SOP Title	**Composition and Management of the HSREB**
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance	Erika Basile	Feb 19, 2025
Dr. Naveen Poonai Chair Health Sciences Research Ethics Board	Naveen Poonai	FEb 19, 2025

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the membership composition requirements of the Health Sciences Research Ethics Board (HSREB).

2. GENERAL POLICY STATEMENT

Each member of the HSREB must be qualified through training, experience and expertise to ascertain the acceptability of submitted research proposals in terms of ethical principles; and applicable regulations, guidelines and standards pertaining to human participant protection.

3. RESPONSIBILITY

This SOP applies to all HSREB members including the Chair, Vice-Chair(s) and to all Office of Human Research Ethics (OHRE) staff.

The HSREB Chair and Director or designee is responsible for ensuring that the composition of HSREB meets the applicable regulatory requirements.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

To promote complete and adequate reviews of the types of research commonly reviewed by the HSREB, the membership of the HSREB must include individuals with appropriate diversity. Therefore, selection of members must include consideration of race, gender, cultural backgrounds, professional expertise, clinical and research experience, scientific and non-scientific expertise, and sensitivity to such issues as community attitudes to assess the research submitted for review.

5.1. Selection of HSREB members

5.1.1. In the selection of HSREB members, equal consideration shall be given to qualified persons of both genders. No appointment shall be made solely on the basis of gender;

5.1.2. The HSREB will make every effort to include cultural and ethnic minorities to represent the population cared for by the research community, within the scope of available expertise needed to conduct its functions;

5.1.3. HSREB membership will not consist entirely of members of one profession;

5.1.4. HSREB members will be selected based on the needs of the HSREB as outlined below and per applicable regulations, guidelines and standards.

5.2. Composition of Members

5.2.1. The membership of the HSREB will be in compliance with Health Canada (Division 5, Part C.05.001 of the Food and Drug Act), Tri-Council Policy Statement (TCPS) on Ethical Conduct of Research Involving Humans (Article 1.3), The International Council on Harmonization Good Clinical Practices (ICH GCP 3.2.1), the Ontario Personal Health Information Protection Act (PHIPA) (S. 15), U.S. Food and Drug Administration Code of Federal Regulations (US FDA CFR 56.107) and Office for Human Research Protections (OHRP) (46.107);

5.2.2. The HSREB Chair and Director or designee will monitor the HSREB membership composition for appropriate membership in relation to the volume of protocol submissions;

5.2.3. The HSREB will include at least five members,

- At least two (2) members who have expertise in relevant research disciplines, field and methodologies covered by the HSREB (for biomedical clinical trials, this will include at least one member who practices medicine or dentistry and who is in good standing with their regulatory body;
- At least one (1) member who is primarily experienced in non-scientific disciplines;
- at least one (1) member knowledgeable in ethics;
- at least one (1) member knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research;
- at least one (1) community member who has no affiliation with the institution;
- at least one (1) member who is knowledgeable in considering privacy issues;
- additional representation as required by applicable legislation or guidelines.

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

5.2.4. A member may not fulfill more than two representative capacities or disciplines;

5.2.5. Members will include men and women, a majority of whom are Canadian citizens or permanent residents and who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed research;

5.2.6. The HSREB should consist of broad representation from across therapeutic areas and include physicians, nurses/health care professionals with clinical and/or research experience, informed community members, and members with expertise in research ethics, relevant law, privacy legislation and may consist of other related disciplines such as pharmacy, epidemiology and biostatistics.

5.2.7. Membership, when regularly required, for the review on topics related to Indigenous peoples or affecting Indigenous communities, should include a member with relevant and competent knowledge and expertise in Indigenous cultures, or the inclusion of an ad hoc advisor for occasional review.;

5.2.8. Additional membership as required by applicable legislation or guidelines

5.3. Alternative Members

5.3.1. The HSREB Chair or designee may ask an alternate HSREB member to attend an HSREB meeting to draw on his/her expertise in an area that may be relevant to that meeting's deliberations, or to establish a quorum for that meeting in the absence of the regular HSREB member;

5.3.2. Only alternate HSREB members of comparable qualifications may substitute for an HSREB member (a non-scientific member may not substitute for a scientific member);

5.3.3. The minutes shall document when an alternate HSREB member replaces a primary HSREB member.

5.4. HSREB Chair and Vice Chair

5.4.1. Whenever possible and practicable, the HSREB Chair will be selected from experienced HSREB members who have expressed interest in becoming the HSREB Chair and who are familiar with the applicable regulations and guidance documents;

5.4.2. The term of office of the HSREB Chair is 3 years and is renewable;

5.4.3. An HSREB member is appointed by the HSREB Chair to serve as Vice Chair. The role of Vice Chair is to assume the duties of the HSREB Chair in the HSREB Chair's absence;

5.4.4. The OHRE staff updates the HSREB membership roster and OHRP registration, if applicable, to reflect this change.

5.4.5. The HSREB Chair and Vice-Chair will be asked to sign a Confidentiality of Information and Conflict of Interest Agreement.

5.5. Appointment –HSREB Members

5.5.1. The HSREB will appoint its members based on nomination from current HSREB members and from the ORE. A candidate may also self-nominate;

5.5.2. When an individual is nominated or expresses interest in serving on the HSREB, a copy of their *curriculum vitae* (CV) will be requested as well as a copy of their TCPS2 training certificate;

5.5.3. The HSREB Chair may review the CV (e.g., external candidate such as community member, lawyer) and with the potential candidates before his/her appointment.

