SOP Title	**Duties of HSREB Members**
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance		20 Jan 2022
Dr. Philip Jones Chair Health Sciences Research Ethics Board		27 Jan 2022

1. PURPOSE

The purpose of this standard operating policy and procedure (SOP) is to describe the duties of the Health Science Research Ethics Board (HSREB) members.

2. GENERAL POLICY STATEMENT

HSREB 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 their duties, HSREB members must be versed in regulations governing human participants' protection and biomedical research ethics, and policies relevant to human research participant protection.

3. RESPONSIBILITY

This SOP applies to the REB Chair, Vice Chair(s), and all HSREB members.

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

4. DEFINITIONS

Please see the glossary of terms.

Corresponding members - HSREB members that are duly qualified but not able to regularly attend HSREB meetings can be designated by the HSREB Chair to perform delegated reviews. Such members are knowledgeable in research ethics and must have been attendees at HSREB 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 HSREB by virtue of a particular office or position held. The Director, Research Ethics and Compliance and the Office of Human Research Ethics (OHRE) staff are ex-officio members.

Substitute/alternate/or Alternate Members –HSREB members that are appointed as a substitute/alternate for a regular HSREB member such that the HSREB can continue to function when

regular members are unable to attend. Substitute/alternate members will fulfill the role of the regular HSREB member for whom they are substituting.

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Attendance

5.1.1. HSREB 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. HSREB members are expected to be available for the entire 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 HSREB members including the HSREB Chair and Vice-Chair(s) are expected to commit to renewable terms of three years as per their letter of appointment.

5.3. Duties

All HSREB 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 HSREB member is expected to fulfill specific duties based on their role(s) on the HSREB 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. **Non-Scientific Members:** are expected to provide input on areas relevant to their knowledge, expertise and experience, professional and otherwise. These members should advise the HSREB 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;

5.3.3. **Scientific Members:** are expected to contribute to the evaluation of a study on its ethical, scientific and statistical merits, and standards of practice. These members should also advise the HSREB if additional expertise in a scientific or non-scientific area is required to assess whether the research protocol, consent document and/or other research materials adequately protect the rights and welfare of subjects;

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

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

5.3.6. **Member(s) knowledgeable in privacy:** are expected to alert the HSREB 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 HSREB. 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 HSREB's decision;

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

- The HSREB Chair can delegate any of their responsibilities, as appropriate to a Vice-Chair or other qualified individual(s),
- Any responsibilities that are delegated by the HSREB Chair must be documented,
- The HSREB Chair or designee facilitates the review process based on organizational policies and procedures, SOPs and applicable regulations and guidelines. The HSREB Chair or designee determines the level of risk of each research project. The HSREB Chair or designee monitors the HSREB's decisions for consistency and ensures that decisions are recorded accurately and communicated to Researchers in writing in a timely fashion,
- The HSREB Chair or designee ensures that all HSREB members are free to participate in discussions during the HSREB meetings. The HSREB Chair or designee can ask a substitute HSREB member to attend an HSREB meeting in order to draw their expertise in an area that may be relevant to the HSREB's review and deliberations of the research,
- The HSREB Chair or designee determines the appropriateness of a Full Board or delegated review of the research,
- The HSREB Chair or designee performs or delegates authority to (an) REB member(s) to perform a delegated review,
- The HSREB Chair or designee signs off on all HSREB decisions in writing,
- For HSREB approval of clinical trials approved by Health Canada, the HSREB approval letter which includes the HSREB attestation, is signed by the HSREB Chair or designee,
- The HSREB 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 HSREB Chair or designee can suspend the conduct of the research if they determine (or they need time to investigate the possibility) that a researcher is not adhering to the HSREB approved protocol or to the REB's policies and procedures,
- The HSREB Chair or designee will report on the activities of the HSREB to the organization on an annual basis,
- The HSREB Chair or designee, in conjunction with the OHRE staff and other organizational representatives as applicable, ensures the HSREB 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 HSREB Chair, in conjunction with the OHRE staff, shall assess the educational and training needs of the HSREB members and OHRE staff, and will address any gaps identified.

- The HSREB Chair or designee reviews and approves REB policies and procedures at set intervals, to ensure the HSREB SOPs meet all current standards.

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

5.4. **Primary Reviewers**

In addition to the duties described in section 5.3 above, HSREB members may be appointed as primary reviewers to review assigned research projects in greater detail and lead the discussion at the meeting. The HSREB utilizes the primary reviewer model for initial review. Reviewers are assigned by the HSREB Chair or designee based upon the member's expertise and experience, with consideration of distribution of workload among HSREB members.

5.4.1. **The Primary Reviewer**:

- conducts an in-depth review of the assigned research project;
- provides in writing (including electronic) and in advance their major concerns of the assigned research project;
- presents their assessment of the research at the convened meeting, leads the discussion, and recommends a decision regarding approval or disapproval of the research;
- may be required to review additional material (e.g., investigator responses) for the purpose of research ethics approval.

Primary reviewers who are not able to participate in a meeting are required to forward a complete written review to the Office of Research Ethics prior to the convened meeting.

5.4 **Continuing Education**

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

5.5 **Conflict of Interest**

5.6.1 All HSREB 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 HSREB 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),Article 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;
1.6. FDA Information Sheets: FAQ Section II, Question 17

2. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyy
202.001	Original	01/22/2014
202.002	Minor administrative revisions for clarification	04/09.2014
202.003	Minor administrative revisions for clarification	05/22/2014
202.004	Minor administrative revisions for clarification	07/29/2014
202.005	Changes to section 5.3.8	10/22/2014
202.006	Minor Administrative Changes	05/11/2016
202.007	Minor Administrative Updates	01/27/2022