SOP Title	**Duties of NMREB Members**
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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 policy and procedure (SOP) is to describe the duties of the Non-Medical Research Ethics Board (NMREB) members.

2. GENERAL POLICY STATEMENT

Each Non-Medical Research Ethics Board (NMREB) member's primary duty is the protection of the rights and welfare of the individual person(s) who are serving as participants in research. In order to fulfill his or her duties, NMREB members must be knowledgeable in regulations and guidelines governing human participants' protection, and policies relevant to human research participant protection.

3. RESPONSIBILITY

This SOP applies to the NMREB Chair, vice chair(s), all NMREB members.

The NMREB Chair or designee are responsible for clearly articulating all required duties associated with membership on the NMREB to potential and current NMREB members.

4. DEFINITIONS

Please see the glossary of terms.

Corresponding members - NMREB members that are duly qualified but not able to regularly attend NMREB meetings can be designated by the NMREB Chair to perform delegated reviews. Such members are knowledgeable in research ethics and must have been attendees at NMREB meetings in the past (i.e. ex officio members) or hold equivalent qualifications. These members are expected to attend a minimum of two meetings per year as well as the educational events.

Ex-Officio members - membership on the NMREB by virtue of a particular office or position held. The Director and the Office of Human Research Ethics (OHRE) staff are ex-officio members.

Substitute or Alternate Members – NMREB members that are appointed as a substitute/alternate for a regular NMREB member such that the NMREB can continue to function when regular members are unable to attend. Substitute/alternate members will fulfill the role of the regular NMREB member for whom they are substituting.

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Attendance

5.1.1. NMREB members are expected to attend regularly scheduled meetings as well as educational events. Members may be asked to step down if they consistently miss more than 25 percent of the scheduled meetings at which their attendance is expected;

5.1.2. NMREB members are expected to be available for the complete meeting, not just the sections for which they may have been assigned as reviewers;

5.1.3. Corresponding and substitute/alternate members are expected to attend a minimum of two meetings per year as well as the educational events.

5.2. Term of Duty

All NMREB members including the NMREB Chair and Vice-Chair(s) are expected to commit to renewable terms of up to three years as per their letter of appointment.

5.3. Duties

All NMREB members (with the exception of ex-officio members), including corresponding and substitute/alternate members as applicable, are expected to review all distributed materials and be prepared to discuss each project and provide his/her input at convened meetings. Each NMREB member is expected to fulfill specific duties based on their role(s) on the NMREB as outlined below. More than one member may fulfill each role.

5.3.1. **Community Member(s):** It is advisable that community members are not currently engaged in research or legal work as their principal activities. Their primary role is to reflect the perspective of the participant;

5.3.2. **Member(s) knowledgeable in relevant discipline:** are expected to provide input on areas relevant to their knowledge, expertise and experience, professional and otherwise. These members should advise the NMREB if additional expertise is required to assess whether the research protocol adequately protects the rights and welfare of subjects, and to comment on the comprehension of the consent document;

5.3.3. **Non-Scientific Members: (for US supported studies only)** are expected to provide input on areas relevant to their knowledge, expertise and experience, professional and otherwise. These members should advise the NMREB if additional expertise in a non-scientific area is required to assess whether the research protocol adequately protects the rights and welfare of subjects, and to comment on the comprehension of the consent document;

5.3.4. **Member(s) knowledgeable in relevant law:** are expected to alert the NMREB to legal issues and their implications, not to provide formal legal opinions nor to serve as legal counsel for the NMREB;

5.3.5. **Member(s) knowledgeable in research ethics:** are expected to alert NMREB to potential ethics issues and options;

5.3.6. **Member(s) knowledgeable in privacy:** are expected to alert the NMREB to privacy issues;

5.3.7. **Consultants:** individuals with competence in special areas may be asked to assist in the review of issues that require expertise beyond or in addition to that available on the

NMREB. The consultant may be required to submit a written report and participate via teleconference, or to attend the meeting to lend his/her expertise to the discussions. The consultant's attendance will not be counted towards quorum and the consultant will not contribute to the NMREB's decision;

5.3.8. **NMREB Chair:** The NMREB Chair or designee provides overall leadership to the REB:

- The NMREB Chair can delegate any of his/her responsibilities, as appropriate to a Vice-Chair or other qualified individual(s),
- Any responsibilities that are delegated by the NMREB Chair must be documented,
- The NMREB Chair or designee facilitates the review process based on organizational policies and procedures, SOPs and applicable regulations and guidelines. The NMREB Chair or designee determines the level of risk of each research project. The NMREB Chair or designee monitors the NMREB's decisions for consistency and ensures that decisions are recorded accurately and communicated to Researchers in writing in a timely fashion,
- The NMREB Chair or designee ensures that all NMREB members are free to participate in discussions during the NMREB meetings. The NMREB Chair or designee can ask a substitute NMREB member to attend an NMREB meeting in order to draw his/her expertise in an area that may be relevant to the NMREB's review and deliberations of the research,
- The NMREB Chair or designee determines the appropriateness of a Full Board or delegated review of the research,
- The NMREB Chair or designee performs or delegates authority to (an) NMREB member(s) to perform a delegated review,
- The NMREB Chair or designee signs off on all NMREB decisions in writing,
- The NMREB Chair or designee can suspend the conduct of any research project deemed to place participants at unacceptable risk pending discussion by the Full Board. The NMREB Chair or designee can suspend the conduct of the research if he/she determines that a Researcher is not adhering to the NMREB approved protocol or to the NMREB's policies and procedures,
- The NMREB Chair or designee will report on the activities of the NMREB to the organization on an annual basis,
- The NMREB Chair or designee, in conjunction with the NMREB Office Personnel and other organizational representatives as applicable, ensures the NMREB members are informed of all new legislation, regulations, policies and guidelines pertaining to human participant research and shall advise the organization on policies and procedures related to research conduct,
- The NMREB chair, in conjunction with the NMREB Office Personnel, shall assess the educational and training needs of the NMREB members and Office Personnel, and will address any gaps identified.
- The NMREB Chair or designee reviews and approves NMREB policies and procedures at set intervals, to ensure the NMREB SOPs meet all current standards.

5.3.9. **Vice Chair:** The NMREB Chair may appoint Vice-Chair(s) to assist or act on behalf of the Chair in particular NMREB matters and at NMREB meetings, either as a general procedure, or on a case-by-case basis. Such delegation must be in writing.

5.4 **Continuing Education**

All NMREB members are expected to participate in continuing education activities, including attendance during NMREB training and education sessions, conferences, seminars and/or reading pertinent articles/books.

5.5 **Conflict of Interest**

5.6.1 All NMREB members and consultants are expected to disclose conflicts of interest prior to the review and/or discussion of items on the meeting agenda.

5.6.2 All NMREB members are expected to follow recusal requirements.

1. REFERENCES

1.1. Health Canada (Division 5, Part C.05.001 of the Food and Drug Act);

1.2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2),Articles 6.4, 6.5;

1.3. The International Conference on Harmonization Good Clinical Practices, Section 3;

1.4. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.107;

1.5. US Food and Drug Administration (FDA) CFR Title 21 Part 56.107, 108(c);

1.6. FDA Information Sheets: FAQ Section II, Question 17

2. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N202.001	Original	12/07/2015
N202.002	Change ORE to OHRE	06/10/2016
N202.003	Removal of Primary Reviewer section	07/07/2016
N202.004	Update to NMREB Chair & (Non)Scientific members	05/11/2018
N202.005	Update to NMREB Chair and some minor admin changes	03/03/2025