



**TERMS OF REFERENCE
FOR
TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)
CAMBRIDGE MEMORIAL HOSPITAL
GRAND RIVER HOSPITAL
ST. MARY'S GENERAL HOSPITAL**

MANDATE

The primary responsibility of the Tri-Hospital Research Ethics Board (THREB) is to make decisions concerning the ethical acceptability of research proposed by the hospital(s), by researchers having an association with the hospital(s), or any research involving patients or staff at Cambridge Memorial Hospital, Grand River Hospital, or St. Mary's General Hospital.

In conducting these activities, the Tri-Hospital Research Ethics Board (THREB) is mandated to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects that is conducted within the hospital(s). THREB complies with guidelines from the *Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS)* and the *Good Clinical Practice: Consolidated Guideline (GCP)* of the International Conference on Harmonization. THREB also endeavours to facilitate compliance with the human subject requirements of two US federal agencies: The Food and Drug Administration and the Office for Human Research Protections, US Dept of Health and Human Services.

Terms of Reference are intended:

1. to protect human research participants from research harms
2. to ensure the ethical acceptability of research with humans
3. to ensure the scientific validity of research with humans
4. to ensure continuing ethical acceptability of research conducted under its auspices
5. to provide education regarding research guidelines to the membership in order to promote adherence by researchers to the Tri-Council Policy Statement and other accepted standards as applicable
6. to ensure submitted proposals are in accordance with the mission, vision, and values of the participating hospitals(s)
7. to determine that any impact on the resources of Cambridge Memorial Hospital, Grand River Hospital or St. Mary's General Hospital has been assessed

AUTHORITY OF THREB

The THREB has the authority to approve or disapprove the ethical acceptability of all research proposals. In keeping with the principles articulated in Article 1.2 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, negative decisions taken by the Tri-Hospital Research Ethics Board with respect to submitted research proposals, shall be final. Conversely, projects approved by THREB may be disallowed at individual participating hospitals on the basis of specific mission values, resource demands or other reasons.

CORPORATE ACCOUNTABILITY

The THREB reports to the Boards of Directors of its member hospitals.

MEMBERSHIP

The THREB will be comprised of representatives approved by the CEO of each hospital:

- two standing members who have broad expertise in the methodologies
or the area(s) of science
- physician representatives
- one member from the discipline of ethics
- two members without affiliation to the hospital(s), recruited from the community
- one clinical pharmacist
- one executive representative from each hospital
- one member who is knowledgeable in the discipline of law.
- Ad-hoc reviewers as necessary.

With the exception of standing committee members, membership will be for a renewable 2 year term.

CHAIRPERSON

The Chairperson is approved by the CEOs for a renewable two year term, and must have experience on a Research Ethics Board with education and expertise in research methodology.

DECISIONS

Although attempts will be made to reach consensus on decisions, a vote of the majority present will be taken as the Tri-Hospital Research Ethics Board's decision provided there is a quorum. Written positions are encouraged to facilitate discussion when a member cannot attend. Committee members must be absent from the meeting for the portion where his/her application (Principal Investigator or Sub-investigator) is being considered or whenever there is a conflict of interest.

QUORUM

A quorum shall be constituted so long as a majority of the total number of voting THREB members are present.

MEETINGS

Meetings will be held monthly at a set time. At the discretion of the Chairperson, scheduled meetings may be cancelled or additional meetings called.

ATTENDANCE

- Members must notify the Chairperson if they are unable to attend a meeting
- Frequent unexplained absences will be addressed by the Chairperson

CONFIDENTIALITY

The THREB is bound by Tri-Council Policy Statement, and the respective hospitals' policies on the release of information. The THREB meeting agenda, minutes, and information contained in research proposals submitted for ethics review are all confidential. Official copies of reviewed proposals will be retained by the Chairperson for as long as legally required.

COMMUNICATION

The Chairperson shall be the THREB's official spokesperson. If contacted for information and/or interviews regarding the THREB and its decisions, members must refer the inquiring party to the Chairperson without comment. In addition, no member may disseminate documentation relating to the THREB without prior and explicit approval of the Chairperson.