IWK Research Ethics
Standard Operating Procedures

Document #	Title:	Effective Date:
RE 3.301	**REB Meeting Administration**	**November 19, 2024**
Pages**: 4**	Responsibility of: **Research & Innovation Advancement**	Date Approved: **November 19, 2024**

POLICY STATEMENT

Except when an expedited review procedure is used, the REB will review proposed research at convened meetings at which a quorum is present. The IWK REB will generally meet at least 10 times a year or as determined by the Chair.

Minutes of the meeting will be recorded by the Manager and retained in the REO as a permanent record of business transacted at each meeting. The minutes should be in sufficient detail to enable the REB to reconstruct its deliberations at a later date, if necessary.

DEFINITIONS

Quorum: Requires a minimum of five (5) members be present (both male and female), of whom two should have expertise in relevant research disciplines, fields and scientific methodologies, one should be knowledgeable in ethics, one knowledgeable in relevant law, and one should be unaffiliated with the IWK.

See Glossary of Terms and Terms of Reference (REB SOP 1.103)

RESPONSIBILITY

This SOP applies to the IWK REB Chair, Manager, all REB Members, REB consultants, REB meeting guests, and Research Ethics Office (REO) staff involved in REB meeting administration.

PROCEDURES

Agenda and Meeting Preparation

The Manager, in consultation with the Chair, will prepare an agenda of meeting content and order of business. If later changes need to be made to the agenda, the Manager will notify the Chair and Members, and provide copies of the revised agenda.

The Manager will provide Members with copies of all applications to be tabled at the meeting, along with any other reports necessary for proper consideration of agenda items.

Members' Review of Meeting Materials Prior to REB Meetings
All Members are expected to review all provided applications and reports prior to the meeting, and to participate actively in Board discussion.

Record of the Meeting
The Manager or designee will record minutes of each meeting. Minutes will be written in sufficient detail to show:

- Meeting attendance; presence of any ad hoc reviewers, guests or observers
- Declarations of conflicts of interest and recusals, if any
- Actions taken by the Board on each agenda item requiring action, including, the basis for disapproving the research
- Summary of the discussion of controversial issues and their resolution
- Voting results, including for, against (if applicable) and members who abstain from voting

Approval of Minutes
Copies of the Minutes will be distributed to members prior to the next Board meeting for review. At the next meeting, minutes may be approved by consensus or vote and signed by the Chair accordingly. Any corrections to minutes accepted by the Board will be, in turn, recorded as corrections to the original minutes and as decisions in the minutes of the current meeting. The REO will retain the approved minutes, as well as the agenda and pertinent materials on file, as a permanent record.

Meetings and Attendance
Board meetings will normally take place with Members physically present around a table to facilitate full and frank debate by Members.

In unusual circumstances, should a member not be able to be physically present during a convened meeting, but be available by telephone, or video-conference link, the meeting can be convened using audio- or video- conferencing link. Members participating by such means may vote provided they have had an opportunity to review all the material the other members have reviewed. Remote participation by members will be documented in the minutes of the REB meeting.

Under very unusual circumstances (e.g. public health alerts and quarantines) the REB Chair may, at his/her discretion, conduct an REB meeting with all REB members attending via simultaneous videoconference or teleconference, provided everyone has received the review materials and quorum is met. This will be recorded in the minutes of the REB meeting.

Approval by Consensus
Members of the REB generally approve studies by consensus, which is noted as a unanimous vote in the REB minutes. Where consensus is not achieved the decision will be made by

majority vote, with the minutes reflecting who was opposed to the majority decision.

Only members who participate in the REB review and discussion should vote/provide their opinion and/or advice.

When there is less than full attendance, decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary as determined by the Chair to provide an adequate research ethics review of the proposals under consideration.

Guests may be invited or permitted to attend REB meetings, subject to execution of Confidentiality and Conflicts of Interest Agreement. Guests must disclose any conflicts of interest including but not limited to vested interest in, or scientific management responsibility for any applications being considered at the meeting.

If requested, investigators, or their delegates and/or team members may attend the REB meeting to present their project and respond directly to any comments or questions raised by the REB.

Record Retention
The REO will retain all relevant records (written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings and correspondence for a period of at least 5 years after the completion of a study/trial and make them available upon request from the regulatory authorities for non-regulated trials. For regulated trials the REO will retain all relevant records for 25 years.

(See Terms of Reference REB SOP 1.103 and Documentation and Document Management REB SOP 3.301)

Note: US regulations will be applied as applicable.

REFERENCES
1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018:
(short name: TCPS 2)
2. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Tile 21, Parts 56, 108, 56. 115
5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.108.
Health Canada Drug and Health Products: Guidance for Industry

Forms/Records:

Form #	Form/Record Name
SOP 301	REB Meeting Administration

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	Updated wording for clarity, added note regarding compliance with US regulations where applicable & update to responsibility (RIA)