

RESEARCH ETHICS BOARD

TERMS OF REFERENCE

1. PURPOSE

Scarborough and Rouge Hospital (SRH) Research Ethics Board (REB) primary purpose is to protect the rights, safety and wellbeing of human participants. SRH REB is also responsible for a) ensuring that research protocols meet the current safety, scientific, ethical and privacy standards; and b) make certain that all research activities are aligned with the best interests of SRH.

The role of the SRH REB is to “approve, reject, propose modification to, or terminate any proposed or ongoing research involving humans.” (TCPS2 Article 6.3)

2. ROLE

SRH REB acts in compliance with all laws, policies, standards and guidelines governing human research, which are applicable to submitted research study, including but not limited to: *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*; *the Personal Health Information Protection Act (PHIPA) 2004*, *Good Clinical Practice: Consolidated Guideline*; Division 5 of the *Canadian Food and Drug Act*; *Code of Federal Regulations Title 45, Part 46*; *The Declaration of Helsinki*; *The Belmont Report*; *International Conference on Harmonization for Good Clinical Practice Guidelines*; as appropriate.

3. RESPONSIBILITIES

- To protect human participants by striving to ensure that research conducted at SRH is conducted according to the highest ethical standards
- To work collaboratively with SRH Research Department
- To recommend modifications to or reject or approve research studies using human participants, as required
- To monitor all approved research studies using human participants, including protocol compliance and the review of serious adverse events (within resource limitations)
- To assure that no research study using human participants shall be undertaken prior to ethics review and formal, written approval
- To assure that no research study using human participants shall continue after approval has expired or has been terminated
- To establish policies and procedures for reviewing the relevant components of research studies using human participants
- To maintain records of all relevant research documentation in conjunction with SRH Research Department
- To form subcommittees of the REB to carry out special functions, as deemed necessary, to fulfill the mandate of the REB
- To provide a formal mechanism for researchers to appeal a decision by the REB
- To facilitate delegated review, when appropriate
- To facilitate crisis research in emergent situations
- To facilitate research under the Special Access Program of Health Canada

4. **MEMBERSHIP**

Chair:

Appointed by the Board of Directors in consultation with the Chief Executive Officer (CEO) and the Chief of Staff (COS), the Chair is appointed for a three-year term, renewable for one further three-year term. Any further appointments to the Chair position may occur only after a three (3) year gap.

Vice Chair:

Appointed by the REB from within its voting membership, the Vice Chair is appointed for a three (3) year, renewable for one further three-year term. Any further appointments to the Vice Chair position may occur only after a three (3) year gap. The Vice Chair will chair REB meetings if the chair is unavailable.

Members

The REB will consist of a minimum of 9 members, including both men and women, from the following areas:

- At least 1 member knowledgeable in medical and research ethics
- At least 2 members with relevant expertise in medical research and research methodology
- At least 1 member knowledgeable in relevant law and privacy issues.
- At least 1 lay community member with no affiliation with the hospital and preferably recruited from the community that the hospital serves.
- At least 1 staff member representing the profession of medicine
- At least 1 staff member representing the profession of nursing
- At least 1 staff member representing allied health professionals
- At least 1 pharmacy staff member
- At least 1 patient/family representative
- At least 1 statistician as an ad hoc member
- Ad hoc members as required
- Manager of SRH Research department
- Administrative representative (Ex-Officio – non-voting)

To enhance independence of REB decision-making, individuals from the hospital's senior executives and Medical Advisory Committee (MAC) shall not serve as REB members.

All members must declare at the beginning of each meeting if they have a conflict of interest with any of the research being presented.

All members will have one vote. All members must have documented "Certificate of Completion" of the online tutorial for TCPS2 CORE guidelines. Copies of the TCPS2 CORE Certificate and each member's current curriculum vitae (dated and signed) are kept on file in the Research Administration office.

