# Scarborough Center For Healthy Communities Research Ethics Board Research Application

**Adapted from Toronto Academic Health Sciences Council**
**Human Subjects Research Application**

**All sections of this application MUST be completed before it will be considered for REB review. If not applicable, indicate "N/A". Unless indicated, the Research Ethics Board Application questions must be completed in the space provided. A complete application must be submitted to each site where this research will take place. A separate protocol must also be included with the application.**

## SECTION I: GENERAL INFORMATION

**1. PRINCIPLE INVESTIGATOR NAME:**

| Title: | Last Name: | First Name: |
|---|---|---|

**2. FULL STUDY TITLE:**

**3. SOURCE OF FUNDING:**

Sponsor Name:
Sponsor Protocol Number (if applicable):
Granting Agency Name:
Internal Funding:
Other:

☐ Funding obtained ☐ Funding applied for (expected date of decision):

☐ **No funding required (explain):**

**4. INVESTIGATORS:**

**A. PRINCIPAL INVESTIGATOR**

| Title: | Last Name: | First Name: |
|---|---|---|
| Dept/Div: | | Program: |
| Telephone: | Pager: | Fax: |
| Street Address: Line 1 | | |
| Line 2 | | |

| City: | Province: | Postal Code: | Email: |
|---|---|---|---|

**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.

_____ _____

Signature of Principal Investigator Date

**B. CO-INVESTIGATOR(S):**

| **Last Name** | **First Name** | **Institution** | **Dept/Div/Program** | **Signature** |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

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

| Title: | Last Name: | First Name: | |
|---|---|---|---|
| Telephone: | Pager: | Fax: | |
| Street Address:<br>Line 1 | | | |
| Line 2 | | | |
| City: | Province: | Postal Code: | Email: |

**Indicate to whom correspondence should be mailed: PI Administrative Contact**

**D. ON STAFF INVESTIGATOR (for studies initiated outside of this institution)*:**
**Not Applicable** ☐

| Title: | Last Name: | First Name: | |
|---|---|---|---|
| Dept/Div: | | Program: | |
| Telephone: | Pager: | Fax: | |
| Street Address:<br>Line 1 | | | |

| | | | |
|---|---|---|---|
| Line 2 | | | |
| City: | Province: | Postal Code: | Email: |
| Signature: | | Date: | |

***For the purposes of the study at this institution, the PI should be a staff member of the institution to be responsible for the conduct of the study.***

**5. FACULTY SUPERVISOR (for student/fellow/resident research studies):**
**Not Applicable**

| | | | |
|---|---|---|---|
| Title: | Last Name: | First Name: | |
| Dept/Div: | | Program: | |
| Telephone: | Pager: | Fax: | |
| Street Address:<br>Line 1 | | | |
| Line 2 | | | |
| City: | Province: | Postal Code: | Email: |
| Signature: | | Date: | |

## 6. DIVISION/DEPARTMENT/PROGRAM APPROVAL

I am aware of this proposal and support its submission for ethics review. I consider it to be feasible and appropriate. I attest that the principal investigator responsible for this study has the qualifications and expertise to carry out this study in a competent and professional manner.

Name (Print) Div./Dept./Program (Print) Signature Date

## 7. STUDY PERIOD:

Expected Start Date: Total Study Duration:

## 8. INVESTIGATOR CLASSIFICATION

Staff Research: ☐ YES ☐ NO

Student Research: ☐ Post-Doctoral ☐ PhD ☐ Master's ☐ Undergraduate ☐ Resident/Fellow
*Note: Where an investigator is a student/trainee, it is expected that the supervisor will be the Principal Investigator. If the supervisor is not on staff at the research site, check with your institution regarding who may be the PI.*

Other (specify):

## 9. PRIOR ETHICS/SCIENTIFIC/SCHOLARLY REVIEW

| 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 |
| ☐ | Scarbrough Center For Healty Communities | | | | ☐ |
| **Other Institutions in the Toronto Area** | | | | | |
| ☐ | | | | | ☐ |
| ☐ | | | | | ☐ |
| ☐ | | | | | ☐ |
| ☐ | | | | | ☐ |

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

**A. Has this proposal received prior scientific peer review?** YES ☐ NO

If YES, indicate where and attach any relevant reviewer comments.

If NO, refer to institutional instruction page regarding possible review requirements.

**B. Is this protocol associated (e.g. extension, roll over) with a previously approved study at this institution?** YES ☐ NO

If YES, indicate:

Name of Principal Investigator:

REB file number:

## 10. MATERIAL TRANSFER AGREEMENT

Is there a material transfer agreement (MTA) involving human material for this study? (*This refers to an agreement for transfer of biological materials (e.g., tissues, cell lines) from the institution to another institution or other entity.*) YES ☐ NO If YES, attach a copy.

