



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

MANDATE and SCOPE

The primary mandate of the Tri-Hospital Research Ethics Board (THREB) is to ensure that research involving the participation of humans meets current scientific and ethical research standards for the protection of human research participants. The THREB has the authority to independently approve, reject, propose modifications to, suspend, or terminate any proposed or ongoing research involving human participants, their data and/or biological materials. This mandate extends to all research conducted at Cambridge Memorial Hospital, Grand River Hospital and St. Mary's General Hospital, with the exception of research reviewed by an alternate Research Ethics Board of Record for the hospital(s) (for example, The Ontario Cancer Research Ethics Board (OCREB), where necessary agreements are in place.

The THREB complies with the Tri-Council Policy Statement (TCPS 2) requirements for activities that require review by an REB. These activities include:

- Research involving living human participants;
- Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals and includes secondary use of biological materials; and
- Research that relies exclusively on the secondary use of data or human biological materials.

The THREB also complies with the International Conference on Harmonization Good Clinical Practice Consolidated Guideline (GCP), Part C Division 5 of the Food and Drug Regulations of Health Canada, the provisions of the Ontario Personal Health Information Protection act (PHIPA) and where applicable, the United States Food and Drug Administration regulations and other applicable laws and guidelines.

RESPONSIBILITIES:

1. To provide research ethics review and oversight to ensure the ethical acceptability of research prior to initiation and throughout the lifecycle of a research study.

2. To approve, require changes to, or reject research studies or proposed changes to approved research studies, and to monitor, suspend or terminate any ongoing research;
3. To place restrictions on a research study;
4. To take any actions considered reasonably necessary to ensure the protection of the rights, safety and wellbeing of participants in research;
5. To recommend policies and procedures governing ethical conduct of research at the 3 hospitals;
6. To act as a resource on matters of research ethics for the 3 hospitals;
7. To provide education regarding research guidelines to the membership of the THREB in order to promote adherence by researchers to the TCPS2 and other accepted standards, as applicable.

AUTHORITY OF THE THREB

The THREB receives its authority from and reports to the Board of Directors of Cambridge Memorial Hospital, the Board of Directors of Grand River Hospital and the Board of Trustees of St. Mary's General Hospital.

In order for the THREB to retain the independence required of it by the TCPS 2, a decision made by the THREB may not be overruled by member hospitals except for reasons other than research ethics.

The decisions of the THREB related to initial study reviews are open to appeal through an appeal mechanism established by the member hospitals.

MEMBERSHIP

The THREB will be comprised of at least five members represented by the following categories:

- At least two members who have broad expertise in the relevant research disciplines, fields and methodologies reviewed by the board;
- At least one physician representative(s);
- At least one member knowledgeable in ethics;
- At least one external community member who has no current employment affiliation with the institutions;
- At least one member affiliated with each hospital who is not a senior institutional administrator member(s);
- At least one member knowledgeable in Canadian law relevant to the research;
- At least one member(s) knowledgeable in privacy issues;
- ad-hoc reviewers as necessary (non-voting).

Membership will be renewable 3 year term based on mutual agreement between the member and the THREB Chair. Members will complete relevant training and education as required by the Chairperson. Members are expected to attend a minimum of 70% of scheduled meetings. Members who cannot attend a meeting are expected to provide written comments to THREB for each of the studies under review at the respective meeting. THREB may have observers attend meetings at the discretion of the Chair.

CHAIRPERSON

The Chairperson is appointed by the Boards of the three hospitals for a renewable three year term(s).

CONFLICT OF INTEREST

All THREB members are required to sign a Conflict of Interest Declaration form, and to declare any conflicts prior to the review of a submission. If there is any doubt concerning conflict of interest, the member is expected to discuss the matter with the THREB Chair. If a member has a conflict with a submission under review, they will be absent for the review and vote, and this will be noted in the meeting minutes.

DECISIONS

Decisions made by THREB are based on scientific and ethical merits of a research study, and are made independently of other interests of CMH, GRH or SMGH. THREB is guided by the following core ethical principles as defined in Article 1.1 of the Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans":

- Respect for Persons,
- Concern for Welfare,
- Justice

For studies that do not qualify for a delegated review process carried out by the Chair and/or a qualified member of THREB, a full board review will occur. 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. THREB is entitled to invite researchers to a meeting to discuss a study under review or for which THREB provides oversight. THREB is also entitled to seek input from ad hoc reviewers at its discretion.

QUORUM

At minimum, the THREB will follow the quorum requirements of TCPS 2 and will apply additional quorum requirements as necessary based on applicable regulations and guidelines that may apply to the study under review.

MEETINGS

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

CONFIDENTIALITY

The THREB meeting agenda and related discussion, minutes, and information contained in study submissions are all confidential. Official copies of reviewed documents will be retained by the THREB Office for as long as legally required. All THREB members and observers of THREB meetings must sign a Confidentiality Agreement Form.