5.5.4. Candidates selected to serve on the HSREB will be asked to sign a letter of appointment and a Confidentiality of Information and Conflict of Interest Agreement.

5.5.5. If during the review of a protocol at a full board meeting any member of the HSREB has a Conflict of Interest with that submission they will leave during the discussion of that submission.

5.6. Ad Hoc Advisors

5.6.1. At his/her discretion, the HSREB Chair or designee may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the HSREB;

5.6.2. The ad hoc advisor may be asked to provide a written report and to participate via teleconference, or to attend the meeting to lend his/her expertise to the discussions;

5.6.3. All consultants shall sign a Confidentiality and Conflict of Interest Agreement;

5.6.4. These individuals may not contribute to the HSREB's decision and their presence or absence shall not be used in establishing a quorum;

5.6.5. Documentation of key information provided by consultants shall be summarized in the HSREB minutes and if available, the written report shall be placed in the specific study's HSREB file in the ORE.

5.6.6. Ad Hoc advisors will be asked to sign a Confidentiality of Information and Conflict of Interest Agreement.

5.7. Observers at HSREB Meetings

5.7.1. HSREB may allow observers to attend its meetings;

5.7.2. Observers shall sign a Confidentiality and Conflict of Interest Agreement;

5.7.3. Where the Board finds that an observer qualifies as an expert in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to the discussion;

5.7.4. Observers shall not participate when the Board discusses its decision, reaches consensus or votes on the application;

5.7.5. The minutes will reflect the presence of any observers as well as his/her expertise and contribution, when applicable.

5.8. Terms of Appointment

5.8.1. Each HSREB member will serve for renewable terms of three years for a maximum 3 consecutive terms. A member may retire for 1 year and then be eligible for reappointment. Under special circumstances the HSREB Chair and the VPR may appoint a member without a retirement year;

5.8.2. Terms will be overlapping to preserve experience and continuity of function of the HSREB.

5.9. Resignations and Removals

5.9.1. An HSREB member may resign before the conclusion of his/her term upon provision of notice to the HSREB Chair;

5.9.2. Members may be asked to step down if they consistently miss more than 25% of the HSREB meetings in which they are scheduled to attend;

5.9.3. The HSREB Chair may otherwise remove members if they are not fulfilling their duties;

5.9.4. Every effort will be made to recruit a similarly qualified replacement prior to the departure of a member to preserve experience and continuity of function of the HSREB.

5.10. Compensation

5.10.1. HSREB members may be reimbursed for parking and other miscellaneous expenses associated with full HSREB meeting attendance;

5.11. Documentation and Posting of the HSREB Membership List

5.11.1. The ORE staff will maintain an updated electronic HSREB membership list;

5.11.2. The HSREB membership list is reviewed and updated as required or with the initiation of new or conclusion/termination of existing terms. The effective date of the updated HSREB membership list will be consistent with an HSREB full board or convened meeting date;

5.11.3. The ORE staff forwards the updated Public HSREB Membership List to Communications at Western University for posting on the ORE web pages. The list includes name, discipline, constituency, gender and citizenship/residency status for all members;

5.11.4. A detailed membership list will be stored and locked in the ORE. This list will contain member contact information. It will be kept confidential for access by HSREB members and ORE staff;

5.11.5. The ORE staff will maintain the HSREB registration with the US OHRP.

5.11.6. The ORE staff updates the HSREB membership roster and OHRP registration to reflect any membership changes. OHRP will be notified within 90 days of any change. Previous versions will be archived;

6. REFERENCES

1. Health Canada (Division 5, Part C.05.001 of the Food and Drug Act);
2. Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans (TCPS), Article 1.3;
3. Ontario Personal Health Information Protection Act (PHIPA), S.15;
4. The International Conference on Harmonization Good Clinical Practices, Section 3.2.1;
5. US Office for Human Research Protections 45 Code of Federal Regulations Title 46.107;
6. US Food and Drug Administration Code of Federal Regulations Title 21 Part 56.107
7. FDA Information Sheets, FAQ Section II, Questions 14 and15

SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
201.001	original	01/20/2014
201.002	Added section 5.3.5 The REB Chair is retained as a consultant under an agreement with the VP Research at Western University and receives a stipend for the time associated with his/her REB duties Section 5.6.1 revised for clarity Minor formatting and grammatical corrections for clarity	04/09/2014
201.003	Added section 5.10.2	07/29/2014

	Administrative changes	
201.004	Addition of 5.2.3.4 Revision to 5.8.2	08/13/2014
201.005	Revisions to sections 5.3-5.6 and 5.9	10/22/2014
201.006	Minor Administrative Changes	05/11/2016
201.007	Administrative Changes Addition of 5.2.2	06/22/2018
201.008	Minor Administrative Changes	09/06/2018
201.009	Minor Administrative Changes; Revision to section 5.2.8	02/21/2020
201.010	Minor Administrative changes; updates to sections 5.5.1 and 5.5.3	01/27/2022
201.011	Revision to 5.2.3 to specify that for research subject to the US Code of Federal Regulations, quorum shall also include a majority (50%+1) of voting members.	02/19/2025