## 11. INVESTIGATIONAL DRUGS OR DEVICES

**Not Applicable** ☐

**A. Does this study involve any of the following (check all that apply):**

- ☐ Investigational New Drugs
- ☐ Investigational Biologics
- ☐ Investigational Natural Health Products (NHP)
- ☐ Investigational Medical Devices
- ☐ Approved drug for a new indication (e.g., new age-group, disease entity)?

**B. If the study involves any of the above:**

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

If no, has a Clinical Trial Application (CTA) been submitted (or will soon be submitted) to Health Canada? ☐ YES ☐ NO

If pending, provide date of submission: _____

Health Canada "No Objection" file #: _____

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

**C. Provide FDA IND number (drug studies) or PMA number (device studies):**

Not Applicable

Pending (if pending, forward to the REB office when available

# SECTION II: STUDY SUMMARY

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

**12. ABSTRACT**

Must be a summary of study **suitable for lay audience**.
(Max. 100 words.)

**13. RATIONALE AND HYPOTHESIS/RESEARCH QUESTION**

Include the significance of the study.
(Max 1/2 page)

**14. STUDY DESIGN**

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

**A. Describe Design/Methodology.**

Indicate Clinical Trial Phase (I, II, III, IV) where appropriate

(Max 1 page)

**B. What are the primary outcome measures?**
☐ Not applicable
(Max ¼ page)

**C. List any criteria for premature withdrawal of a subject from the study for safety concerns.**
☐ Not applicable
(Max ¼ page)

**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).
(Max ¼ page)

**E. Does the study involve deception or intentional lack of disclosure?** YES NO
If YES, explain justification and how subjects will be debriefed.
(Max ¼ page)

**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.
(Max ¼ page)

**15. SUBJECTS/CONTROLS**

**A. How will subjects be chosen (main inclusion/exclusion criteria)?**
If applicable, how was the proposed control group selected?
(Max ¼ page)

i. What is the age range of eligible subjects?

**B. Number to be enrolled at this institution:** ☐ **Total study enrolment:** ☐

**C. Approximate size of eligible population from institution/practice:**

**D. Is sample size justified in the protocol?** ☐ YES ☐ NO
If NO, provide sample size justification.
(Max ¼ page)

**16. DATA ANALYSIS**
Briefly explain what methods will be used to analyse study data.
You may refer to protocol for this question.
(Max ¼ page)

## SECTION III: ETHICAL ISSUES

**17. RECRUITMENT AND CONSENT**
*Note: Any document to be viewed by the subject (e.g. consent/assent forms, information sheets, recruitment posters/letters) must be included with your submission. Refer to the other materials in this package for more 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. Indicate who will identify potential subjects.
(Max ¼ page)

ii. Explain how enrollment in multiple studies is managed in this patient population at this institution.
Not Applicable
(Max ¼ page)

**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). Attach a copy of the script or any written materials if applicable.**

(Max ¼ page)

**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.*
(Max ¼ page)

i. How much time will be given to subjects to review the information before being asked to give consent?

**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 any of the following? (check any that apply):**

☐ women of child-bearing potential ☐ pregnant women
☐ healthy volunteers ☐ children less than 16 years of age
☐ students
☐ staff
☐ individuals who may require translation or who are illiterate
☐ none of the above

The above list identifies research that may require special consideration, e.g. regarding confidentiality, voluntariness, risk or capacity to consent. If the research will involve any of the above attach a summary explaining how the subject's interests will be protected, how capacity will be determined (if applicable) 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).

## 18. 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

(Max ¾ page)

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
(Max ¼ page)

ii. Does participation in this study affect alternatives for future care? (e.g. development of antibodies that could prohibit future treatment with this or similar compounds) YES ☐ NO
If YES, explain.
(Max ¼ page)

## 19. PAYMENTS TO SUBJECTS

**Indicate what payments, if any, will be provided to subjects:**

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:

## 20. 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:

(Max ¼ page)

**A. Is an interim analysis planned?** ☐ YES ☐ NO
If YES, describe briefly.

**B. Is there a data and safety monitoring board (DSMB).** ☐ YES ☐ NO

If NO, please justify:

If YES, is it independent of the sponsor? ☐ YES ☐ NO

**21. POTENTIAL CONFLICTS OF INTEREST**

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 to the Chair of the REB, detailing these activities and how they will be managed. 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

**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. BUDGET**

Attach an itemized study budget (applies to full board and expedited review studies).

