IWK Research Ethics
Standard Operating Procedures

Document # **RE 2.201**	Title: **Duties of REB Members**	Effective Date: **November 19, 2024**
Pages**: 5**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY STATEMENT

The Research Ethics Board (REB) member's primary duty is the protection of the rights and welfare of the individual human beings who are participants of research. Each REB member must ensure that all research that falls under its review meets the highest ethical standards for research involving humans. All REB members must consider a number of factors in its review of research protocols including: social and scientific merit; the risks and benefits to participants; participant vulnerability; participant selection and recruitment; privacy and confidentiality; the free and informed consent and assent processes; and inclusiveness and justice. Above all, members must ensure that the research respects the rights, dignity, welfare, and autonomy of research participants.

The REB member must understand that s/he is not serving on the Board to expedite the approval of research, but to serve as a link between the investigator and the research participants. In order to fulfill his or her duties, REB members should be knowledgeable in regulations governing human participants' protection and biomedical research ethics, and policies relevant to human research participant protection. The REB will be and must be seen to be fair and impartial, immune from pressure from the institution's administration, the investigators whose protocols are brought before it, or any other professional or nonprofessional source.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

This SOP applies to the REB Chair, Manager, REB members, and Research Ethics Office (REO) staff. The REB Chair and REO Manager or designee is responsible for communicating the required duties associated with membership of the REB to potential and current REB members.

PROCEDURES

Attendance

Research Ethics Board members are expected to attend all regularly scheduled meetings as well as educational events, and are expected to be available for the complete meeting, not just the sections for which they have been assigned as reviewers.

Members must notify the REO if they will be absent for a meeting so that an appropriate alternate (if necessary) may attend in his/her place.

Members may be asked to step down if they are unable to fulfill their duties.
Alternate REB members are expected to attend the identified meetings for which they have confirmed their willingness to replace a regular REB member.

Duties

Members, including alternate members as applicable, are expected to review the distributed materials and be prepared to discuss each project and provide his/her opinion at convened meetings. Each REB member is expected to fulfill specific duties based on their role(s) on the REB as outlined below.

- Community Members. Community members are expected to provide input according to their knowledge of the local community and be willing to discuss issues and research from that perspective. The primary role of the community member is to reflect the perspective of the participant. He/she shall not be affiliated with the sponsor, institution or investigator nor be part of the immediate family of a person who is affiliated with the institution. It is advisable that community members are not currently engaged in research or legal work as their principal activities.
- Non-Scientific Members**.** Are expected to provide opinions in areas relevant to their knowledge, expertise and experience, professional and otherwise. These members should advise the REB if additional expertise in a non-scientific area is required to assess whether the research protocol adequately protects the rights and welfare of participants, and to comment on the comprehension of the consent document.
- 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 REB if additional expertise in a scientific or non-scientific area is required to assess whether the research protocol, consent document and other research materials adequately protect the rights and welfare of participants.
- Members knowledgeable in relevant law. Are expected to alert the REB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel for the REB.

- Members knowledgeable in research ethics. Are expected to alert REB to potential ethics issues and options.
- Members knowledgeable in privacy. Are expected to alert the REB to privacy issues.
- 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 REB. 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, nor may consultants take part in any REB vote.

REB Chair

The Chair's duties include but are not limited to:

- Chairing meetings of the REB
- Responsibility for ensuring that the REB review process conforms to all regulatory requirements including TCPS2 and ICH GCP
- Assignation of duties to Members, including authority to delegated reviews when appropriate
- May suspend the conduct of a research project or clinical trial deemed to place individuals at unacceptable risk, pending discussion by the full REB
- May suspend the conduct of research if he/she determines that an investigator is not following the REB's policies or procedures, pending review by the REB
- Will ensure that REB members are informed of new legislation, regulations and guidelines that bear on REB review. This duty will be discharged jointly with the Manager
- Will review REB SOPs periodically, as defined in: Standard Operating Procedure: Development and Maintenance REB SOP 1.105
- When necessary, may delegate any of his/her responsibilities, as appropriate, to other qualified individuals as defined in: Signing Authority REB SOP 2.204

Primary Reviewers

In addition to the duties described above, REB members may be appointed as primary reviewers to review specified research projects in greater detail and lead the discussion at the meeting. The REB utilizes the primary and secondary reviewer model for initial review. Reviewers will be assigned by the Chair based upon the member's expertise and experience, with consideration of distribution of workload among REB members. The Primary Reviewer will:

- Will carry out an in-depth review of the assigned research project materials with a focus on protocol, procedures and overall study design
- Will submit a written review of the assigned research project to the Chair, and present his or her assessment of the research at the convened meeting, leading the discussion and recommending a decision regarding approval or disapproval of the research
- May be required to review and approve or reject additional material arising (e.g., investigator responses)

Secondary Reviewers

The Member assigned to be the secondary reviewer will carry out an in-depth review of the specified research project, but with particular focus on the informed consent process, engagement of participants and compensation plan. The reviewer will be expected to speak to his or her assessment of the research at the convened meeting, adding to the discussion as appropriate, and to recommend a decision regarding approval or disapproval of the research. The Secondary Reviewer may also sometimes be required to review additional material (e.g., investigator responses) for the purpose of final disposition of the Application.

Continuing Education

All REB members are encouraged to participate in continuing education activities, including attendance during REB educational events, conferences, seminars, and/or reading pertinent articles/books. Also see Training and Education: REB Members and REO Staff REB SOP 2.202.

Conflict of Interest

REB members and consultants are required to comply with the conflict of interest policy as defined in: Disclosure and Documentation of Conflicts of Interest REB SOP 2.203.

Note: US regulations will be applied as applicable.

REFERENCES

1. Health Canada (Division 5, Part C.05.001 of the Food and Drug Act);
2. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018: (short name: TCPS 2), Article 6.4, 6.5;
3. The International Conference on Harmonization Good Clinical Practices, Section 3;
4. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.107;
5. US Food and Drug Administration (FDA) CFR Title 21 Part 56.107;

Forms/Records:

Form #	Form/Record Name
SOP 201	Duties of REB members

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 8, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo
1.2	November 19, 2024	Added note regarding compliance with US regulations where applicable