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| **TITLE** | **202: HREB Organization and Responsibilities of HREB Members** |
| **SCOPE** | The activities of the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA) |
| **APPROVAL AUTHORITY** | Ethics Director |
| **EFFECTIVE DATE** | April 2024 |

## 1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the organization and operations of the HREB to ensure continuity of membership and the expertise to meet guidelines, regulations and institutional mandates. It also describes the responsibilities of the HREB members.

## 2.0 DEFINITIONS

See the Glossary of Terms.

## 3.0 RESPONSIBILITIES

HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

The HREB Chairperson or designee is responsible for clearly articulating all required responsibilities associated with HREB membership to potential and current HREB members and for monitoring HREB membership.

HREB members are responsible for fulfilling their responsibilities as specified in this SOP.

## 4.0 PROCEDURE

HREB membership (e.g. appointments, terms) will meet applicable legislated and regulatory composition requirements and maintain the appropriate diversity, experience and expertise for the type and volume of research reviewed.

Each HREB member's primary responsibility is the protection of the rights and welfare of the individual human beings that are serving as the participants of research. In order to fulfill their responsibilities, HREB members are expected to be knowledgeable of the guidelines and regulations governing human participants' protection and research ethics, and the policies of the HREA germane to human participant protection.

## 4.1 Appointments and Terms of Duty

**4.1.1** HREB members will be appointed in accordance with the HREA Act, Section 7(1).

**4.1.2** HREB members will be appointed for a term not exceeding 3 years and are eligible to be reappointed. Terms will be overlapping to preserve the experience level, expertise, and continuity of the HREB.

**4.1.3** Community members (meeting membership requirements) will be solicited from the greater local community.

**4.1.4** The HREB Chairperson will be appointed in accordance with the HREA Act, Section 7(3).

**4.1.5** The HREB Chairperson will serve for a term mutually agreed by the HREA Board of Directors and the HREB Chairperson.

**4.1.6** HREB members and HREB Chairpersons will sign a letter of appointment and a *Confidentiality of Information and Conflict of Interest Agreement* upon appointment.

## 4.2 Responsibilities

**4.2.1** HREB members attending an HREB meeting will review the relevant materials submitted for each item under review or consideration by the HREB, prepare comments in advance of the meeting, and be prepared to discuss each agenda item and provide input at the Full Board HREB meeting.

**4.2.2** Each HREB member will fulfill specific responsibilities based on the role as outlined below. More than one HREB member may fulfill each role, though individuals who can fulfill more than one role shall not act in a dual capacity during the discussion and review of an application while attending a Full Board HREB meeting.

**4.2.3** **Scientific members:** Scientific members will contribute to the evaluation of the research on its ethical, scientific, and statistical merits and standards of practice. These members will advise the HREB if additional expertise in a scientific or non-scientific area is required to assess whether the research adequately protects the rights and welfare of participants.

**4.2.4** **Non-scientific members:** Non-scientific members will provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. Non-scientific members will advise the HREB if additional expertise in a non-scientific area is required to assess whether the research adequately, protects the rights and welfare of participants, and to comment on the comprehension of the consent document.

**4.2.5** **Community member(s):** Community members will provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective. Their primary role is to reflect the perspective of the research participant.

**4.2.6** **Member(s) knowledgeable in relevant law:** Members knowledgeable in relevant law will alert the HREB to legal issues and their implications, but not provide formal legal opinions nor to serve as legal counsel to the HREB.

**4.2.7** **Member(s) knowledgeable in ethics:** Members knowledgeable in ethics will guide the HREB in identifying and addressing ethics issues related to the research under review.

**4.2.8** **Ad hoc advisors:** Individuals with competence in special areas may be invited by the Chairperson of the HREB or designee to provide input on issues that require expertise beyond, or in addition to, that available on the HREB. The ad hoc advisor may be required to submit a written report and to participate via teleconference or to attend the HREB meeting to lend their expertise to the discussions.

**4.2.9** **HREB Chairperson:** The role of the HREB Chairperson is to provide overall leadership for the HREB. The Chairperson:

- represents the HREB in its interactions with applicants and researchers;
- fosters collaborative relationships and effective communication with HREB stakeholders including, but not limited to, HREB members, REO personnel, researchers, study sponsors, and government agencies;
- delegates responsibilities to the "Acting Chairperson", or to other qualified individuals, as necessary and appropriate;
- assists and promotes the "Acting Chairperson" in fulfilling their responsibilities;
- assists in the recruitment of HREB members;
- assists in the orientation of new HREB members, as required;
- ensures that applicable regulations, guidelines, policies and standards are consistently applied throughout the ethics review processes;
- works with the Ethics Director in updating HREB standard operating procedures (SOPs) and in the establishment of quality improvement mechanisms for the HREB.
- Determines exceptions to (SOPs) and reports such circumstances or decisions back to the HREB, REO and/or the HREA Board of Directors, as appropriate;
- is responsible for the overall quality of the ethics review, including full board HREB and delegated reviews;
- ensures that projects accepted for review are consistent with the HREB mandate;
- chairs the bi-weekly HREB meetings;
- ensures that, when a research application receives a full board review:
    - the reviewer(s) assigned by the REO have the appropriate experience and expertise;
    - the meeting does not proceed unless quorum is met and maintained, and the members in attendance collectively have the specific expertise, relevant competence, and knowledge necessary to provide an adequate research ethics review of the projects under consideration at that meeting;
    - any conflicts of interest are identified and managed appropriately;
    - all of the pertinent elements of an ethics review are considered during the HREB's deliberations;
    - all members are encouraged to participate in discussions of research projects under review;

