

## UNITY HEALTH TORONTO RESEARCH ETHICS BOARD TERMS OF REFERENCE

### AUTHORITY

The Unity Health Toronto Research Ethics Board (“**REB**”) shall report directly to the Unity Health Board of Directors. Unity Health Toronto consists of Providence Healthcare, St. Joseph’s Health Centre and St. Michael’s Hospital.

The Chair of the REB shall make annual reports to the Research and Education Committee of the Unity Health Board of Directors. The REB maintains an arm’s-length relationship with Unity Health. Unity Health retains the authority to disallow the conduct of research even if approved by the REB. However, a disapproval by the REB cannot be overturned.

### PURPOSE AND RESPONSIBILITIES

The REB is responsible to ensure that research involving the participation of humans meets current scientific and ethical research standards for the protection of human research participants. The REB has the mandate to independently approve, reject, propose modifications to, or to terminate any proposed or ongoing research involving human participants or human biological materials, which is conducted within, or by members of Unity Health.

The REB shall be responsible for the following tasks:

- Reviewing all proposed research from scientific and ethical perspectives before the research is started;
- Reviewing adverse event reports;
- Conducting continuing review; and
- Reviewing amendments before the amendments are implemented.

Decisions made by the REB are based on scientific and ethical merits of the research study, and are made independently of other interests of Unity Health. The REB is guided by the following core 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; and
- Justice.

The REB is attentive to local, national, and international trends in research ethics that may bear directly on research carried out by Unity Health. The REB is guided in decision-making regarding research protocols by (a) the Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans, (b) the ICH Good Clinical Practice: Consolidated Guideline, (c) the Catholic Health Association of Canada: Health Ethics Guide, (d) Canadian and Ontario laws and regulations. REB members are expected to be knowledgeable of current research ethics guidelines, regulations and institutional policies governing human research.

## MEMBERSHIP

The Chair shall be appointed by the Board of Directors through its Research and Education Committee.

The members shall be appointed by the Chair and the membership shall be:

- At least two (2) members with expertise in relevant research disciplines, fields and methodologies covered by the REB (for biomedical clinical trials, this will include at least one member who practices medicine or dentistry and who is in good standing with their regulatory body)
- At least one (1) member who is primarily experienced in non-scientific disciplines;
- At least one (1) member who is knowledgeable in ethics;
- At least one (1) member who is knowledgeable in Canadian laws relevant to the research being reviewed;
- At least one (1) member who is knowledgeable in considering privacy issues;
- At least one (1) member from the community who has no affiliation with Unity Health, and who is not part of the immediate family of a person who is affiliated with Unity Health;
- Any additional people with relevant expertise appointed by the Chair and/or as required by applicable legislation or guidelines.

A member may not fulfill more than two representative capacities or disciplines during a Board meeting.

The following hospital personnel and/or service providers are not eligible to be members of the REB:

- Senior management and senior administration personnel (Director Level or above, except for the Director, Research Ethics)
- Unity Health Legal counsel; and
- Staff of the Risk Management department (Manager Level or above)

## QUORUM

Quorum shall include a minimum of five (5) voting members, including both men and women, of whom:

- at least two (2) members with expertise in the relevant disciplines, fields and methodologies covered by the REB;
- at least one (1) member who practices medicine or dentistry and who is in good standing with their regulatory body (for biomedical clinical trials);
- at least one (1) member whose primary experience and expertise are in a non-scientific discipline;
- at least one (1) member knowledgeable in ethics;
- at least one (1) member from the community who has no affiliation with the organization(s) and who is not part of the immediate family of a person who is affiliated with the organization;
- at least one (1) member knowledgeable in the relevant law;
- at least one (1) member who is knowledgeable in considering privacy issues;
- additional representation as required by applicable legislation or guidelines.

For research which is subject to the US Code of Federal Regulations, quorum shall also include a majority (50% + 1) of the current voting members.

## **MEETINGS**

The REB shall hold at least twelve (12) meetings each year. Meetings will be held in person unless the Chair determines that there is an exceptional circumstance mandating that meetings be held through another means. Individual use of videoconferencing, teleconferencing or other technologies to attend a meeting may be permitted by the Chair from time-to-time provided that a quorum is able to participate in an interactive manner in the REB's deliberations and decisions.

REB decisions will be made by majority vote of the REB members present at a convened Board meeting, with the exception of those who have recused themselves due to conflict of interest. Whenever possible, consensus will be sought.

The REB is entitled to invite researchers to a meeting to discuss a proposal under review. The REB shall accommodate reasonable requests from researchers to attend a meeting to discuss a proposal under review or that was reviewed by the REB. Researchers shall not be present when the REB is deliberating (i.e., making a decision).

The REB is entitled to seek input from ad hoc reviewers at its discretion. The REB is entitled to have observers attend REB meetings at the discretion of the Chair. All observers are required to sign a confidentiality agreement.

## **GENERAL TERMS**

Each REB member is responsible to identify any conflicts of interest that he or she may have with respect to the REB's deliberations and to declare any such conflicts to the Chair. Where appropriate or if requested by the Chair, such REB member shall remove him or herself from the applicable deliberations. The minutes should reflect that a Conflict of interest was declared and whether the REB member removed him or herself from the deliberations.

Each REB member has the responsibility to respect the confidentiality of the proposals and submission materials as well as the REB's deliberations.

Approved by the Unity Health Board of Directors on 15 March 2022.