

# Health Research Ethics Board (HREB) Terms of Reference

## Mandate of the HREB

The HREB ensures the ethical acceptability of health research involving human subjects as defined by the Health Research Ethics Act (HRE Act). The HREB renders a decision of *approve*, *approve subject to changes*, and *refuse to approve* upon review of ethics applications, in line with national and provincial ethics standards. The HREB is also responsible for the continuing review of all approved health research and the monitoring of research activities of persons engaged in health research.

## Guiding Principles

In reaching a decision, the HREB follows the guidelines provided in the HRE Act, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), the ICH-Good Clinical Practice Guidelines (ICH-GCP), and other guidelines or standards approved by the HREA.

## Appointment to the HREB

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

The HREA shall be guided by the principles respecting the appointment of members to a Research Ethics Board (REB) contained in the TCPS2 and the HRE Act. The HREB shall be comprised of not fewer than 10 members. The HREA shall consider gender diversity when appointing members to the HREB.

## Committee Structure of the HREB

The HREB will have three committees responsible for reviewing applications to conduct health research:

- HREB-Clinical Trials (CT): A committee responsible for reviewing clinical trials;
- HREB-Non-Clinical Trials (NCT): A committee responsible for reviewing all health research other than clinical trials and genetics/genomics research;
- HREB-Genetics/Genomics (GG): A committee responsible for reviewing genetics and genomics research

Please refer to Appendix A for details on the types of research that is reviewed by these three committees.

One or more member from each respective committee shall be designated as the Chairperson(s) or Co-Chairperson. The Chairperson(s) shall oversee the work of that committee.

## Chair HREB

The chairperson of the research ethics board shall be selected by a majority vote by all members of the research ethics board. The Chair HREB will sit as a non-voting member on the HREA Board of Directors. The Chair HREB may also hold the position of Chairperson of a committee.

The membership of each committee will be drawn from the membership of the HREB and will be constituted based on TCPS2 guidelines and the HRE Act. Each committee will have administrative support from Research Ethics Office (REO) staff personnel who will manage the business of the committee and who report to the Ethics Director.

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## Membership

### Appointed Voting Members

The HREB shall have members formally appointed in one capacity for each of the following membership categories:

- at least 2 persons who have experience in the conduct of health research;
- at least one person knowledgeable in ethics;
- at least one person knowledgeable in the law related to health research. This person must not be legal counsel or risk manager for the institution where the research will be conducted; and
- at least one person to represent the general public.

For each of the membership categories, two or more individuals may be appointed to fulfill a role. A member may be approved for more than one membership category. A member may sit on one or more committees. A member shall cast only one vote in the capacity assigned to them for the purpose of the committee meeting.

When appointing members of the HREB, consideration will be given to diversity including of race, gender, cultural backgrounds, research expertise, healthcare or professional experience, organizational affiliation, and sensitivity to such issues as community attitudes to assess the research submitted for review.

### Appointed Non-Voting Members

The HREB shall have a non-voting member formally appointed in the capacity of a person knowledgeable in privacy. The Privacy Representative will serve as a non-voting member of the HREB, providing expert guidance on the protection of personal and personal health information in the context of health research. The privacy member may simultaneously be assigned a voting role where formally approved in a dual role.

### Other Members

Other non-voting members attend HREB or committee meetings and may provide insight and guidance to the HREB. These members may participate in discussions but do not vote.

Examples of non-voting members include:

- REO staff personnel (e.g. Ethics Officer)

## Term of Appointment

The term of appointment for HREB members and the Chairperson(s) will comply with TCPS2 and the HRE Act. Terms of members and their re-appointment 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 throughout the members' organizations and the community. Initial appointments to the HREB will be for a term not exceeding three years. Appointments may be renewed for up to two additional three-year terms but shall not exceed a period longer than 9 consecutive years. A member whose term has expired continues to serve until reappointed or replaced.

## Responsibilities of HREB Members

Members of the HREB are expected to:

- attend orientation and information sessions, and maintain current knowledge about the HREB and research ethics review processes;
- successfully complete the TCPS2 tutorial within three months of appointment;

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- sign and abide by a Confidentiality of Information and Conflict of Interest Agreement;
- attend HREB meetings regularly;
- review all applications to conduct health research assigned to them, and be prepared to provide input at a meeting, and;
- participate in activities related to the work of the HREB, such as policy review and revisions to HREB application documents.

Frequent unexplained absences from HREB meetings without prior notice to the staff of the REO, or material failure to meet the outlined responsibilities of an HREB member, may constitute ceasing to function as a member of the HREB. If discussions with the member fail to resolve issues relating to an HREB member's attendance or performance, the Chairperson HREB shall discuss the matter with the Chairperson of the HREA.