5. **REPORTING**

SRH REB reports to the Board of Directors. (TCPS2 Article 6.2) SRH may not override an REB decision to reject a research proposal. An appeal of the REB decision to reject a research proposal can only be brought in accordance with Section C of the TCPS2 Chapter 6, Section C. (TCPS2 Article 6.3) REB Meeting minutes as well as an annual report by the REB Chair will be presented to the Board.

An REB approval applies to the ethical acceptability of the research, and does not, in itself, constitute authorization for the research to proceed. (TCPS2 Article 6.3) The Board of Directors retains the authority to deny REB-approved research; circumstances and rationale for doing so would be initiated through the advice and recommendations of the CEO and/or Chief of Staff presented to the Board.

6. DELEGATED REVIEW

The Chair and/or Vice-Chair plus one ethicist and two additional Board members (knowledgeable in medical and research ethics) will perform delegated reviews. Proposals not meeting criteria for delegated review will be returned to the researcher and will require review by the full REB. The members reviewing a delegated protocol recommend approval in order for the protocol to be granted REB approval.

As per TCPS2, when research is of minimal risk, a review can be delegated. Examples of categories that may be delegated include:

- Research that involves minimal risk
- Minimal risk changes to approved research. This may include administrative changes, minor protocol amendments
- Annual renewals of approved minimal risk research
- Annual renewals of more than minimal risk research where the remaining research risk is minimal.
- Annual renewals of more than minimal risk where there is no significant change, no increase in risk and that the chair has deemed a delegated review to be appropriate. ¹

7. EMERGENCY RESEARCH REVIEWS AS PER TCPS2

In cases of crisis research or research under the Special Access Program, the Chair has the authority to convene a special, reduced quorum of the REB to review the study promptly. Such a quorum must fulfill the minimum requirements for REB membership set out from time-to-time in the laws and guidelines listed above. Currently, a quorum for crisis review is made up of a minimum of 5 members: 2 members with broad expertise in research methodology and/or medical science; 1 member knowledgeable in medical and research ethics; 1 member knowledgeable in relevant law and in considering privacy issues, and 1 community member.

8. FAMILY MEDICINE RESIDENCY PROGRAM RESEARCH PROJECTS

In affiliation with the University of Toronto, SRH is host to DFCM ([Department of Family & Community Medicine](#)) Residency program where family medicine residents do their entire 2 year residency program at the hospital. One of the requirements of their residency, is to complete a research project each year. In recognition of this learning experience, the REB will provide the residents with the opportunity to present their research applications to the ~~full~~ REB board so that the residents can gain the experience of the REB submission, review, and approval process.

9. QUORUM

The quorum for full REB review of normal research studies is 50% + 1 of the voting members, of which four must include: a physician, a non-physician, a member knowledgeable in medical and research ethics, a member with expertise in applicable law and/or privacy, and a community member.

10. VOTING

All members, except the Chair and Administrative representative are voting members.

An initial vote on a research study proposal by the full REB requires consensus. If consensus cannot be achieved, further information can be requested from the researcher, seek external advice or otherwise reflect upon the issues of contention. At the next REB meeting for which there is quorum, another vote will be taken. If consensus is not achieved, the study will pass with a minimum 75% votes of majority of the members present.

The members reviewing crisis research or research under the Special Access Program must all agree to approve it. If full agreement cannot be achieved, the researcher will be invited to re-submit the proposal for review by the full Board, time constraints permitting.

11. MEETING AND ATTENDANCE

REB shall meet monthly or as required. Attendance can be in person or via teleconference. More than 3 unexplained absences by members in a calendar year should be construed as a notice of resignation.

12. TERMS OF REFERENCE REVIEW

The Terms of Reference and membership will be reviewed annually.

REFERENCES

Secretariat on Responsible Conduct of Research. (2014). *Tri-council Policy Statement - Ethical Conduct for Research Involving Humans*. (TCPS2) Government of Canada.