

Research and Ethics Board

Terms of Reference

PURPOSE

The Research Ethics Board (“REB”) is a body established by the Board of Directors to independently protect the rights and welfare of human research subjects.

The REB’s purpose is to ensure that all human subjects research, which includes research involving human remains, cadavers, tissues, biological fluids, embryos and fetuses, (hereinafter referred to as “research”) meets current ethical and scientific standards and is in compliance with the following legislation, guidelines, policies and regulations as required:

- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2010 (TCPS2);
- Part C, Division 5 of the Health Canada Food and Drug Regulations; Part 4 of the Canadian Natural Health Product Regulations; and the Canadian Medical Devices regulations, as applicable;
- International Conference on Harmonization for Good Clinical Practice (ICH/GCP) Consolidated Guidelines E6: Good Clinical Practice;
- U.S. Department of Health and Human Services Office for Human Research Protections Terms of Federalwide assurance (FWA) for International (non-U.S.) institutions;
- U.S. Food and Drug Administration,
- U.S. Department of Health & Human Services Code of Federal Regulations Title 45 Part 46 Protection of Human Subjects;
- Personal Health Information Protection Act, 2004 (Ontario) (PHIPA); and
- The Corporation’s research policies and procedures.

SCOPE

The REB reviews research involving human subjects conducted within or under the auspices of the Corporation. The REB will review all research conducted that meets any of the following criteria. The research:

- is conducted by any of the Corporation’s employees, privileged staff, professional staff, agents, contractors, students, and volunteers in relation to their role within the Corporation; or
- is conducted at any of the Corporation’s sites; or
- is performed as part of an individual’s academic responsibilities or an individual’s employment responsibilities; or
- is conducted with any hospital resources/money/space; or
- is being performed as part of the Corporation’s training program; or
- the name of the Corporation will be used as part of an individual’s credentials for any type of publication, presentation or abstract.

RESPONSIBILITIES

The REB is responsible for:

- reviewing and approving all research brought before it to ensure its conduct meets current ethical and scientific standards;
- ensuring appropriate safeguards and strategies are in place to minimize and mitigate risks that may arise in the conduct of research;
- ensuring that all research has a favorable benefit /risk ratio;
- conducting continuing review of on-going research;
- acting as a resource on matters of research ethics for the Corporation;
- facilitating dispute resolution with researchers to resolve issues of concern to the REB; and
- maintaining detailed proceedings and minutes of REB deliberations and decisions.

AUTHORITY

The REB has the authority and responsibility to approve, propose modifications to, or reject research, monitor ongoing research, and to suspend or terminate any research being carried out within or under the auspices of the Corporation.

The Corporation retains the authority to reject any REB approved research.

A decision made by the REB to reject research may not be overridden by the Corporation.

ACCOUNTABILITY

The REB office will be accountable for retaining monthly meeting minutes and for providing an annual report, or upon request by the Board of Directors, for the purposes of oversight.

MEMBERSHIP & COMPOSITION

The REB shall consist of one Chair, one Vice-Chair, and additional membership as specified below.

CHAIR

The Chair of the REB is appointed by the Board of Directors upon consultation with and recommendation of the Chief of Staff.

The Chair is appointed for a three (3)-year renewable term.

VICE-CHAIR

The Vice-Chair of the REB is appointed by the Board of Directors upon consultation with and recommendation of the Chief of Staff and the REB Chair.

The Vice-Chair is appointed for a three (3)-year renewable term. The Vice-Chair shall support the Chair in all aspects of his /her duties. In the Chair's absence or when the Chair has a conflict of interest, the Vice-Chair will act as Chair.

COMPOSITION

The REB membership shall consist of a minimum of seven (7) voting members that meet the following criteria:

- At least one (1) member must be a physician (for regulated clinical trials);
- At least two (2) members have expertise in relevant research disciplines, fields, and methodologies covered by the REB;
- At least one (1) member is knowledgeable in ethics;
- At least one (1) member is knowledgeable in the relevant law, but is not legal counsel to the institution;
- At least one (1) community member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and
- At least one (1) member knowledgeable in privacy laws.

