SOUTHLAKE
REGIONAL HEALTH CENTRE

596 Davis Drive
Newmarket, Ontario
L3Y 2P9

Tel. (905) 895-4521, ext. 6638
Fax. (905) 952-3068
Website: www.southlakeregional.org
REBsubmissions@southlakeregional.org

Research Department

SRHC Research Ethics Board Application for Full Board Review: Researching Involving Humans

INSTRUCTIONS: (Do not include this instruction page in your REB Submission)
This Application is primarily intended for research requiring Health Canada approval and/or more than minimal risk.

1. **REB Submission Requirements:**
   Applications to the Southlake Regional Health Centre Research Ethics Board (SRHC REB) must include the following documentation as applicable to the research project submitted for review. Incomplete submissions will not be processed (upon request).
   - Certificates of completion for mandatory research ethics training as per SRHC policy.
   - A signed and dated application form
   - The protocol/research proposal (version clearly identified and dated) with accompanying study materials including but not limited to:
     - o Informed consent document (electronic copy must be in Word format)
     - o Product Monograph / Device Manual
     - o Qualified/Principal Investigator curriculum vitae (CV) (signed and dated)
     - o Any educational materials, advertisements/recruitment materials, questionnaires, etc. intended for research participants
     - o Data collection forms
     - o Study Budget

2. **REB Submission Process/Contact Information:**
   Send signed REB Applications and related study materials via email to: rebsubmissions@southlakeregional.org
   - Additional information about the SRHC REB, submission deadlines and standard operating procedures is available on the SRHC website.
   - Inquiries/questions can be directed to the REB Administrator at 905-895-4521 ext. 6638 or via email.

3. **REB Applications for Minimal Risk Research, meeting the criteria below, must be completed on the "REB Delegated (Expedited) Review Application for Minimal Risk Research" form.**
   a) Secondary use of data: the use of data contained in records collected for a purpose other than the research itself (e.g. medical chart review) (Note: no REB approval is required for use of previously collected, publicly available, anonymized research data)
   b) Collection of biologic samples by non-invasive means (e.g., mouth swab) or taking additional blood samples for research at the time of clinically-indicated blood drawing. The allowable amount will be based on the age, weight, and health of the participants. No genetic testing is involved.
   c) Collection of data through non-invasive procedures routinely used in clinical practice not involving x-rays or microwaves (such as ECG, ultrasound, hearing testing, or moderate exercise).
   d) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior).
   e) Research employing survey, interview, oral history, focus group or program evaluation. (invasive questions in vulnerable circumstances/ context or significant nuisance/inconvenience do not qualify)
   f) Biomedical clinical trials not subject to prior authorization by Health Canada involving:
      i. Drugs or natural health products that are being used according to the approved labelling,
      ii. Class i medical devices
      iii. Phase iv biomedical clinical trials or observational studies involving natural health products that are being used according to the approved labelling.
      iv. Biomedical clinical trials where the only difference from standard care is that research subjects are randomized among two or more existing current standards of intervention.

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Date: mm/dd/yy ☐ **Original Application** ☐ **Revised Application**

1. IDENTIFICATION

a. Applicant Name: _____
Affiliated Institution: _____
Current Position at Institution: _____
Mailing Address: _____
Telephone: _____
Email: _____

b. Full Study Title:

c. Protocol/Research Proposal Version Date/Number: _____

2. FUNDING

a. ☐ Industry ☐ Granting Agency ☐ Academic Funding ☐ Other ☐ Not Funded

b. Name of Funding Source: *(if applicable)* _____

3. CONTRACT RESEARCH ORGANIZATION (CRO) / SPONSOR CONTACT INFORMATION *(complete as applicable)*

a. Sponsor Name: _____
Contact Person: _____
Mailing Address: _____
Telephone: _____
Email: _____

b. CRO Name: _____
Contact Person: _____
Mailing Address: _____
Telephone: _____
Email: _____
Role of CRO: ☐ Project Management ☐ Monitoring ☐ Other: _____

