

IWK Research Ethics Board Terms of Reference (Document Control: January 23, 2025)



A. Purpose:

The IWK Health Research Ethics Board (REB) is mandated by IWK Health to ensure all research involving human participants carried out under the auspices of IWK Health is of the highest quality, protects the interests of the human participants and of society generally, and complies with the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects \(TCPS 2 \(2022\)\)](#).

The REB shall function as an autonomous entity within IWK Health.

Recognizing the importance of research and the need to ensure the ethical conduct of research, the REB is built upon the guiding core ethical principles of the TCPS 2 (2022): respect for persons, concern for welfare, and justice.

The independent functioning of the REB requires REB members and IWK researchers to navigate a course between the two main goals of providing the necessary protection of participants and serving the legitimate requirements of research through a transparent and accountable process for review of the ethical acceptability of research.

The authority of the IWK REB derives directly from the IWK Board of Directors. The IWK Board of Directors does not influence the decisions of the REB.

Appointments to the REB are made upon the recommendation of the Research Management Committee - Ethics. Such recommendations shall be made to the IWK Health CEO who appoints members as the representative of the IWK Board of Directors.

B. Functions/Responsibilities

The IWK REB is required to:

1. Be current on ethical issues related to human subject research, to educate the IWK Health community on these issues and to formulate policies on these matters.
2. Review, approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants conducted at the IWK or by members of the IWK, including anyone affiliated with IWK Health conducting such research at or under the auspices of IWK Health.
3. Assess and limit the risks to participants in research involving humans, and where more than minimal risk is identified, to satisfy itself that the design of the research project can address the questions being asked in the research.
4. Determine guidelines and review processes for events related to approved research (e.g.

amendments, safety reporting, study personnel changes).

5. Inform the process for the review or audit of ongoing research projects under the Research Review program.
6. Serve as a resource to the research community, communicating with and advising researchers on guidelines, procedures and other matters relating to the conduct of research with humans.
7. Meet regularly to discharge its responsibilities, and to keep and maintain minutes of such meetings. These records are to be accessible to researchers, as pertaining to their application, and to authorized representatives of IWK Health and funding agencies.
8. Liaise with REBs of affiliated institutions to optimize efficiencies, coordinate activities and to ensure consistency of decisions among such institutions.
9. Keep the IWK Board of Directors informed of substantive issues in terms of policy, process and compliance and submit a written report annually on the activities of the REB to the Board.
10. US regulations will be applied as applicable.

C. Committee Composition:

The IWK REB will strive to maintain a robust membership. Appointed members will reflect a breadth of IWK research experience and disciplines, as well as Equity, Diversity, Inclusiveness, Reconciliation and Accessibility principles.

1. Representatives of the research community who possess broad expertise in the methods or in the areas of research that are supported by the REB, for example:
 - a. Department of Obstetrics and Gynaecology
 - b. Department of Surgery
 - c. Department of Pediatrics
 - d. Department of Emergency Medicine
 - e. Department of Diagnostic Radiology
 - f. School of Nursing
 - g. Department Microbiology and Immunology
 - h. Others, e.g., Psychology, Psychiatry, etc.
2. At least one member is knowledgeable in bioethics.
3. At minimum one practicing or non-practicing lawyers to provide a legal lens.
4. At minimum one member who has no affiliation with the IWK, recruited from the community served by the institution (Lay members).
5. Research personnel with extensive experience and training in a given research-related field as

available.

Appointment to the REB is for a three-year term, with terms of individual members overlapping. An appointment is renewable upon mutual agreement and review and approval of the CEO. The Research Management Committee-Ethics (RMC-E) will recommend a Chair or Vice-Chair from the REB membership to the CEO for appointment. The position is renewable.

Ad-Hoc Advisors

When an additional perspective is required, an ad-hoc population or community representative (e.g., Indigenous, BIPOC, LGBTQIA2S+) will be invited to attend the REB meeting in a non-voting capacity and they are not included in the quorum for the REB.

D. Committee Support:

The ethics staff of the Research Innovation & Advancement office will fulfill the REB's administrative duties.

E. Quorum

Quorum for a meeting involving full ethics review must be a minimum of five REB members who collectively possess the stipulated minimum requirements of background and experience. The following members must be in attendance:

- Two members with expertise in relevant research disciplines.
- A member knowledgeable in ethics.
- A member knowledgeable in relevant law (required only for biomedical research).
- A community member

F. Meeting Schedule

The REB will meet on the third Tuesday of every month, either virtually or in person.

G. Committee Evaluation:

Committee evaluation shall be an ongoing process to ensure that composition aligns with membership and quorum requirements as outlined above and that the number of members is sufficiently large to not overburden members.

H. Decision Making

The REB shall make decisions on the ethical acceptability of research. Decisions shall be by voting of all members present as declared by the Chair/Vice-Chair. Total voting will be recorded as follows: recused,

votes for, votes against, abstained. In accordance with the TCPS 2 (2022), if a minority within the REB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort will be made toward resolution. This may include consultation with the researcher, external advice, peer review or further reflection by the REB.

IWK Health cannot grant approval for any research project that has not already received ethics clearance from the Research Ethics Board (REB).

I. Reporting

The REB shall prepare an Annual Report to the Board of Directors. The Annual Report shall include an overview of all REB activity for the year.

Approved by the Research Management Committee - Ethics: January 31, 2025