IWK Research Ethics
Standard Operating Procedures

Document # **RE 4.403**	Title: **REB Delegated Review Procedures**	Effective Date: **November 19, 2024**
Pages**: 4**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY STATEMENT

Although submitted research projects will normally be reviewed by the full Board, an alternative delegated review option may be used by the Board, in which the review will be carried out by one or two specifically nominated Members without referral to the Board as a whole. This process is reserved for those projects in which the risk is clearly minimal. The Chair will decide which projects are suitable for delegated review, and the Chair will designate the specific reviewers for each project.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

This SOP applies to the REB Chair, REO Manager, REB members, and Research Ethics Office (REO) staff.

PROCEDURES

Determination of Qualification for Delegated Review

When a research study is submitted for review, the ethics coordinator will perform an initial assessment of the research to determine if the activities may qualify for delegated review, but the Application will thereafter be referred to the Chair for final decision.

Full review by the convened Board is the default for research involving human participants; however, the Chair may deem some projects eligible for delegated REB review. In deciding to submit an Application to delegated review, the Chair will take into consideration*, inter alia*, the following:

- The degree of anticipated risk to the participants

- The research involves greater than minimal risk, but the Application has been approved by an external Review Board at a similar institution, and that the full report from such review is made available to the IWK Board
- If the approval being sought is limited to minimal-risk changes to previously approved research

Administrative Process for Delegated Reviewer(s)

- For research that meets the criteria, delegated review may be conducted by the REB Chair, or by one or more of the Members as delegated by the Chair or the convened Board
- Delegated reviewers may exercise all of the authorities of the REB, except that they may not reject the Application, in that they may recommend approval, deferred approval or reference for full review by the Board
- Delegated reviewers may seek, through the Chair, the help of an external consultant. The consultant's opinion may be taken into account by the reviewers, but the consultant may not take part in the final decision making
- Members acting as delegated reviewers must not have a conflict of interest for the research
- No letter of approval will be signed by other than the Chair, unless the Member has been specifically delegated by the Chair to do so

Continuing Review: Proposed Revisions to the Protocol and/or Informed Consent Form, Amendments and Renewals

- Research that was previously reviewed by delegated review procedures may be reviewed at the time of continuing review using delegated review procedures
- Research that was previously reviewed by the convened REB may be reviewed at the time of continuing review using delegated review procedures when there are no, or only minimal-risk, changes, to previously approved research. However, if the reviewer determines that the risks are now more than minimal, the matter should be referred to a regular meeting of the Board for decision
- The REB Chair, or designee, may use delegated review procedures for changes proposed to consent documents that do not affect the rights, safety and welfare of study participants and do not involve increased risk or significant changes in study procedures

Serious Adverse Events and Safety Updates

- The Chair may authorize delegated review procedures for reports of unanticipated problems (including serious adverse events) and safety updates such as reports from Data Safety Monitoring Committees
- If the Chair subsequently considers that action is needed to protect the safety or welfare of research participants, he/she may initiate such action at once or may refer the matter to the Board at its next meeting

Additional Items

The Chair may use delegated review procedures for other types of minor changes to previously approved research and miscellaneous items, including the following:

- Participant materials such as: Recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards
- Protocol deviation reports
- Translations of English documents previously-approved by the Board
- Correspondence from the investigator
- Board minutes provisionally approved by the convened REB

Notification of the REB

- The Chair will notify Members at the next available Board meeting of any and all new research submissions that were approved using delegated review procedures.

Documentation

- The type of REB review conducted (i.e., full or delegated) will be noted in the review and approval letters sent to the investigator
- All Applications and other items approved by delegation since the previous meeting will be tabled at the following Board Meeting and included in the minutes thereof

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),Chapter 1 section C; Chapter 2 section B; Article 6.12;
2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.102, 46.110;
4. US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.102, 56.110;

Forms/Records:

Form #	Form/Record Name
SOP 403	REB Delegated Review Procedures

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