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4. GENERAL STUDY DESCRIPTION *(check all that apply)*

a. ❑ Clinical Trial ❑ Study of Mechanism of Human Disease
❑ Therapies or Interventions of Disease Research
❑ Development of New Technology Related to Disease
❑ Psychological Interventions
❑ Other: _____

b. Anticipated start date: _mm_/_dd_/_yy_

c. Anticipated duration of study: _____ years _____ months

d. Number of anticipated research participants:
i. Worldwide: _____
ii. At site: _____

e. Study Phase: ❑ Pilot ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ N/A

f. First in man? ❑ Yes ❑ No ❑ N/A

g. Study Design: ❑ Randomized Controlled ❑ Randomized ❑ Open Label ❑ Blinded ❑ Cohort
❑ Case Controlled ❑ Other: _____

h. Test Article: ❑ Drug/Biologic ❑ Device ❑ Natural Health Product ❑ N/A
❑ Other:_____

i. Has this study been subject to previous scientific/peer review? ❑ Yes ❑ No

j. If the study is subject to regulatory approval, please check below all that apply: ❑ N/A
❑ Health Canada ❑ FDA ❑ Other: _____

k. Safety Monitoring:
Is site monitoring planned by the sponsor in accordance with ICH GCP? ❑ Yes* ❑ No* ❑ N/A

If YES* above:
i. Percent of sites to be monitored: _____
ii. Monitoring frequency: Every _____ weeks
iii. Monitoring will be conducted by: ❑ Sponsor ❑ CRO ❑ Other: _____

If NO* site monitoring is planned please explain: _____
_____

l. Will study safety data be periodically reviewed by an expert group of advisors such as Data Safety Monitoring Committee or Board (DSMC or DSMB)? ❑ Yes ❑ No ❑ N/A

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m. Device Studies: *(if applicable)*

i. Health Canada Device Category:

☐ Class I ☐ Class II ☐ Class III ☐ Class IV

ii. Risk Determination (for FDA Regulated Studies): ☐ N/A

☐ Significant Risk (SR) Device Study

☐ Non-Significant Risk (NSR) Device Study

Risk Determination By:

☐ FDA ☐ Sponsor Only (FDA determination pending)

n. Does this study require the use of a placebo? ☐ Yes* ☐ No

If YES* above, provide justification and the plan to minimize the risks to participants who may receive the placebo:

_____

_____

o. Does this study involve the use of an active comparator? ☐ Yes* ☐ No

If YES* above, please describe the usual standard of care at the research site:

p. Will any biological samples be collected? ☐ Yes* ☐ No

If YES* above, check all that apply:

☐ Blood ☐ Tissue ☐ Other: _____

q. Does this study involve genetic testing? ☐ Yes ☐ No

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5. RESEARCH SITE INFORMATION

a. Primary location of where the research will be conducted:

☐ Southlake Regional Health Centre

☐ Other: Institution/Site Name: _____

Address: _____

Telephone: _____

b. If any of the research procedures/study visits will be conducted at a secondary location (e.g. private healthcare provider office), please provide the details below:

Institution/Site Name: _____

Address: _____

Telephone: _____

Specify the procedures/study visits that will occur at the secondary location:

6. MULTI-SITE RESEARCH

a. Does this study involve research sites outside the jurisdiction of the SRHC REB? ☐ Yes ☐ No

b. Has another ethics board or regulatory authority (including non-Canadian) reviewed this study leading to a negative decision (nc approval) OR leading to a request to modify the protocol/research proposal that is being submitted with this application?

☐ Yes* ☐ No ☐ Unknown ☐ N/A – Research is only being conducted locally within the jurisdiction of SRHC REB

If YES* above, please provide the name of the ethics board or regulatory authority, the reasons and nature of the decision below and attached any relevant correspondence.