Do the funds presently available or applied for cover all requirements to conduct the project? ☐ YES ☐ NO

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

## 24. CONTRACT/RESEARCH AGREEMENT

☐ **No Contract/Research Agreement Involved**

☐ **Contract/Research Agreement Involved**
**Name of sponsor/agency:**

**Has the contract/research agreement been submitted for review and signing (see institution specific instruction page)?** **YES** ☐ **NO**

**A. Liability**

i. Is there external (non-institutional) 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 (specify):

**B. Publication Agreements**

i. Is there an agreement between the investigator and the sponsor regarding use, publication or disposal of the data? YES ☐ NO

If YES, does the funding agency or sponsoring company place any? restrictions on publication of findings or reporting of interim results? YES ☐ NO

If YES, explain any restrictions.

ii. Does the contract/research agreement permit the disclosure of research results, including SAEs, to stakeholders (subject and/or guardian, sponsor, REB, REBs of other sites, and regulatory agencies) if required to protect the health of subjects? YES ☐ NO

# SECTION V: PRIVACY AND CONFIDENTIALITY

## 25. PRIVACY AND CONFIDENTIALITY

Under the Personal Health Information Protection Act (Bill 31) which came into force in Ontario on Nov. 1, 2004, the following information must be provided to the Research Ethics Board (REB) when requesting approval of research studies involving the collection, use and disclosure of personal health information.

**A.** Describe all personal health information required to be collected and the potential sources of this information. If subject identifiers will be used on data collection forms (e.g., names, initials, DOB, OHIP #, Hospital ID# etc.), provide justification.
(Max 1/3 page)

**B.** Describe how the personal health information will be used in the research.
(Max 1/3 page)

**C.** If personal health information is to be linked to other information, provide the following details: **NA** ☐

i) Describe the information that the personal health information will be linked to.

ii) Explain how the linkages will be made.

iii) Explain why these linkages are required.

**D.** Explain why the research cannot reasonably be accomplished without using personal health information.
(Max 1/4 page.)

**E.** If consent to the disclosure of the personal health information is not being sought from the individuals to whom the information relates, provide justification as to why it would be impractical to obtain explicit consent.

**F.** Describe the *reasonably foreseeable* harms and benefits that may arise from the use of the personal health information, and how the harms will be addressed.
(Max ¼ page)

**G.** Describe all persons who will have access to the personal health information, their roles in relation to the research and reason for access, and their related qualifications.

| Name | Institution | Qualifications | Role/Reason for Access |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

**H.** i) Describe the safeguards that will be imposed to protect the confidentiality and security of the personal health information.
(Max ¼ page)

ii) Indicate how long personal health information will be retained in an identifiable form and why.

iii) Who will have access to these data in the future.

**I.** Describe how and when the personal health information will be disposed of or returned to the health information custodian.
(Max ¼ page)

**J.** Has the investigator applied for approval to another REB? ☐ Yes ☐ No
If yes, provide the response to or status of the application.

**K.** Describe whether the investigators' interest in the disclosure of the personal health information or the performance of the research would likely result in an actual or perceived conflict of interest with other duties of the researcher.
Not Applicable

**L.** Describe the anticipated public or scientific benefit of this study.

## SECTION VI: DECLARATION

I certify that the above declaration is accurate and is/will be in force until the data is destroyed. I acknowledge that I, and all members of my research team, are aware that all charts will be reviewed in the Health Information Management Department,

I agree to adhere to the policies and procedures of SCHC, and the Research Ethics Board approval, with respect to confidentiality and privacy of all health information to which I may have access. If identifying information is collected, the information will be kept secure and Identifiers removed at the completion of collection. I acknowledge that I, and my research team, are prohibited from releasing any identifying client information received from SCHC, unless I am specifically authorized to do so by SCHC or required by law. I accept full responsibility for protection of information that has been accessed and/or collected by members of my research team.

I assume full responsibility for the scientific and ethical conduct of this study as described in this application and submitted protocol, and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), the Personal Health Information Protection Act (PHIPA), and any other relevant regulations or guidelines. I certify that all members of my research team involved in this study at SCHC are appropriately qualified and will undergo appropriate training to fulfill their role in this study.

Name of Principal Investigator Signature of Principal Investigator Date

## For SCHC USE ONLY (Internal)

## SECTION VI Program Manager/Director

1. Does the study or research conform to the values and policies identified for SCHC research
   - ☐ YES
   - ☐ NO
2. *Does the study have resource implications for SCHC*
   - ☐ YES (identify resources requirements-human resource, financial etc)
   - ☐ NO
3. Manager/Director is in support of the research and is able to commit to the resource requirements pending approval of the research and ethics committee?
   - ☐ YES
   - ☐ NO
4. Does the study or research falls within the normal scope of practice/authority of the practitioner or team.
   - ☐ YES
   - ☐ NO