Health Research Ethics Board (HREB) Terms of Reference

The Tasks of the HREB

- To ensure the ethical and scientific acceptability of health research involving human subjects conducted by researchers – physicians, faculty, students, members of health agencies – with participants living in Newfoundland and Labrador.
- To approve, reject, comment on and make recommendation for modification of research projects to meet the appropriate ethical and scientific standards.
- To provide, through the Health Research Ethics Authority (HREA), opportunities to researchers and research support staff for education in the ethical conduct of research.

Guiding Principles

In reaching a decision the HREB will follow the guidelines provided in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) and the ICH-Good Clinical Practice Guidelines (ICH-GCP) and other guidelines or standards approved by the HREA. Copies of guidelines may be obtained from the Ethics Office by emailing info@hrea.ca or accessed from the HREA website: www.hrea.ca.

Appointment of the HREB

The members of the HREB shall be appointed by the HREA following consultation with the Minister of Health and Community Services, the President of Memorial University and the Chief Executive Officer of the Eastern Regional Health Authority.

The HREA shall be guided by the principles respecting the appointment of members to a Research Ethics Board (REB) contained in TCPS2. The HREB shall comprise not fewer than 10 members.

Committee Structure of the HREB

The HREB will have two subcommittees responsible for reviewing health research protocols:

- HREB-CT: A subcommittee responsible for reviewing clinical trials
- HREB-NCT: A subcommittee responsible for reviewing all health research other than clinical trials

The HREA shall appoint one of the members of the HREB subcommittee as the Chair who shall oversee the work of that subcommittee. The Chair will have had extensive research experience and will normally have served at least three years on a TCPS2 compliant REB. One of the Chairs will sit as an ex-officio member of the HREA Board. The Vice-Chair is appointed by the HREA from among the members of the HREB subcommittee on the recommendation of the Chair and Ethics Officer.

The membership of each sub-committee will be drawn from the membership of the HREB and will be constituted based on TCPS2 guidelines.

Each subcommittee will have a dedicated staff person who will manage the business of the subcommittee and who reports to the Ethics Director.

Membership

Voting Members

Each subcommittee shall have:

- at least two persons who have experience in the conduct of health research involving human subjects governed by the HREB
- at least one person knowledgeable in ethics
- at least one person knowledgeable in the law related to health research involving human subjects
- at least one person to represent the general public

The majority of the HREB members will be Canadian citizens or permanent residents; both men and women must be represented.

Some members may represent more than one core constituency, e.g. a lawyer with experience as a health researcher. Members may be appointed to share a position. No more than two members with specific expertise may be appointed to share a position for alternate attendance at meetings.

Ex-officio Members

Ex-officio members attending meetings by virtue of their position may participate in discussion but do not vote.

Examples of Ex-officio members include:
Ethics Officer
Privacy Representative

Term of Appointment

The term of appointment for HREB members, the Chair and Vice Chair will comply with Article 6.6 of TCPS2. Terms of members and their rotation will balance the need to maintain continuity with the need to ensure diversity of opinion, and the opportunity to spread knowledge and experience gained from HREB membership. Initial appointments to the HREB will be for one, two or three years to ensure overlap of membership. Appointments may be renewed for additional terms.

Responsibilities of HREB Members

Members of the HREB are expected to:

- attend orientation and information sessions
- successfully complete the TCPS2 tutorial within three months of appointment
- sign an Oath of Confidentiality
- attend meetings regularly
- review all studies assigned to full review
- participate in functions related to the work of the HREB

Frequent unexplained absences from HREB meetings without prior notice to the staff of the Ethics Office or failure to meet the outlined responsibilities of an HREB member may be construed as a notice of resignation. If discussions with the member fail to resolve the issues outstanding, a letter of dismissal will be sent to the member by the Chair of the HREA.

Ad hoc Advisors

Ad hoc advisors may be invited to attend HREB meetings to contribute specific expertise to meeting discussion.

The HREB subcommittees, at their discretion, may co-opt persons on an ad hoc basis to review or provide scientific opinion or advice on a specific application requiring special expertise. These persons need not have experience on a REB. These persons neither vote nor participate in HREB deliberations. Their attendance will be noted in the minutes.