All members will be Canadian citizens or permanent residents. Membership will have representation from scientific and non-scientific communities. Membership will strive to consist of members from diverse backgrounds (i.e., race, gender, and cultural backgrounds). Membership will include members from a diversity of professional backgrounds and healthcare programs within the Corporation.

Members are selected by the Chair of the REB or designee. REB membership recruitment may be supported through consultation with the delegate of the Board of Directors. Members of the REB will serve for a three (3)-year renewable term. Terms will be overlapping to ensure adequate experience and continuity of function of the REB.

REB members are accountable to the Chair or designee for their attendance and REB commitments.

The REB Chair or designee may otherwise remove an REB member at any time, if they are not fulfilling their designated REB duties in a timely, competent and ethical manner.

Non-voting members include REB administrators and ad hoc advisors with particular expertise who will be consulted on an as needed basis.

To ensure independence of REB decision-making, individuals from the Corporation's Senior Administration shall not serve as REB members.

MEETING FREQUENCY & ATTENDANCE

The REB shall meet monthly for a minimum of 10 pre-scheduled face-to-face meetings per year and at the call of the REB Chair.

Use of videoconferencing, teleconferencing or other technologies to attend a meeting may be permitted by the Chair provided that a quorum is able to participate in an interactive manner in the REB's deliberations and decisions.

QUORUM

A quorum for a full REB meeting shall consist of at least seven (7) voting members for regulated clinical trials and six (6) voting members for all other research with the following representation required:

- At least one (1) member must be a physician (for regulated clinical trials);
- At least two (2) members have expertise in relevant research disciplines, fields, and methodologies covered by the REB;
- At least one (1) member is knowledgeable in ethics;
- At least one (1) member is knowledgeable in the relevant law;
- At least one (1) community member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution;
- At least one (1) member knowledgeable in privacy laws (PHIPA).

At least one of these members must represent the non-scientific community.

Membership, when required will include:

- at least one member who has expertise in complementary or alternative care or pediatric health research; and
- At least one member, when possible, who is from an identifiable Aboriginal community or Native center, when the REB reviews research that recruits participants from that community.

PROCESS FOR DECISION MAKING

A proportionate approach to research ethics review in the context of both initial and continuing review of research will be used. The level of review is based on the foreseeable risks, potential benefits and ethical implications of the research.

Above minimal risk research will receive Full Board review; minimal risk research may receive Delegated review. Full Board decisions will be made by majority vote with the exception of those who have recused themselves in accordance with the conflict of interest policies and procedures. The REB Chair abstains from voting except to break a tie vote. For greater clarity, members that have any real or apparent conflict of interest regarding research under review will recuse themselves from deliberation and decision (i.e., will not vote).

Delegated reviews will be managed through 3 Tiered Review Classification System. The reviews will be completed by the designee, Chair/Vice-Chair or Chair/Vice-Chair in consultation with one or more other REB members(s). If the delegated reviewer(s) is not able to resolve issues with respect to delegated reviews, the research will be brought to the full REB for deliberation and decision.

The REB Chair/ Vice-Chair may delegate signing authority for REB review and approval decisions related to Tier 1 delegated review to a designee. The REB Chair or designee

may only delegate signing authority to REB members or REB Office Personnel with the skill and knowledge necessary for the effective exercise of the authority.

Ad Hoc Advisors

At his/her discretion, the REB Chair or designee may invite individuals with expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB.

The ad hoc advisor may be asked to participate in the REB meeting to lend his/her expertise to the discussions. The ad hoc advisor may not contribute directly to the REB's decision and their presence or absence shall not be used in establishing a quorum.

Where appropriate, members of the REB may form sub-committees to deal with specific issues. Sub-committees will report their findings and recommendations to the REB.

REB decisions are open to appeal through an appeal mechanism established by the Corporation.

Approved by the Board of Directors March 30, 2017