



St. Joseph's Health Centre (SJHC)

HUMAN SUBJECTS RESEARCH APPLICATION FORM GUIDELINES

Acknowledgement: We would like to thank the Toronto Academic Health Sciences Council (TAHSC) for the permission to use their document and to modify it to fit the needs of St. Joseph's Health Centre.

N.B.: Research projects requiring REB review are those that intend to generate new knowledge and/or techniques that are intended for external dissemination. Activities or projects that are related to practice measurement, quality improvement and other organized data collection efforts that do not impose any added burden to patients or other potential subject groups do not necessarily require REB review.

All research projects involving staff (including staff acting as investigators outside the Institution), students (i.e., research within the institution or using institutional resources), or patients must obtain ethical approval from the Research Ethics Board (REB) before research can begin. The REB is responsible, on behalf of the institution, for ensuring that **all** research involving human subjects under the auspices of its institution meets current ethical standards. Heads of departments/divisions/programs are responsible for ensuring that all such research is submitted for ethics review.

Proposals are reviewed by the full board, and for most chart review applications, in an expedited manner (reviewed by Chair or designated representative as opposed to the Board). Submissions are reviewed in the order of their arrival at the REB office.

If you are submitting TAHSC Applications elsewhere, please recall that our application form is slightly different.

If you did not obtain this form from the website or the REB Office, please ensure you are using the most updated form (go to www.stjoe.on.ca > About Us > Research and Research Ethics Board). All forms must be **typed**. **All signatures are required before your application may be processed.**

Please see the Consent Form Guidelines & Sample Consent Form on the website to ensure requirements are met.



After REB approval, minor changes to the protocol and any changes to the Informed Consent Form must be submitted as an **amendment** and reviewed by the REB. Amendments may be submitted in the form of a letter with all information related to the change.

Please submit 7 copies (including required signed originals) of the following documents that are applicable to your study.

- **Application Form (1 signed original)** – including any study materials given or seen by subjects (e.g. information letters, advertisements, consent form)
- **Study Budget & Impact Form- Appendix 1 (1 signed original)** - should provide the details of study expenses and departmental signatures
- **Consent Form** - should be in it's final form, including SJHC letterhead
- **Study Protocol** (including data collection forms)
- **Investigator's Brochure (2 copies only)** – from pharmaceutical companies

* Submissions for REB review should be sent to:

Thereza Dos Santos, REB Coordinator
St. Joseph's Health Centre, Rm 7S712
30 The Queensway
Toronto, ON, M6R 1B5
Tel: (416) 530-6486 (X4193)
Fax (416) 530-6054
santost@stjoe.on.ca

If this is a sponsored study, please note that there are **REB fees** associated with the REB review process. Please contact the REB coordinator for an invoice guide.

THE HUMAN SUBJECT RESEARCH APPLICATION FORM - INSTRUCTIONS

If this is a multi-centre study, you will likely need to submit a separate REB application for each site at the site's REB office. Please keep references to the protocol to a minimum and be very specific when references are made so that the information is clear to the reviewer. Your responses should be written in lay language and understandable to those outside your area of expertise. Your consent form should be at a grade 8 level.

The following are further explanatory notes regarding some items on the application form. The numbering corresponds to the items on the application form.



SECTION I: GENERAL INFORMATION

1. FULL STUDY TITLE

Include the FULL title as it appears on the protocol.

4. INVESTIGATORS

- 4.A.** The Principal Investigator (PI) is the responsible leader of the research team and must be clearly designated for each site. Usually there is one PI per protocol. For investigators responsible for a study at a particular site (in multi-centre trials), the local investigator may complete the Local Study Lead section.

For “clinical studies” as defined by Health Canada (i.e. involving an investigational drug or medical device), the Principal Investigator/Local Study Lead must be a Qualified Investigator (a physician or, where applicable a dentist, and a member in good standing of a professional medical or dental association).

7. MATERIAL TRANSFER AGREEMENT

This refers to an agreement for the transfer of biological materials (e.g., tissues, cell lines) from the institution to another institution or other entity. The agreement usually originates from the institution sending out the materials. If biological material is to be transferred from this institution to another institution or entity, please indicate what arrangements are in place to ensure that appropriate consent has been obtained for this use and that donor confidentiality will be protected.

8. INVESTIGATIONAL DRUGS OR DEVICES

Investigational drugs or devices include all drugs or medical devices requiring Health Canada approval, as well as all approved drugs or medical devices being tested for a new indication (e.g., age group, disease entity), dosage or method of administration.

Studies involving investigational drugs or medical devices must apply for authorization for research use from Health Canada. For investigational drug trials a “Clinical Trial Application” form must be submitted to Health Canada. Please provide a copy of the authorization or “No objection” letter from Health Canada as soon as it becomes available. In general, final REB approval for the study will not be granted until the no objection letter has been provided. For certain medical device studies (class III and IV devices), however, Health Canada requires REB approval first.

If results are to be submitted for US Food and Drug Administration (FDA) approval, please provide the IND number.