Observers at Meetings

Observers may attend HREB meetings with the permission of the Chair. Normally, observers will not attend more than six consecutive meetings. Observers do not vote or participate in HREB deliberations.

Working and Advisory Groups

The HREB may ask persons with special expertise and experience to serve on working or advisory groups to assist the HREB. At least one current or past member of a TCPS2- compliant REB must be part of any such group. These groups will report in writing to the Ethics Officer.

Professional Development

The Ethics Officer will provide orientation to HREB members. All members are required to successfully complete the TCPS2 training module and will be expected to attend seminars, workshops and educational sessions addressing relevant issues.

Oath of Confidentiality

All members of the HREB and any observers attending meetings are required to have a signed Oath of Confidentiality on file in the Ethics Office.

Conflict of Interest or Bias

HREB members are in clear conflict of interest or may have a bias when, for example, their own research projects are under review by the HREB or when they have been in direct academic conflict or collaboration with a researcher whose proposal is under review; HREB members must withdraw from the meeting when such projects are under consideration.

The minutes of the meeting must state that the member was absent from the meeting for both the discussion and voting with respect to any relevant project.

Compensation of HREB Members

The members of the HREB shall serve without remuneration but may be reimbursed for their travel and other expenses incurred as a member of the HREB on a scale approved by the Minister.

The Chair and Vice Chair of the HREB, in addition to reimbursement of their travel and other expenses, shall be compensated for carrying out their duties on a scale approved by the Minister.

Liability of Members

The members of the HREB are not personally liable for anything done or omitted to be done in good faith while carrying out their duties as a member of the HREB. HREB members are provided liability insurance through the HREA.

Meetings

Meetings of each HREB subcommittee will be held every other week throughout the year totaling approximately 24 meetings of each HREB subcommittee. Typically there is a one meeting break during the summer.

Quorum and Required Constituencies

A quorum shall be in accordance to the TCPS2 minimum requirements of membership representation. The quorum for a meeting should include a member knowledgeable in ethics, at least two members who have expertise in relevant research disciplines, fields and methodologies covered by the HREB, a member who is knowledgeable in the relevant law and a community member. The quorum must include two clinicians on the clinical trials subcommittee.

Decisions

The HREB arrives at its decisions by vote. The Chair of each HREB subcommittee facilitates the meeting and ensures all relevant issues are discussed. The Chair votes in the case of a tied decision.
The decisions of the HREB are promptly reported to the researcher and relevant agencies.

Delegated Review

Where research projects are considered to be of minimal risk in accordance with the TCPS2, the application may be sent for delegated review. The Chair will invite one or more current or past members of the HREB to provide delegated review for that application. The decision of this delegated review is provided to the HREB-NCT subcommittee at the next full board meeting. If ethical concerns are raised by a delegated reviewer, the application will be sent to the HREB-NCT subcommittee for review, discussion, and vote. Notifications of approvals follow the process outlined for decisions of the HREB.

Appeals

Decisions of the HREB may be appealed to an Appeal Board as per the HREA legislation and TCPS2 recommended procedures. The Appeal Panel is appointed by the HREA from among past members of the HREB, the Human Investigations Committee (HIC) or a TCPS2-compliant REB. The HREA will appoint a member of the Appeal Panel as Chair. When an appeal is lodged, the Chair of the Appeal Panel shall

appoint an Appeal Board consisting of 5 members of the Panel to review the decision of the HREB or research ethics body approved by the HREA. The constitution of the Appeal Board will comply with TCPS2 guidelines. The terms of appointment are the same as those for the HREB.

Annual Report

An annual report of the activities of the HREB shall be sent to the HREA not later than September 30 in a calendar year for inclusion in the report from the HREA to the Minister of Health and Community Services, the President of Memorial University and the Chief Executive Officer of Eastern Regional Health Authority. The HREB report will include the names of members, their constituencies and terms of office; number of meetings held; number of applications submitted in the categories of new, renewal and amendment; number of applications sent for delegated and full board review; number of approvals in each category; number of applications by type, setting, data sources, status of principal investigator; meetings and educational events organized by the HREB.