

# 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, opportunities to researchers and research support staff for education in the ethical conduct of research.

## Guiding Principles

In reaching a decision the Health Research Ethics Board will follow the guidelines provided in *Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans* and *ICH-Good Clinical Practice* and other guidelines or standards approved by the Health Research Ethics Authority (HREA) for the purpose. Copies may be obtained from the Office of Research and Graduate Studies (Medicine) or from the HREA website: [www.hrea.ca](http://www.hrea.ca)

The guiding ethical principles are:

- respect for the autonomy of person
- free and informed consent
- respect for justice and inclusiveness
- ensuring privacy and confidentiality
- balancing of risks and benefits

## Appointment of the Committee

The members of the HREB shall be appointed by the Authority 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 Authority shall be guided by the principles respecting the appointment of members to a Research Ethics Board 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 committee responsible for reviewing clinical trials of drugs and devices
- HREB-NCT: A committee responsible for reviewing all research other than clinical trials of drugs and devices

The Chair and Vice-Chair will serve as the chairs of each of the subcommittees. The Chair of the HREB is appointed by the HREA from among the clinical research members of the HREB and will have had extensive research experience, expertise in clinical practice and pharmaceuticals and will normally have served at least three years on a TCPS-compliant research ethics board; he/she sits as an *ex-officio* member of the HREA board. The Vice-Chair is appointed by the HREA from among the researcher members of the HREB on the recommendation of the Chair and Ethics Officer and serves as the chair of the HREB-NCT subcommittee.

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 (ethics coordinator) who will manage the business of the committee and who are directly responsible to the Ethics Officer.

## **Membership**

### ***Voting Members***

Each subcommittee shall have:

- at least two persons who have experience in the conduct of the human health research 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
- at least one person whose primary experience and expertise are in a non-scientific discipline

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 non-science credentials. 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.

Members of the HREA Board  
Ethics Officer  
Manager of the Patient Research Centre

### **Term of Appointment**

The term of appointment for members, the Chair and Vice Chair will normally be not more than three years. Appointments may be renewed for one term. Initial appointments to the HREB will be for one, two or three years to ensure overlap of membership. Members who have served two consecutive terms may be reappointed to the Committee after a period of one year without membership on the Committee.

### **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 REO 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. They do not vote. Their attendance will be noted in the minutes.

The research ethics review subcommittees of the HREB, at their discretion, may also 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 Research Ethics Board. These persons neither vote nor participate in HREB

deliberations. A list of persons co-opted on an *ad hoc* basis and the dates of the meetings they attend will be retained in the REO.

### **Observers at Meetings**

Observers may attend HREB meetings with the permission of the Chair but, normally, they 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 Board. Current or past members of a TCPS2- compliant Research Ethics Board (REB) will form the majority of any such group. These groups will report in writing to the full HREB.

### **Professional Development**

The HREB Chair and EO 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 REB 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 his or her duties as a member of the HREB. HREB members are provided liability insurance through the HREA.

### **Meetings**

Meetings of each subcommittee will be held every other week throughout the year totaling approximately 24 meetings of each subcommittee with a one meeting break in August or September. Special meetings may be called by the Chair or Vice-Chair and may be requested by any member of the Committee.

### **Quorum and Required Constituencies**

A quorum shall be 50% + 1 of the current voting membership of each subcommittee. The quorum for a meeting should include a member knowledgeable in ethics, members knowledgeable to review the science, a lawyer and a lay member. The quorum must include a clinician if applications for clinical trials are being reviewed.

### **Decisions**

The Committee arrives at its decisions by vote. The chair of each 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 Committee are promptly reported to the Investigator and relevant agencies.

### **Expedited Review**

Where research projects are considered by the Chair to be of minimal risk in light of the Tri-Council Policy Statement<sup>2</sup>, the application may be sent for expedited review. The Chair will invite two current and/or past members of the Committee to function for the Committee in providing expedited review for that application. The decision of this review subcommittee is provided to the full Committee. If ethical concerns are raised by any one of the three reviewers, the application will be sent to the full Committee for review, discussion, and vote. Notifications of approvals follow the process outlined for decisions of the full Committee.

## **Appeals**

Decisions of the Committee may be appealed to the standing Appeals Panel as per TCPS2 recommended procedures. The Appeals Panel is appointed by the Health Research Ethics Authority from among past members of the HREB, HIC or a TCPS2-compliant research ethics board. At least one member must be knowledgeable in ethics, one a lawyer and one a lay person. When an appeal is lodged, the Chair of the Appeals Panel will select from among its members, an Appeals Board to review the decision of the HREB or other authorized Research Ethics Body. The constitution of the 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 1 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 expedited and full 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.