SECTION II: STUDY SUMMARY

9. ABSTRACT, 10. RATIONALE AND HYPOTHESIS/RESEARCH QUESTION

Please ensure that the abstract, rationale and hypothesis/research question are written in lay language. Please strive to make your submission understandable to



those outside your area of expertise. For studies involving investigational new drugs or devices or use of an approved product for a new indication, please provide justification to support the investigational use in this project.

11. STUDY DESIGN

11.A. Design/methodology

Describe the basic study design and method. If this is a randomized trial, explain how subjects will be assigned to each group. If this is a pilot study, indicate briefly how the data will be used to develop a full follow up study.

11. B. Primary outcome measures

Please list the primary endpoints, or key data items that are required to answer the study question.

11. C. Criteria for Early Withdrawal

Please indicate what endpoints or stopping rules will serve as triggers/thresholds for early withdrawal for subject safety (e.g. regarding treatment failure/adverse events), such as blood pressure levels, laboratory values, disease status assessments, etc.

11. E. Deception or Lack of Disclosure

The Tri-Council Policy Statement (TCPS) permits the REB to approve a consent procedure which does not include, or which alters some information about the study only when the deception or lack of disclosure poses no more than minimal risk, the research could not practicably be carried out in another way, the subjects are provided with full disclosure at a later date (where possible) and the deception or lack of disclosure does not involve a therapeutic intervention. Deception or lack of disclosure is used most often in social science or psychology research, where full disclosure would likely affect the responses of the subjects and thus invalidate the research.

11. F. Study Restrictions

List in this section any restrictions on medications/treatments or lifestyle, such as diet, exercise, smoking, exposure to sun, driving, etc. Specify the duration of restrictions and the reasons the restrictions are necessary.

12. SUBJECTS/CONTROLS

Selection of subjects must be equitable. Please include the rationale for the choice of control group if applicable. If a vulnerable population is used (e.g., children, incompetent adults), please include justification for this choice (e.g., has the research question been previously addressed in a less vulnerable population?). Justification is not required at institutions where these vulnerable populations are the primary patient population (e.g., paediatric or geriatric centres). If a group (e.g, women of childbearing potential, the elderly) is excluded from a study involving a general patient population, this should be justified.



12. D. Sample Size Justification

For quantitative studies, include sample size calculations and source for standard deviation. For qualitative studies indicate approximate sample size and rationale. You may refer to the protocol for this information.

12. E. Checklist of Study Subjects

The purpose of this checklist is to quickly flag for the REB any study populations that may raise special concerns. "Subjects unable to communicate" refers to patients who are mentally competent, but who, because of certain conditions (e.g. stroke), are unable to communicate or have difficulty communicating their intentions. "Involuntary patients" refers to persons who are hospitalized without their consent for the treatment of mental illness. "Borderline incompetent" refers to patients who fall in the grey area between competent and incompetent, and whose capacity may fluctuate over time.

13. STUDY INTERVENTIONS or PROCEDURES INVOLVING HUMAN SUBJECTS

13.A. Changes/additions to Standard of Care

Describe any procedures involving interaction with human subjects. This includes procedures performed for the study in addition to standard of care - clearly outline procedures performed purely for research purposes (e.g. extra blood samples, evaluations, telephone surveys, questionnaires). Please include all patient contact and be as specific as you can. Please attach a copy of all instruments (i.e. questionnaires, interview scripts, rating scales) to be used.

13. B. Usual Standard of Care

This section must specify what is standard of care specifically as it relates to the study interventions, and how participation in the study will alter standard care if applicable (i.e. what would happen if the study were not being done).

14. DATA ANALYSIS

Explain what methods will be used to analyse the study data. You may refer to the protocol.

SECTION III: ETHICAL ISSUES

15. RECRUITMENT AND CONSENT

15. A. Identification of potential subjects.

Please specify how potential subjects will be identified and by whom. Respect for patient privacy requires that patient records be reviewed by persons who have access to patient information as part of their normal professional duties, or their delegates (e.g. study coordinator working on behalf of investigator who has access).

Health Records include but are not limited to: slides (e.g. pathology), radiology films/reports, surgical lists and databases.



The REB must review all study-related materials that will be given to subjects, including advertisements or letters regarding recruitment. Please note that no specific dollar amount of payments to subjects should be listed in the advertisement.

15. B,C. and D. Initial contact with subjects and consent process.

Indicate who will make the initial contact and who will conduct the informed consent discussion. Issues to consider include whether the contact person is known to the subject/authorized third party, has access to patient information as part of their normal professional duties, or is able to assess capacity to consent. Consideration will be given as to whether the person approaching the prospective subjects has any relationship with them that might make them feel pressured or coerced into participating (e.g. is this person their physician or employer or teacher?).

15. E. Special situations for informed consent.

If enrollment of persons who may have problems with the standard process of informed consent is expected, please indicate what special procedures will be followed to protect subject interests and promote subject autonomy. For subjects whose capacity may change during the research period, please describe what plans are in place to regularly assess capacity. Please also refer to the separate informed consent instructions for more detail regarding informed consent requirements.

16. RISK/BENEFIT ESTIMATES

It is the expectation of the Tri-Council Policy Statement that proposed research will be designed to benefit participants where possible. Studies that involve significant risk without a balance of significant benefit may be inappropriate.