  - when decisions are reached through a vote, the vote is conducted properly and in accordance with HREB SOPs; and
  - the minutes of the meeting are an accurate reporting of the meeting, revised as necessary, and approved by the HREB members;
- ensures that when a research application receives a delegated review, the HREB procedure for delegated review is followed;
- meets with researchers and organizational representatives, as required, in relation to projects submitted for initial and ongoing review;
- holds responsibility for all final decisions related to approvals of initial and ongoing ethics reviews for research projects overseen by the HREB;
- while respecting the integrity, confidentiality and independence of the ethics review process, communicates to the HREB, appropriate organizational representatives, and/or the HREA Board of Directors any matter that may be of concern to the responsible conduct of research by researchers;
- suspends the conduct of any research project deemed to place individuals at unacceptable risk pending discussion by the Full Board, or in which a researcher is not adhering to the HREB approved protocol or following the HREB's policies or procedures;
- participates in continuing education relevant to the HREB, when possible, with the expectation that information gained will be shared with the HREB, the REO, and other relevant parties; and
- serves as a resource for HREB members, REO personnel and researchers, and provides leadership and guidance in identifying opportunities for ongoing development and education of HREB members and REO personnel.

## 4.3 Primary and Secondary Reviewers

**4.3.1** **Primary and Secondary Reviewers:** HREB members with applicable expertise will act as a primary and/or secondary reviewer for assigned research projects at Full Board meetings. The primary and secondary reviewers will present their findings resulting from review of all of the HREB submission materials and provide an assessment of the soundness and safety of the research and recommend specific actions to the HREB. They will lead the discussion of the research project during the HREB meeting. The primary and secondary reviewers will review additional material(s) as requested by the HREB for the purpose of reaching a final review decision.

## 4.4 Training and Education

**4.4.1** HREB members will follow training and education procedures outlined in SOP 103.

## 4.5 Attendance

**4.5.1** HREB members are expected to attend the regularly scheduled HREB meetings.

**4.5.2** HREB members will notify the REO if they will be absent for an HREB meeting to ensure that quorum can still be met.

**4.5.3** HREB members will be available for the entire HREB meeting, not just the segments in which they have been assigned as reviewers.

## 4.6 Resignations and Removals

**4.6.1** An HREB member may resign before the conclusion of their term upon provision of notice to the HREB Chairperson or designee. The vacancy will be filled as quickly as possible.

**4.6.2** 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, will 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.

**4.6.3** The HREB Chairperson or designee, or HREA Board of Directors may otherwise remove an HREB member at any time, if they are not fulfilling their designated HREB responsibilities in a timely, competent and ethical manner.

**4.6.4** An HREB member shall resign immediately upon determination of research misconduct, mismanaged conflict of interest or any other relevant behavior that could be perceived as compromising their ethical judgment.

**4.6.5** Every effort will be made to recruit a similarly qualified replacement prior to the departure of a member to preserve the level of experience and expertise and to ensure the continuity of the functions of the HREB.

## 4.7 Compensation

**4.7.1** 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 responsibilities on a scale approved by the Minister.

## 4.8 Liability and Coverage

**4.8.1** HREB members are not personally liable for anything done or omitted to be done in good faith while carrying out their responsibilities as a member of the HREB.

## 4.9 Documentation

**4.9.1** The REO Personnel will maintain an updated electronic HREB membership list.

**4.9.2** The HREB membership list will be reviewed and updated as required, or with the initiation of new or conclusion/termination of existing terms.

**4.9.3** The current HREB membership list and archived lists are maintained and available through the

REO Office. The HREB membership list is also posted on the HREA's publicly accessible.

**4.9.4** CVs, other supporting documents related to education and expertise, signed members' letters of appointment and confidentiality agreements for all current and past HREB members will be maintained in the REO office.

**4.9.5** REO Personnel will maintain the HREB membership roster, which includes:

- names of HREB members;
- earned degrees;
- area(s) of expertise and organizational affiliation(s); and
- the representative capacity of HREB members:
  - role on the REB (e.g. scientific, nonscientific); and
  - indications of HREB members experience (such as board certification, licenses)

sufficient to describe each HREB member's chief anticipated contribution to HREB deliberations (as applicable).

**4.9.6** A detailed membership list will be maintained by the REO Personnel. This list will contain HREB member contact information and additional information on areas of expertise for the purposes of communication and reviewer assignment. It will be kept confidential for access only by HREB members and the REO Personnel.

**4.9.7** The HREB Chairperson or appropriately designated REO Personnel will update the HREB registration with the U.S. Office for Human Research Protection (OHRP) when applicable.

## 4.10 Conflict of Interest

**4.10.1** HREB members will follow HREA conflict of interest policies and procedures.

## 5.0 REFERENCES

*The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 6: https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

*Health Research Ethics Authority Act: An Act to Establish A Health Research Ethics Authority For The Province (2011).* Retrieved from: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)

*U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.107-109):* Electronic Code of Federal Regulations (eCFR)
*U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 50 (21 CFR 56.115(a)(5)):*
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.115

*Federalwide Assurance (FWA) for the Protection of Human Subjects:*
https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html