The Chairperson of the HREA may determine that an HREB member has ceased to function as a member of the HREB. In that case, the HREB member will be advised in writing. The HREA will appoint a person as a replacement HREB member for the remainder of the term of the person being replaced.

### Ad hoc Advisors

The HREB may consult ad hoc advisors in the event that it requires specific expertise or knowledge, in addition to that held by its appointed members, to adequately review the ethical acceptability of an application to conduct health research.

Ad hoc advisors are consulted for a specific research ethics review and for the duration of that review. While ad hoc advisors may complement the HREB through their experience, knowledge or expertise, their input is a form of consultation that may or may not be relied upon in the final decision of the HREB. Consultation with an ad hoc advisor shall not alter the composition and representation of the HREB.

An ad hoc advisor is not a member of the HREB, and shall not cast a vote, or be counted for the purpose of determining whether quorum requirements under TCPS2 have been met. Their attendance at an HREB meeting will be noted in the meeting minutes.

### Observers at Meetings

Observers may attend HREB meetings with the permission of the presiding Chairperson. Observers will not vote or participate in HREB deliberations.

Examples of observers at meetings include:

- new HREB members in training
- students (e.g. Master of Health Ethics Program)

### 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.

### Professional Development

The Ethics Officer(s) will provide orientation to newly appointed HREB members. All members are required to successfully complete the TCPS2 (2022) training module and remain current on applicable policies and procedures provided by the HREA staff. HREB members are encouraged to avail of continuing education relevant to the HREB.

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## **Conflict of Interest**

HREB members will comply with HREA and HREB policies and SOPs, including with respect to conflict of interest.

## **Compensation of HREB Members**

As per the HRE Act, 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 Chairperson(s) of the HREB or its committees, in addition to reimbursement of their travel and other expenses, shall be compensated for carrying out their duties in the manner and amount agreed to by the Minister and the Chairperson.

## **Liability of Members**

A member of the HREB, including a Chairperson, or a person advising the HREB is not personally liable for anything done or omitted to be done in good faith while carrying out their duties under the HRE Act. HREB members are provided liability insurance through the HREA.

## **Meetings**

Meetings of each HREB committee will be held every other week throughout the year or as necessary. Any break in the meeting schedule would be contingent on the HREB meeting legislated review timelines as per subsection 10(5) of the HRE Act.

## **Quorum**

A quorum of the HREB shall be constituted in accordance with the minimum conditions of constituting a quorum contained in the TCPS2 and the HRE Act. The quorum for a meeting shall 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 law related to health research involving human subjects, and at least one person to represent the general public.

Ad hoc advisors, observers, REO staff personnel attending HREB meetings will not be counted in the quorum for the HREB, nor allowed to vote on HREB decisions. No decisions of the HREB may be made in the absence of a quorum.

## **Decisions**

HREB decisions are made either by consensus or a majority vote of the HREB members present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict of interest policies.

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

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## **Delegated Review**

Where applications to conduct health research are considered to be of minimal risk in accordance with the TCPS2, the application may be sent for delegated review as described in SOP #302. Delegated reviewers or the Chairperson may call on other reviewers within the HREB, or refer an application back to the full HREB if they determine that full board review is required. The outcome of any delegated reviews is provided to the relevant HREB committee at its next meeting.

Where delegated reviewers consider a refusal to approve decision, the application shall be referred to the full board of the relevant HREB committee for review and final decision. Notifications of approvals follow the process outlined for decisions of the HREB.

## **Summary Review of research approval from a Qualifying Research Ethics Body**

Where an application to conduct health research has already been approved by a Qualifying Research Ethics Body (See Policy HREB-03), the application may be eligible to undergo a summary review process. The particulars of the summary review process will be determined by the HREB in accordance with the risk profile of the proposed research, and it shall be carried out in accordance with TCPS2.

The HREB will fulfill its responsibility by indicating and documenting their acceptance of the reviewing REB's decision and retaining all documentation arising within the summary review process, including the Qualifying REB's approval letter(s) and research ethics application materials.

A summary review will result in the HREB issuing a decision of approve, refuse to approve, or approve subject to conditions.

## **Monitoring and Review of Ongoing Health Research**

The HREB is responsible for monitoring health research being conducted in Newfoundland and Labrador. The health research within the HREB's monitoring mandate is all research which has been approved by the HREB, and all minimal risk health research of which the HREA has been notified and an acknowledgement provided [See HREA Policy GEN-05].

