



SOP Title	Composition and Management of the NMREB
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
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1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the membership composition requirements of the Non-Medical Research Ethics Board (NMREB).

2. GENERAL POLICY STATEMENT

Each member of the NMREB 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 NMREB members including the Chair, Vice-Chair(s) and to all Office of Research Ethics staff.

The NMREB Chair and Director or designee is responsible for ensuring that the composition of NMREB 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 NMREB, the membership of the NMREB must include individuals with appropriate diversity. Therefore, selection of members must include consideration of race, ethnicity, gender, cultural backgrounds, professional expertise, clinical and research experience, and sensitivity to such issues as community attitudes to assess the research submitted for review.

5.1. Selection of NMREB members

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

5.1.2. The NMREB 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. NMREB membership will not consist entirely of members of one profession;

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

5.2. Composition of Members

5.2.1. The membership of the NMREB will be in compliance with the Tri-Council Policy Statement (TCPS) on Ethical Conduct of Research Involving Humans (Article 1.3) and Office for Human Research Protections (OHRP) (46.107);

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

5.2.3. The NMREB will include at least five members,

- At least two members who have expertise in relevant research disciplines, field and methodologies covered by the NMREB;
- at least one member knowledgeable in ethics;
- at least one member knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager);
- at least one community member who has no affiliation with the institution

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 methodology and ethics of the proposed research;

5.2.6. The NMREB should consist of broad representation from across disciplines with research experience, informed community members, and members with expertise in research ethics, relevant law and privacy legislation;

5.2.7. At least one member, when possible, who is from an identifiable Aboriginal community or Native center, when the NMREB reviews research that recruits participants from that community;

5.2.8. Additional membership as required by applicable legislation or guidelines

5.3. Alternative Members

5.3.1. The NMREB Chair or designee may ask an alternate NMREB member to attend an NMREB 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 NMREB member;

5.3.2. Only alternate NMREB members of comparable qualifications may substitute for an NMREB member;

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

5.4. **REB Chair and Vice Chair**

- 5.4.1. Whenever possible and practicable, the NMREB Chair will be selected from experienced NMREB members who have expressed interest in becoming the NMREB Chair and who are familiar with the applicable regulations and guidance documents;
- 5.4.2. The term of office of the NMREB Chair is 3 years and is renewable;
- 5.4.3. An NMREB member is appointed by the NMREB Chair to serve as Vice Chair. The role of Vice Chair is to assume the duties of the NMREB Chair in the NMREB Chair's absence;
- 5.4.4. The NMREB Office Personnel updates the NMREB membership roster and OHRP registration, if applicable, to reflect this change.
- 5.4.5. The NMREB Chair and Vice-Chair will be asked to sign a Confidentiality of Information and Conflict of Interest Agreement.

5.5. **Appointment – NMREB Members**

- 5.5.1. The NMREB will appoint its members based on nomination from current NMREB members and from the Office of Human Research Ethics (OHRE). A candidate may also self-nominate;
- 5.5.2. When an individual is nominated or expresses interest in serving on the NMREB, a copy of their *curriculum vitae* (CV) will be requested as well as a copy of their TCPS2 training certificate;

The NMREB Chair will review the CV, interview the potential candidate and make the final determination regarding his/her appointment;
- 5.5.3. Candidates selected to serve on the NMREB will be asked to sign a letter of appointment, confirmation of citizenship and a Confidentiality of Information.
- 5.5.4. If during the review of a protocol at a full board meeting any member of the NMREB 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 NMREB 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 NMREB;
- 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 NMREB'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 NMREB minutes and if available, the written report shall be placed in the specific study's NMREB file in the OHRE.

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

5.7. Observers at NMREB Meetings

5.7.1. NMREB 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 NMREB 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 NMREB 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 NMREB.

5.9. Resignations and Removals

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

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

5.9.3. The NMREB 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 NMREB.

5.10. Compensation

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

5.11. Documentation and Posting of the NMREB Membership List

5.11.1. The OHRE staff will maintain an updated electronic NMREB membership list;

- 5.11.2. The NMREB 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 NMREB membership list will be consistent with an NMREB full board or convened meeting date;
- 5.11.3. The OHRE staff forwards the updated Public NMREB Membership List to Communications at Western University for posting on the OHRE 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 OHRE. This list will contain member contact information. It will be kept confidential for access by NMREB members and OHRE staff;
- 5.11.5. The OHRE staff will maintain the NMREB registration with the US OHRP.
- 5.11.6. The OHRE staff updates the NMREB 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. Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans (TCPS), Article 1.3;
- 2. Ontario Personal Health Information Protection Act (PHIPA), S.15;
- 3. US Office for Human Research Protections 45 Code of Federal Regulations Title 46.107;

SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N201.001	Original	12/01/2015
N202.002	Change ORE to OHRE	06/09/2016
N202.003	Update to NMREB Chair	08/14/2018