Approval Application outlines the status and progress of the project. 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. This is

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

consistent with the REB's responsibilities around monitoring ongoing protocols that have received ethics approval.

Re-approval Applications are 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 SJCG_REO@tbh.net. Failure to apply for REB Re-Approval will result in suspension or termination of REB approval.

AMENDMENT APPLICATION

Researchers must obtain the approval of the REB before amending an approved research project and any of the related research documents. Examples 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,
- PI or Research Team members,
- Extent and duration of the research,
- Recruitment methods or number of participants.

Please note: 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 PI must promptly report, in writing to the REB, the required amendment, as well as a deviation report explaining the reason for the immediate change.

Significant changes to the approved research project/protocol may constitute a new application. Consider if there is a change to the research question, recruitment, and/or risk to participants. Please consult SJCG_REO@tbh.net

Amendment Applications are reviewed by delegated or full-board review, as determined by the REB Chair. Submit an electronic copy of the REB Amendment Application including all supporting documents to SJCG_REO@tbh.net.

Clearly indicate all amendments/changes in all documents. Submit a tracked changes and clean version of each document that has changed. Ensure version dates are incremented appropriately.

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net

SERIOUS ADVERSE EVENT REPORT

Serious adverse events (SAEs) are all adverse events that are both serious and unexpected, or all unanticipated medical device SAEs that occur and that are related or possibly related to the study drug or treatment. Report SAEs to the REB promptly and include the following details:

- The status of the study and summary of participants enrolled.
- A detailed description of the event including an assessment as to whether the event reaction was mild, moderate or severe.
- An opinion expressed by the PI that the event is both serious and unexpected and a justification of that opinion.
- An opinion expressed by the PI 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 PI 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 research team response to the event and the participant outcome.

PROTOCOL DEVIATION/VIOLATION REPORT

A protocol deviation 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. The REB may request further information.

Protocol deviations/violations must address the following points:

- Date of the deviation,
- Date the PI was made aware of deviation/violation,
- Date Sponsor notified, if applicable,
- Brief description of the deviation/violation,
- Indication of the impact on participant safety,
- Corrective action taken resolve the issue.

St. Joseph's Hospital
Corporate Office
35 Algoma St. N.
Thunder Bay, ON P7B 5G7
(807) 343-2431
sjcg.net