The HREB may appoint one or more of its members, or another person, to conduct a review of record keeping, research methodology, conduct towards human research participants, or research results relating to a health research project. The results of a review will be provided to the Chairperson, who may direct that it be provided to the HREB for consideration at an HREB meeting.

The HREB may cancel, or suspend pending correction of deficiencies, a health research project where it is of the opinion that the health research being conducted does not conform to the approved health research project; record keeping is inadequate; the research methodology being applied is not in keeping with the approved methodology; or conduct towards human participants is improper.

## **Annual Report**

An annual fiscal year report of the activities of the HREB shall be prepared for the HREA not later than June 30 annually. The HREB will report on the activities of the HREB including membership, workload and other related activities.

These Terms of Reference will be reviewed September 15, 2026 to ensure accuracy and every three years thereafter.

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### Appendix A

Examples of research reviewed by the three HREB committees:

Clinical Trials Committee	Genetics/Genomics Committee	Non-Clinical Trials Committee
Medical device trials	Genetics research, including cancer genetics	Epidemiological observational research
Natural Health Product Trials	Genomics research	Qualitative research
Pharmaceutical trials	Human microbiome research	Secondary use research
Psychotherapy trials	Transcriptome research	Medical Education research
Surgical trials	Epigenomic/Epigenetic research	
	Proteome research	

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### **HREB-CT – This committee will review clinical trial research.**

**Clinical Trials:** any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes. Interventions include, but are not restricted to, drugs, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products (NHPs), process-of-care changes, preventive care, manual therapies, and psychotherapies. Clinical trials may also include questions that are not directly related to therapeutic goals (e.g., drug metabolism) in addition to those that directly evaluate the treatment of participants.(TCPS2)

Examples:

- **Medical device trial** – A clinical trial that tests the safety and/or efficacy of one or more instruments used in the prevention, diagnosis, mitigation, or treatment of a disease or abnormal physical condition, or in the restoration, correction or modification of body function or structure. (e.g. Pacemaker, ICD, hip implant, MRI machine)
- **Natural Health Product (NHP) trial** – A clinical trial testing the safety and/or efficacy of one or more natural health products (e.g. vitamins and minerals, herbal medicines, homeopathic preparations, energy drinks, probiotics, and many alternative and traditional medicines).
- **Pharmaceutical trial** – A clinical trial designed to test the safety and/or efficacy of a pharmaceutical product.
- **Psychotherapy trial** – A clinical trial testing the safety and/or efficacy of one or more psychotherapeutic approaches to behavioural disorders or other mental illness.
- **Surgical trial** – A clinical trial that compares the safety and/or efficacy of different surgical techniques.

### **HREB-GG – This committee will review all health research related to human genetics, genomics, and other related research (e.g. human microbiomics, transcriptomics, epigenomics and proteomics).**

Human genetic research involves the study of genetic factors responsible for human traits and the interaction of those factors with each other, and with the environment. It includes the identification of genes that comprise: the human genome; functions of genes; the characterization of normal and disease conditions in individuals, biological relatives, families, communities and groups; and studies involving gene therapy. (TCPS2)

- **Genetics** - the study of heredity.
- **Genomics** - the study of genes and their functions, and related techniques.

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- The **main difference** between genomics and genetics is that genetics scrutinizes the functioning and composition of the single gene, whereas genomics addresses all genes and their inter relationships in order to identify their combined influence on the growth and development of the organism. (WHO)

**HREB-NCT** - This committee will review health research that is outside the scope of the HREB-CT and HREB-GG. Examples include:

- **Epidemiological observational research** – An epidemiological study that does not involve any intervention by the researcher. Such a study may be one in which nature is allowed to take its course, with changes in one characteristic being studied in relation to changes in other characteristics.
- **Qualitative research** – An approach that aims to understand how people think about the world and how they act and behave in it. This approach requires researchers to understand phenomena based on discourse, actions, and documents how and why individuals interpret and ascribe meaning to what they say, what they do, and to other aspects of the world (including other people) they encounter.
- **Secondary use research** - refers to the use in research of information originally collected for a purpose other than the current research purpose, but then re-used to answer other research questions. Examples include health care records, school records, biological specimens, vital statistics registries or unemployment records, all of which are originally created or collected for therapeutic, educational or administrative purposes, but which may be sought later for use in research.
- **Medical Education research** – refers to research related to health education (e.g. curriculum development in nursing or medicine).

Approved by HREA Board of Directors August 21, 2025  
Adopted by HREB September 15, 2025