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7. RESEARCH TEAM

a. Is the Qualified/Principal Investigator or any sub-investigators subject to FDA debarment, disqualification or any other restrictions related to the conduct of this research? ❑ Yes ❑ No

b. **Qualified/Principal Investigator:**

i. Same as Applicant listed on page 1? ❑ Yes ❑ No*

If NO* above, please complete the follow information below:
Investigator Name: _____
Affiliated Institution: _____
Current Position (Status): _____
Mailing Address: _____
Telephone: _____
Email: _____

ii. Any Disciplinary Actions or License Restrictions: ❑ Yes* ❑ No ❑ N/A

If YES* above, please describe:
_____

c. **Study Coordinator:** *(if applicable)*
Study Coordinator Name: _____
Affiliated Institution: _____
Current Position (Status): _____
Mailing Address: _____
Telephone: _____
Email: _____

d. **Additional Research Team Personnel:** *(if applicable)*

NAME	**CREDENTIALS**	**AFFILIATED INSTITUTION** (e.g. SRHC)	**PROJECT ROLE** (e.g. Sub-Investigator, Study Coordinator, Research Assistant)	**ACCESS TO IDENTIFIABLE IDENTIFYING OR INFORMATION?** (Y/N)	**SRHC Research SOP Training?** (Y/N)
				Select	Select
				Select	Select
				Select	Select
				Select	Select
				Select	Select
				Select	Select

SL0768_15 (04/16) "Research Department" Review (04/19)

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8. QUALIFIED/PRINCIPAL INVESTIGATOR TRAINING/EDUCATION

a. Is a current copy of the Qualified/Principal Investigator CV on file with the SRHC Research Office?
❑ Yes ❑ No* *(If NO*, please attach)*

b. List below the Qualified/Principal Investigator education/training for the ethical conduct of research involving humans *(check all that apply and submit certificates of completion in accordance with SRHC policy)*:
❑ TCPS2 (CORE Web based Tutorial) ❑ GCP (Good Clinical Practice) ❑ Sponsor Training
❑ National Institutes of Health (NIH) Web-Based Training Course
❑ CITI (specify course) _____
❑ Other: _____
❑ None

c. If no previous training, please describe the GCP/research ethics training that will be provided to the Qualified/Principal Investigator and research staff prior to study commencement:
_____

9. DECLARATION OF CONFLICT OF INTEREST (COI)

a. Does the Qualified/Principal Investigator or any other member of the research team have any real, potential or perceived conflict of interest (COI) to declare? (e.g. financial, personal, institutional, dual role as both the researcher and healthcare provider).
❑ Yes* ❑ No

If YES* above:
i. Name(s) of Individual(s) Declaring COI _____
ii. Describe the nature of the COI: _____
_____
iii. What steps are planned by the Qualified/Principal Investigator to manage and/or minimize this conflict so that potential participants can make an informed autonomous decision?

10. PRIVACY AND CONFIDENTIALITY OF PERSONAL HEALTH INFORMATION (PHI)

- Identifiable Information: Information that may reasonably be expected to identify an individual (e.g. full name, health card number, health record number) or in combination with other available information (e.g. part of a date of birth and address).
- De-Identified Information: Originally collected with identifiers which have subsequently been removed and usually replaced with a code number or initials; a master list is kept linking the code number to the participant.
- Anonymized Information: Originally collected with identifiers which have subsequently been removed and no linkage to the participant.
- Anonymous Information: Originally collected without any identifiers therefore never associated or linked to an individual.

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a. Source(s) of PHI collection: *(check all that apply)*
- ☐ Directly from study participant
- ☐ Indirectly from study participant (e.g. information from documents/records or human biological materials previously collected for medical treatment)

i. Identify the indirect source(s) of PHI: *(check all that apply)*
- ☐ Hardcopy records
- ☐ Electronic records
- ☐ Databases
- ☐ Other: _____

b. Where are the sources of PHI located? *(check all that apply)*
- ☐ Site(s) where research is being conducted (as described in Section #5)
- ☐ Primary Physician
- ☐ Other Healthcare Facility: *(please specify)* _____

c. Will identifiable PHI (information or biological specimens) be collected? ☐ Yes ☐ No

d. If PHI is shared and sent outside of your research site to any 3rd party (e.g. governmental agency, community research partner, study sponsor), will the information be de-identified or anonymized?
☐ Yes* ☐ No ☐ N/A

