

REB Study #: _____ (office use only)



St. Joseph's Health Centre (SJHC) HUMAN SUBJECTS RESEARCH APPLICATION FORM

All sections of this application must be completed before it will be considered for REB review. Please type all responses into this application form. Application will not be processed unless required signatures are received and a budget is submitted (if applicable). Please keep references to the protocol to a minimum and be very specific when references are made. Please ensure you are using the most current version of this form, as found on www.stjoe.on.ca > Education > Research > Research Ethics Board.

SECTION I: GENERAL INFORMATION

1. **FULL STUDY TITLE:**

2. **SPONSOR:** Not Applicable

A. **SPONSOR PROTOCOL NUMBER (if applicable):**

B. **SOURCE OF FUNDING (if applicable):**

3. **STUDY PERIOD:**

Expected Start Date:

Total Study Duration:

4. **INVESTIGATORS:**

A. **PRINCIPAL INVESTIGATOR:**

Title:	Name:		
Telephone:	Pager:	FAX:	Email:
Institution Name:			

Dept/Division:	Program:
Mailing Address:	

LOCAL STUDY LEAD (SJHC) – if different from PI above:

Name:			
Telephone:	Pager:	FAX:	Email:
Dept/Division:		Program:	
Mailing Address:			

B. CO-INVESTIGATOR(S):

Not Applicable

Name	Institution/Program/Dept.	Contact Telephone Numbers & email addresses

C. STUDY COORDINATOR OR RESEARCH ADMINISTRATIVE CONTACT FOR THIS APPLICATION (if not the PI):

Not Applicable

Name:			
Telephone:	Pager:	FAX:	Email:
Institution name:			
Mailing Address:			

Please indicate to whom correspondence should be sent: PI Administrative Contact

5. FACULTY SUPERVISOR (for student/fellow/resident research studies):

Not Applicable

Name:			
Telephone:	Pager:	FAX:	Email:
Institution Name:			
Dept/Division:		Program:	

Mailing Address:

6. PROJECT CLASSIFICATION (more than one may be checked)

Research: YES NO

Quality Improvement: YES NO

Student Research: Post-Doctoral PhD Master's Undergraduate Resident/Fellow

Chart Review: YES NO

Other (Please specify):

7. MATERIAL TRANSFER AGREEMENT

Is there a material transfer agreement (MTA) involving human material for this study?

YES NO

If YES, please attach a copy.

8. INVESTIGATIONAL DRUGS OR DEVICES

Does this study involve the use of any investigational new drugs or medical devices or the use of an approved drug for a new indication (e.g., new age-group, disease entity)?

YES NO

If YES:

Is "No objection" or authorization letter from Health Canada attached?

YES NO

If no, has Clinical Trial Application (CTA) been submitted to Health Canada?

YES NO

If "No objection" letter or authorization is pending, please forward approval letter to the REB office as soon as it is available.

Please provide FDA IND number (drug studies) or PMA number (device studies):

Not Applicable Pending (if pending, please forward to the REB office when available)

SECTION II: STUDY SUMMARY

NOTE: THIS IS NOT A SUBSTITUTE FOR THE FULL PROPOSAL.

9. ABSTRACT

Must be a summary of study suitable for lay audience; maximum 100 words.

10. RATIONALE AND HYPOTHESIS/RESEARCH QUESTION

Include the significance of the study.

11. STUDY DESIGN

(Many of these questions apply to clinical research studies. If any of the items are not applicable to your study, please indicate N/A):

A. Describe design/methodology.

(Please indicate Phase where appropriate)

B. What are the primary outcome measures?

Not applicable

C. List any criteria for premature withdrawal of a subject from the study for safety concerns.

Not applicable

D. Is a placebo used in this study?

YES NO

If YES, how is this justified (e.g., no alternative standard treatment available)? Include any provisions in place to reduce risks to subjects assigned to placebo (e.g., increased monitoring, rescue medication).

E. Does the study involve deception or intentional lack of disclosure?

YES NO

If YES, explain justification and how subjects will be debriefed.

F. Will the subject be withdrawn from or denied usual therapy for any condition in order to participate in the study or be subject to other restrictions?

YES NO

If YES, explain.

11G. PROTOCOL COMPLIANCE

How will the study protocol/plan be disseminated to those involved in the study (ie. co-investigators, study coordinators, research assistants, etc.) to ensure protocol compliance?

12. SUBJECTS/CONTROLS

A. How will subjects be chosen (main inclusion/exclusion criteria)?

If applicable, how was the proposed control group selected?

