SOUTHLAKE REGIONAL HEALTH CENTRE
RESEARCH ETHICS BOARD TERMS OF REFERENCE

ESTABLISHMENT AND AUTHORITY

The establishment and authority for decisions made by the Southlake Regional Health Centre Research Ethics Board (SRHC REB) is delegated by the Board of Directors through the Administrative Management Committee (AMC) of the Southlake Regional Health Centre (the 'Institution'). The SRHC REB is an autonomous body operating independently from direction by the Institution. It has been granted the authority to conduct review and ethics approval, rejection, propose modifications or terminate ethics approval of proposed or ongoing research involving human participants under the auspices of the Institution.

Notwithstanding ethical approval of a research project, the Institution retains the right to limit application of research based on resource impacts.

MANDATE

- To ensure that all research under its oversight is designed and conducted in such a manner that it protects the rights, welfare and privacy of research participants.
- To be guided in decision-making by ethical principles and to ensure compliance with all applicable regulations and guidelines. These include, but are not limited to: (a) the Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans, (b) the ICH Good Clinical Practice: Consolidated Guideline, (c) The Canadian General Standards Board for Research ethics oversight of biomedical clinical trials, (d) Canadian and Ontario laws and regulations, (e) US regulations as applicable.
- The core governing principles of the SRHC REB are as defined in the Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans" which are:
    - Respect for Persons;
    - Concern for Welfare;
    - Justice
- To operate and support clinical research through the provision of efficient, timely and regulatory compliant ethics review processes.
- To serve as the Board of Record for all research conducted under the auspices of the Southlake Regional Health Centre notwithstanding the right of the Institution to delegate ethics review and oversight of research to external REBs for multi-jurisdictional clinical trials and/or research that falls under an existing Official Board of Record agreement.
- To accept reviews undertaken by an external REB as authorized by the Institution while jointly overseeing local reportable unanticipated problems (as defined in SRHC REB standard operating procedures) resulting from research involving SRHC patients, staff, physicians and volunteers.
- To serve as the Board of Record for multi-jurisdictional research as authorized by the Institution on a study by study basis.
- To prepare an annual report each June regarding activities of the committee for submission to the Medical Advisory Committee and Administrative Management Committee.
- To respond to any complaints arising from research in accordance with SRHC SOPs.
- To serve as a consultative body relating to education and research within the organization.

COMPOSITION

The REB shall consist of at least five voting members, who are Canadian citizens or permanent residents under the *Immigration Act*, composed of both men and women, with varying backgrounds to promote complete and adequate review of research activities commonly conducted and of whom:

- at least two members have expertise in relevant research disciplines, fields and methodologies covered by the SRHC REB;
- at least one member is knowledgeable in ethics;
- at least one member is knowledgeable in the relevant law who is not SRHC legal counsel or risk manager.
- at least one community member* who has no affiliation with SRHC or a sponsor, and who is not part of the immediate family of a person who is affiliated with SRHC.
- at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.
- Additional membership as required by applicable legislation or guidelines.

A member may not fulfill more than two representative capacities or disciplines.

* The primary role of the community member is to reflect the perspective of a research participant and is considered equivalent to a SRHC Patient/Family Advisor (PFA) volunteer.

Non-Voting Members:
REB administrative staff who have the knowledge, experience and training that is comparable to what is expected of REB members may be appointed and serve as non-voting members of the REB in accordance with the provisions set out in SRHC SOPs.

Ad Hoc Advisors:
In the event that the REB is reviewing a project that requires particular community or participant representation or specific disciplinary or methodological expertise that is not available from its members, it may consult with an ad hoc advisor(s). Consultation with an ad hoc advisor shall not alter the composition and representation of the REB.

APPOINTMENTS

REB Chair:
The AMC shall appoint an REB Chair for a two-year term, to provide overall leadership for the REB and to facilitate the REB review process based on the adopted policies, SRHC SOPs and applicable regulations. There shall be no restriction on renewal and the AMC may renew the term of the Chair every two years at its pleasure.

REB Voting Members:
The REB Chair shall be responsible for appointing the remaining REB members (including the REB Vice-Chair, or alternate members if required) with staggered two-year terms beginning at the point of appointment. There is no limit on the number of terms the REB Chair, Vice Chair, members and alternate members may serve on the REB.

MEETINGS/QUORUM

The REB convened meetings shall be face-**to**-face, at least monthly and at the call of the Chair if required.
A quorum shall consist of a minimum of 50% + 1 of the voting membership present (in person, via teleconference or videoconference). In addition, members must be present representing the minimum role/capacity as defined in the Composition of the REB.

REB decisions made at convened board meetings shall be made by consensus or a majority vote of REB members present, with exception of those who have abstained or recused themselves in accordance with conflict of interest policies.

The REB Administrator shall provide monthly meeting minutes to the Administrative Management Committee (AMC) and to the Medical Advisory Committee (MAC).

REB members shall be accountable for their attendance and any member who misses more than three consecutive meetings without notification to the Chair and without due cause may be asked to resign from the Board at the discretion of the Chair.

APPEALS

REB decisions are open to appeal in accordance with the applicable REB SOPs.

CONFIDENTIALITY

Each member of the SRHC REB shall abide by the REB Member Confidentiality & Conflict of Interest Undertaking, in addition to any other statement of confidentiality that the Board member may have signed as a SRHC employee or volunteer.

All Ad Hoc Advisors and observers of an REB meeting shall sign a Confidentiality of Information and Conflict of Interest Agreement.

EDUCATION/TRAINING

New REB members shall attend an orientation session facilitated by the REB Administrator and shall complete the Tri-Council Policy Statement On-Line Tutorial and Biomedical Research Ethics Training Course (CITI-Canada) within three months of joining the Board. Copies of completion certificates shall be submitted to the REB Administrator and will be kept on file in the REB Office.

Members of the REB should report on any additional training/education at REB meetings and provide evidence of this education (e.g., copy of conference agenda, certificates of training, etc.) to the Chair (or designate) through the Research Office for filing.

SIGNING AUTHORITY

The Chair (or designate) will have signing authority on behalf of the REB in accordance with SRHC REB standard operating procedures.