If YES* above, skip i-iii below and continue to Section #11

i. Explain why sending identifiable PHI outside of the research site is necessary to conduct the research:

ii. Indicate how the identifiable PHI will be transferred securely outside of the research site: *(check all that apply)*
- ☐ eCRF
- ☐ Web enabled
- ☐ Fax
- ☐ Encrypted Email
- ☐ Private Bonded Courier
- ☐ Registered Mail
- ☐ Other: _____

iii. What security measures by the recipient are in place to protect identifiable PHI that is transferred from the research site:

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11. STUDY DATA SECURITY, STORAGE, RETENTION AND DISPOSAL

a. What is the method(s) of data storage at the research site? *(check all that apply)*
- ❑ Desktop computer
- ❑ Laptop computer
- ❑ USB Drive
- ❑ Hardcopy
- ❑ Other: _____

b. What security measures are in place to protect data at the research site?
- ❑ Computer or Network Firewall
- ❑ Encryption
- ❑ Password
- ❑ Locked Hardcopy File
- ❑ Other: _____

c. How long will study data be stored at the research site?
- ❑ In accordance with institutional (hospital/site) standard operating procedures/policies
- ❑ Other: _____ *(specify duration)*

d. Will the study data be linked or combined with any other data sets? ❑ Yes* ❑ No

If YES* above:

i. What other data set: _____

ii. How linkage will be made: _____

iii. Provide list of data elements: _____

iv. If data sets are anonymous is there a reasonable prospect that the linkage could generate identifiable information?
❑ Yes ❑ No ❑ N/A

e. Secondary Use:
Will study data or biological specimens be stored for possible future research? ❑ Yes* ❑ No

If YES* above:

i. Will informed consent be sought from study participants for possible secondary uses?
❑ Yes ❑ No

ii. Where will the data or biological specimens be stored?_____

iii. Who will have access?_____

iv. Identify the security measures in place to provide protection and respect for the privacy of research participants
_____

v. Will the future use of study data or biological specimens be subject to ethical review/oversight?
❑ Yes ❑ No

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12. INFORMED CONSENT

a. Is expressed (written) consent being obtained?
❑ Yes ❑ No*

If NO above, your study must meet the minimal risk criteria (see instruction page) and the REB Application for Delegated (Expedited) Review must be submitted. This form will not be accepted by the SRHC REB for minimal risk research.

b. What procedures will be followed to conduct the informed consent process? *(check all that apply)*
❑ SRHC SOPs/Policies ❑ Other *(please attached a copy)*

c. Identify the study personnel who will primarily be conducting the informed consent process:
❑ Study Coordinator ❑ Research Assistant ❑ Qualified/Principal Investigator ❑ Co/Sub Investigators

d. Who will provide consent?
❑ Research Participant ❑ Legal Authorized Representative ❑ Parent/Legal Guardian*
If this study involves minors, an assent form is required for participants under 16 years of age.

e. Will this study require the need for an Authorized Legal Representative to be involved in the informed consent process?
❑ Yes ❑ No

f. Will provisions be made to provide non-English speaking participants with information in a language understandable to them (both written and oral)?
❑ Yes ❑ No ❑ N/A – Only English speaking participants will be enrolled

g. Will the informed consent process be conducted in a location that will provide privacy for potential participants?
❑ Yes ❑ No

h. Do you confirm that you will provide participants with a signed copy of the REB Approved study information and consent form, sufficient time to read the document to consider participation, and ample opportunity to have their questions answered by a qualified/knowledgeable member of the research team? ❑ Yes ❑ No

i. Describe the process whereby participants will be able to withdraw their consent, if given (attach any associated documentation):

j. If material incidental findings are likely (significant unanticipated discoveries that would affect the participant's welfare), describe how will participants be informed:

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13. STUDY POPULATION

a. ☐ Healthy Volunteers
☐ Volunteers undergoing treatment for a medical condition: _____ *(specify)*

b. Will recruitment materials be utilized? (e.g. posters, advertisements) ☐ Yes* ☐ No