- i. What is the age range of eligible subjects?:
- ii. Before patients are approached, Meditech should be checked to see if they have requested to not be asked to participate in research studies. Will this be done? If not, please explain.

**B. Number to be enrolled at this institution:
Approximate total study enrolment (if known):**

C. Estimate size of eligible population from SJHC during recruitment (or other relevant timeframe):

D. Is sample size justified in the protocol?

YES NO

If NO, please provide sample size justification.

E. Will this research involve any of the following?:

- | | |
|---|---|
| <input type="checkbox"/> genetic research | <input type="checkbox"/> women of child-bearing potential |
| <input type="checkbox"/> tissue samples | <input type="checkbox"/> pregnant women |
| <input type="checkbox"/> tissue samples – to be used in separate or future research other than the current proposal | |
| <input type="checkbox"/> healthy volunteers | <input type="checkbox"/> infants/children |
| <input type="checkbox"/> students | <input type="checkbox"/> fetal tissue or placenta |
| <input type="checkbox"/> staff | <input type="checkbox"/> incompetent subjects |
| <input type="checkbox"/> prisoners | <input type="checkbox"/> borderline incompetent subjects |
| <input type="checkbox"/> involuntary subjects | <input type="checkbox"/> subjects unable to communicate |
| <input type="checkbox"/> emergency patients | <input type="checkbox"/> seniors |
| <input type="checkbox"/> none of the above | |

13. STUDY INTERVENTIONS or PROCEDURES INVOLVING HUMAN SUBJECTS

Not Applicable (e.g. observational studies). If not applicable, go directly to 14. DATA ANALYSIS.

A. Changes/additions to usual standard of care.

Indicate what procedures are to be carried out in the study, that are NOT considered part of the diagnostic, therapeutic "routine" or standard care of the subject or how standard care is altered. Attach a copy of all instruments (i.e., questionnaires, rating scales, etc.)

B. Usual standard of care.

Document what is the usual standard of care at this institution for this population, as it relates to the study procedures discussed above.

Not Applicable

C. What are the incremental risks associated with the study as compared to usual standard of care?

Do not refer to other sections of this form.

D. Subject Time Commitments.

Indicate time commitment (length, number, and frequency of test sessions) or duration of visits.

14. DATA ANALYSIS

Briefly explain what methods will be used to analyze study data. You may refer to protocol.

SECTION III: ETHICAL ISSUES

15. RECRUITMENT AND CONSENT

Note: All study-related materials that will be given to subjects (e.g. information letters, advertising, consent forms) must be included with your submission for REB review. Please refer to the Consent Form Guidelines for detailed instructions.

A. How will potential subjects be identified and/or referred?

- Healthcare professional
- Permanent Health Record/Clinical Chart
- Other Existing Database (specify):
- Advertisements, including web based recruitment tools (attach a copy if applicable)
- Other (specify):

i. Please indicate who will identify potential subjects.

B. Explain who will make initial contact with subjects or authorized third party and how (e.g. in person, phone, letter, e-mail/web site). Please attach a copy of the script or any written materials if applicable.

C. Describe the consent process (e.g., Will consent be written, oral, telephone (include script), and who will obtain consent). If the study population requires special consent considerations (e.g. child, incompetent adult, unable to communicate) you may refer to item E. of this section.

D. Is there a relationship between the subjects and:

Person obtaining consent YES NO

Investigator YES NO

If YES, explain the nature of the relationship (e.g., physician, employer) and what steps will be taken to minimize a potential perception of coercion.

E. Will this research involve (check any that apply):

Children?

Incompetent (or borderline incompetent) adults?

Individuals who are temporarily unable to provide an informed consent (e.g. unconscious, emergency)?

Competent individuals who have difficulties with or are unable to communicate (e.g., stroke, locked-in)?

Individuals who may require translation?

Individuals who are illiterate?

None of the above

If any of the above populations are involved, attach a summary explaining how capacity will be determined (if applicable), how the subject's interests will be protected, and how surrogate consent and assent (if applicable) will be obtained. Where inability to provide an informed consent is expected to be temporary, describe what plans are in place to regularly assess capacity and to obtain consent if the individual later becomes capable of providing consent.

For subjects who have limited skills in English or are illiterate, attach a summary explaining what special procedures are in place (e.g., translated forms, translator, impartial witness).

16. RISK/BENEFIT ESTIMATES

A. Potential Benefits to Subjects

List anticipated benefits if any. No direct benefits anticipated.

B. Potential Harms (Injury, Discomforts and Inconveniences) to Subjects (including psychological factors):

i. Document the risks to subjects involved in this research. NO known risks

a. For studies involving placebo, washout, or withholding of treatment, indicate risks related to absence of treatment.

