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 Authority Act (HREA 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 HREA 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 HREA Act. The HREB shall be comprised of not fewer than 10 members.

Committee Structure of the HREB

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

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

The HREA shall appoint one or more of the members of the HREB subcommittee as the Chairperson(s) who shall oversee the work of that subcommittee. Each subcommittee may have more than one Chairperson. One of the Chairpersons will sit as an ex-officio member on the HREA Board of Directors.

The membership of each sub-committee will be drawn from the membership of the HREB and will be constituted based on TCPS2 guidelines and the HREA Act. Each subcommittee will have administrative support from Research Ethics Office (REO) staff personnel who will manage the business of the subcommittee and who report 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
- at least one person knowledgeable in ethics

- at least one person knowledgeable in the law related to health research involving human subjects. This person must not be legal counsel or risk manager for the institution where the research will be conducted
- at least one person to represent the general public
- one (1) member who is primarily experienced in non-scientific disciplines
- The membership will include consideration of race, gender, cultural backgrounds, research, healthcare or professional experience, organizational affiliation, and sensitivity to such issues as community attitudes to assess the research submitted for review. Members may be appointed to share a position.

Non-voting Members

Non-voting members attend meetings by virtue of their position and 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)
- Privacy representative

Term of Appointment

The term of appointment for HREB members and the Chairperson(s) will comply with TCPS2 and the HREA Act. 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 throughout the members' organizations and the community. 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 Confidentiality of Information and Conflict of Interest Agreement;
- attend HREB meetings regularly;
- review all applications to conduct health research assigned to full board review and be prepared to provide input at the meeting;
- review applications to conduct health research assigned via the delegated review process (if applicable); 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 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 Chairperson of the HREA Board of Directors.

Ad hoc Advisors

The HREB may consult ad hoc advisors in the event that it requires further specific expertise or knowledge to competently 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 considered in the final decision of the HREB.

Consultation with an ad hoc advisor shall not alter the composition and representation of the HREB. Ad hoc advisors will not be counted in the quorum for the HREB, nor allowed to vote on HREB decisions. Their attendance at full board meetings will be noted in the meeting minutes.

Observers at Meetings

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

Examples of observers at meetings include:

- new 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 HREB members. All members are required to successfully complete the TCPS2 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, when possible.

Conflict of Interest

HREB members will comply with HREA policies and SOPs regarding conflict of interest.

Compensation of HREB Members

As per the HREA 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, 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 or as necessary. Any break in the meeting schedule would be contingent on the HREB meeting their legislated review timelines as per subsection 9(4) of the HREA Act.

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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 HREA 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, a community member and a member who is primarily experienced in non-scientific disciplines.

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. Decisions without a quorum are not valid or binding.

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.

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 REB or refer projects back to the full REB if they determine that full board review is required. The decision of delegated reviews is provided to the relevant HREB subcommittee at the next full board meeting.

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

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 report will report on the activities of the HREB including membership, workload and other related activities.

Appendix A

Examples of research reviewed by the three HREB subcommittees:

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	

HREB-CT – This committee will review all 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.

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HREB-GG – This committee will review 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.
- 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)