If YES* above, REB approval is required before use.

c. Will any individuals be excluded from the research based on demographic factors such as age, gender or race?
☐ Yes* ☐ No

If YES* above, please explain: _____
_____

d. Will the study participants be recruited only from within the primary or secondary research site(s) as specified on this application?
☐ Yes ☐ No *(please specify other recruitment sources)* _____

e. Will any vulnerable populations (see definition below) **within the context of this research** be enrolled? ☐ Yes ☐ No*

Vulnerable Populations: Individuals whose specific circumstances may limit their ability to fully safeguard their own interests or whose willingness to volunteer in the research may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation. Vulnerability is often caused by limited capacity, or limited access to social goods, such as rights, opportunities and power.

If *NO* above, Continue to Section #14.

f. Specify the vulnerable population(s) to be enrolled: *(check all that apply)*

☐ Minors/Children
☐ Economically or educationally disadvantaged participants
☐ Participants unable to consent for themselves
☐ Participants with diminished decision making capacity
☐ Incapable of legally informed consent
☐ People experiencing an immediate medical emergency
☐ Employees of the institution (site/hospital)
☐ Pregnant Women
☐ Other: Specify: _____

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g. Is the vulnerable population the primary research population? ☐ Yes ☐ No*

If NO* above:

i. Justify the inclusion of vulnerable persons if not required to meet study objectives:

ii. How will the vulnerable population(s) be treated differently in order to protect their rights and welfare?

iii. How will informed consent be obtained from the vulnerable population?

14. PARTICIPANT COMPENSATION

Will any compensation, incentives or reimbursement of expenses be available to participants?

☐ Yes* ☐ No

If YES* above, please provide details including amounts and frequency of payment(s) (e.g. per study visit):

15. PUBLICATION AND DISSEMINATION OF RESULTS

a. Does the sponsor/funding agency place any restrictions on the publication or reporting of results that in any way limit the negative outcome reporting of the Qualified/Principal Investigator?

☐ Yes* ☐ No ☐ N/A

If YES* above, please specify the restrictions:

b. Describe how the results of this study will be made publically available: ☐ N/A

i. ☐ Peer/Scientific Journal
☐ Peer/Conference Presentation
☐ Clinical Trial Registry Name:_____ Clinical Trial Code #:_____
☐ Other: _____

ii. Describe any additional methods that may be used to share study results with study participants: *(if applicable)*

_____

c. If genetic testing is involved in this study, will the participants (or legal representatives/parents/guardians) be informed of the results in conjunction with genetic counseling?

☐ Yes ☐ No ☐ N/A

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16. AGREEMENTS

a. Is there a Clinical Trial Agreement for this study? ☐ Yes ☐ No ☐ Pending

b. Is there a Data Sharing Agreement for this study? ☐ Yes ☐ No ☐ Pending

c. Is there a Material Transfer Agreement for this study? ☐ Yes ☐ No ☐ Pending

17. ATTESTATION OF QUALIFIED/PRINCIPAL INVESTIGATOR

I agree to abide by and comply with ethical standards, legislation, guidelines, and procedural requirements of Southlake Regional Health Centre and the Southlake Regional Health Centre Research Ethics Board; of the Tri-Council Policy Statement, of my profession, and of those of any other institution in which this research is undertaken. I am entitled to provide health care under the applicable laws and in good standing with my respective regulatory authority (if applicable).

I am aware of my responsibilities as the Qualified/Principal Investigator to:

- be familiar with the required standards, guidelines, policies and applicable legislation
- monitor the research to ensure that it is conducted in an ethical manner
- notify the SRHC REB of any unanticipated issues or changes to the research
- comply with any requests made by the SRHC REB during the life of the research and abide by REB reporting requirements such as annual renewal of research, unanticipated problems, deviations and notice of study closure
- supervise all team members and ensure that they are well versed in the conduct of ethical research

Name of Qualified/Principal Investigator: *(print first, last)*

Signature: **Date:** mm/dd/yy

Name of person completing this form: *(print first, last)*

Signature: **Date:** mm/dd/yy