Not Applicable

b. Include a summary of the data regarding reproductive risks such as teratogenicity or embryotoxicity of the study drug, any risk with breastfeeding, or risk to men regarding conception.

Not Applicable

ii. Is enrollment in multiple studies likely to be an issue in this subject population?

YES NO

If YES, please indicate how this will be addressed.

iii. Does participation in this study affect alternatives for future care?

YES NO

If YES, please explain.

iv. Might potentially hazardous duties be required of research personnel?

YES NO

If YES, please describe.

17. CONFIDENTIALITY

A. What subject identifiers will be used on data collection forms (e.g., names, initials, DOB)?

If personal identifiers such as names, OHIP, or Hospital ID numbers will be used, please justify.

B. If existing records (e.g., health records, other records/databases) are to be used, describe how permission was obtained.

Not Applicable

C. Protection of data:

i. Who will conduct data collection? Please be specific.

- Investigators/delegate
 Outside Agency. Name:
 Other (Please specify):

ii. Indicate how data will be stored:

- Computerized files
 Audio recordings
 Hard copy
 Video tape
 Other (Please specify):

iii. Where will hard copy data be stored (ex. filing cabinets, specify department name, room number, address, etc.) and who will have access to this area?

Not Applicable

iv. If storing study data in computerized files please specify where the database is located and who has access.

v. Not Applicable

Is the computer password protected?

vi. Will data be transferred electronically?

YES NO

If YES, by what medium? (e.g. e-mail, diskette or CD, memory stick)

vii. Describe security measures in place to protect confidentiality.

viii. What will happen to the data at the end of the study (e.g., anonymized, destroyed)?

ix. Who will have access to data in the future?

x. How will confidentiality be maintained during long term storage of study records?
 Not Applicable

18. PAYMENTS TO SUBJECTS

Indicate what payments (or equivalent, e.g. gift certificates), if any, will be provided to subjects:

Not Applicable

Reimbursement for expenses incurred as a result of research. Amount: \$
Specify (e.g., travel, meals)

Gifts for participation Value: \$

Compensation for time Amount: \$
If compensation for time will be provided, please justify:

19. MONITORING

A. Is there a steering committee?

YES NO Not Applicable

B. Is there a plan for monitoring of the study (e.g., sponsor-initiated site visits)?

YES NO Not Applicable

If YES, describe.

C. Is an interim analysis planned?

YES NO

If YES, describe briefly.

D. Is there a data safety monitoring board (DSMB).

YES NO

If YES, is it independent of the sponsor?

YES NO

20. CONTINUING REVIEW

Indicate the suggested level of continuing review required for this study (check all that apply). At a minimum, annual renewal is required.

annual renewal

- more frequent renewal; indicate interval:
- other (e.g. audit, observation of consent process, interview with participants);
Please specify:

21. FINANCIAL INTERESTS

Does the principal investigator or any co-investigators involved in this research study or any member of their immediate family:

- Function as an advisor, employee, officer, director or consultant for the study sponsor?
- Have direct or indirect financial interest in the drug, device or technology employed (including patents or stocks) in this research study?
- Receive an honorarium or other personal benefits from the sponsor (apart from fees for service)?
- None of the Above**

If any of the above conflicts apply, append a letter detailing these activities to the Chair of the REB. Please disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project.

22. PUBLICATION /DISSEMINATION OF RESULTS

A. Is there an independent steering committee regarding publication?

- YES NO N/A

B. How will the results be communicated to subjects and other stakeholders (e.g. advocacy groups, scientific community)?

Check all that apply:

- Individual debriefing at end of test session
- Publication (e.g., journal article, presentation)
- Group debriefing
- No plan
- Letter of appreciation at end of study
- Other (specify):

SECTION IV: FUNDING and CONTRACTS

23. FUNDING

No Funding Required (explain)

Funding Required
Source:

- Obtained Applied for (expected date of decision):

Do the funds presently available or applied for cover all requirements to conduct the project?

- YES NO

If NO, please explain how the shortfall will be made up:

24. BUDGET

Attach an itemized study budget form (see Appendix 2).

25. CONTRACT

No Contract Involved
If no contract involved, do not complete the remainder of item 25.

Contract Involved
Name of sponsor/agency:

Has the contract/research agreement been submitted for review and signing by St. Joseph's Health Centre's Administration?