6. B. Potential Harms

Please describe all risks associated with the study interventions and the likelihood of these events occurring. If there are no known risks, check the appropriate box.

16. B.ii. There may be occasions where a number of different research projects focus on a particular patient population, and individual patients may be eligible for more than one study. Enrollment in multiple studies raises concerns whether the studies are ongoing simultaneously or in succession. In this situation, investigators must explain what extra precautions are in place to ensure patient safety and welfare.

16. B.iii. If participation in the study may affect a patient's options for future care (e.g., making them ineligible for other standard therapies or the development of antibodies which might prevent future treatment with the investigational agent), please explain what options will and will not be available.



17. CONFIDENTIALITY

Study data and samples must be kept secure from theft, interception, unauthorized reading and copying. Investigators must state their means of protecting study data or samples from such violation, for instance by coding systems and/or security systems.

17. B. Access to existing records for research purposes may involve a variety of data stewards or custodians, including the hospital, individual clinician's offices, registries, and government departments. These different custodians may have different policies regarding access to records. Please indicate in this section what is the source of any records that will be used for this study, what are the requirements for access, and whether the requirements have been met.

17. C. x Please indicate in this section what provisions have been made to protect confidentiality of study records during long-term storage (e.g. after the study has been completed). Please note that Health Canada requires that study records for investigational drug or device trials must be stored for 25 years, to be available for possible inspection.

18. PAYMENTS TO SUBJECTS

Subjects should not be expected to incur expenses as a direct result of participation in a research study; reimbursement for out-of-pocket expenses (e.g. travel) is encouraged. Payment should not be used in such a way that it could be construed as an undue inducement to participate (e.g. unreasonable amount, payment tied to completion of study). Reimbursement should be for expenses, time or inconvenience, but should not be used to encourage subjects to accept increased risk. If reimbursement for time is proposed, please explain. It is expected that any payments will be pro-rated.

19. MONITORING

Monitoring refers to oversight activities performed by groups other than the REB, such as the study sponsor (e.g. site visits to check for GCP compliance, interim analysis of results by a data and safety monitoring board or steering committee).

At a minimum, annual renewal is required. Annual renewal will be assumed unless more frequent review is specifically requested.

20. CONTINUING REVIEW

Continuing review refers to the ongoing oversight by the REB or the institution after the initial approval of a research study. Continuing review includes review of serious adverse event (SAE) reports, annual (or more frequent) review and re-approval of the study, and other activities deemed appropriate for the continued protection of research subjects. The Tri-Council Policy Statement (TCPS) requires investigators to suggest the appropriate level of continuing review. Please note that the final decision regarding the appropriate level rests with the REB.



21. FINANCIAL INTERESTS

The term "conflict of interest" refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, a researcher's professional judgments. The bias such conflicts could conceivably impart may inappropriately affect the goals of research.

"Apparent" or "perceived" conflicts of interest refer to situations which appear to present a conflict to an outside observer, although they may not give rise to an actual conflict. The mere appearance of a conflict may be as serious and potentially damaging as an actual conflict.

"Immediate family" includes an investigator's spouse and dependent children (including stepchildren).

22. PUBLICATION/DISSEMINATION OF RESULTS

Since the contribution to knowledge is one of the primary purposes of medical research, researchers are encouraged to publish the results of their research. Furthermore, where possible, researchers are strongly encouraged to share the study results of the research with the subjects who made the research possible, and/or with the relevant patient communities.

SECTION IV: FUNDING and CONTRACTS

23. FUNDING

If no funding is involved for this study, describe how the research will be supported.

24. BUDGET

Please include a detailed, itemized budget listing expenses for the study. The REB will consider aspects such as investigator payments, reimbursement for subjects, and whether there are adequate funds to cover study treatments and procedures.

25. CONTRACT

If no contract is involved, DO NOT complete the remainder of this question.

*** Contracts should be sent for review to:**
(Please note contract review may take time).

Joan Sinclair, Head of Research
30 The Queensway, Rm 7S705
Toronto, ON, M6R 1B5
Tel: (416) 530-6486 (X4200)
Fax: (416) 530-6502
Email: sinclair@stjoe.on.ca



25.A. Liability

Please indicate who will cover the costs of treatment not covered by the provincial health plan in case of injury directly resulting from participation in a research study (i.e. sponsor, institution, other).

26. SIGNATURES

Original signatures must be received in order that REB applications be processed.

26.B. Division/Department/Program Approval

The application forms for all projects submitted for review will require the signature of the Division/Department Head/Program Director where the research is to be conducted. The signature indicates agreement that the Division/Department/Program supports the project. When the Division/Department Head/Program Director is the investigator, the signature of an individual one level above the investigator is required.

26.C. PI Agreement

The signature of the Principal Investigator is required.

APPENDIX 1

Indicate in the table where this application is being submitted, including sites where an application has been or will be submitted, and REB review status.

APPENDIX 2: Study Impact & Budget Form

If your study has an impact on any department, this form must be completed and signed by appropriate heads of department. Please include any costs or reimbursements associated with the study.