YES NO PENDING

A. Liability

i. Is there liability insurance?
 YES NO

ii. If the subject suffers an injury as a result of participation in the study, who will cover reasonable out-of-pocket expenses to ensure that immediate medical care is provided?
 Sponsor Institution
 Other (Please specify):

26. SIGNATURES:

A. FACULTY SUPERVISOR (for student/fellow/resident research studies):

Not Applicable

Faculty Supervisor (Print)

Faculty Supervisor (Signature)

Date

PLEASE NOTE:

ALL REQUIRED SIGNATURES MUST BE RECEIVED IN ORDER TO BE PLACED ON THE REB AGENDA AND PROCESS YOUR APPLICATION FORM.

- A. LOCAL STUDY LEAD AGREEMENT** - I will oversee all study-related activities that occur at St. Joseph's Health Centre. I am responsible for designating a replacement for myself should I be unavailable for an extended period of time (if there is to be patient involvement during that time). If I am will be unavailable, I will inform the REB Coordinator (santost@stjoe.on.ca) and the clinical directors that have approved this study below.

Name of Local Study Lead
(Print)

Signature of Local Study Lead

Date

B. DIVISION/DEPARTMENT/PROGRAM APPROVAL

I am aware of this proposal and support its submission for ethics review. I have reviewed any agreements associated or have arranged to have study contracts, associated with the conduct of this study at SJHC. I consider it to be feasible and appropriate.

Clinical Approval:

Name (Print)

Div./Dept./Program (Print)

Signature

Date

Administrative Approval, if applicable:

Name (Print)

Div./Dept./Program (Print)

Signature

Date

- C. PRINCIPAL INVESTIGATOR AGREEMENT** - I assume full responsibility for the scientific and ethical conduct of the study as described in this REB application and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects and any other relevant regulations or guidelines. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified and experienced or will undergo appropriate training to fulfill their role in this project.

Name of Principal
Investigator (Print)

Signature of Principal Investigator

Date

APPENDIX 1

Application submitted to (check all that apply):		*Ethics Review and Approval Status (check all that apply and indicate date where applicable):			
		Application To Be Submitted	Applied, Review Pending	Reviewed	Approved
<input type="checkbox"/>	St. Joseph's Health Centre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Baycrest Centre for Geriatric Care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Bloorview MacMillan Children's Centre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Centre for Addiction and Mental Health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Hospital for Sick Children	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Mount Sinai Hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	St. Michael's Hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Sunnybrook and Women's College Health Sciences Centre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Toronto Rehabilitation Institute	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	University Health Network	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

***Please include all relevant correspondence related to ethics review (i.e., REB review letter, replies, approval form). If applying to more than one site, please indicate which will be the primary site for ethics review:**

REB File #: _____ Study: _____

APPENDIX 2

Please complete the Study Impact & Budget Form indicating the impact associated with this Protocol by Department. If “yes” is checked, a signature of the individual authorized to sign for the department must be obtained; this signature indicates to the REB that the signee has agreed upon the specific costs associated with their department.

STUDY IMPACT & BUDGET FORM

Note: Please ensure you include the date with your signature.

	IMPACT?		COST		TOTAL COST	DEPARTMENTAL APPROVAL	
	Yes	No	Per Visit	Total for study		PRINT NAME	<u>SIGNATURE & DATE</u>
Staffing: <i>Protocol Management</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Data Management</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Nursing</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Data Entry Clerk</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Other:</i>	<input type="checkbox"/>	<input type="checkbox"/>					
Pharmacy:	<input type="checkbox"/>	<input type="checkbox"/>					
Laboratory: <i>Haematology</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Biochemistry</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Blood Gases</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Pregnancy Testing</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Pharmacokinetics</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Shipping & Pkg.</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Other:</i>	<input type="checkbox"/>	<input type="checkbox"/>					
Diagnostic Imaging:	<input type="checkbox"/>	<input type="checkbox"/>					

Cardiac Monitoring:							
<i>ECG</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Echo/gram</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Scans</i>	<input type="checkbox"/>	<input type="checkbox"/>					
<i>Other:</i>	<input type="checkbox"/>	<input type="checkbox"/>					
Patient Records:	<input type="checkbox"/>	<input type="checkbox"/>					
	<input type="checkbox"/>	<input type="checkbox"/>					
	<input type="checkbox"/>	<input type="checkbox"/>					
	<input type="checkbox"/>	<input type="checkbox"/>					
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Equipment: <i>Space</i>							
<i>Furniture</i>							
<i>Materials & Supplies</i>							
<i>Computer support</i>							
<i>Other:</i>							
Travel/Presentation:							
Photography:							
Professional Services:							
Miscellaneous:							
TOTAL							