SOP Title	**HSREB Delegated Review Procedures**
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
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1. PURPOSE

This standard operating procedure (SOP) describes the process for determining if research meets the criteria for Delegated ethics review and the delegated review process.

2. GENERAL POLICY STATEMENT

A proportionate approach to ethics assessment should be adopted by the Research Ethics Board (REB) based on the general principle that the more invasive or harmful the proposed research, the greater the care in assessing the research. Full Board review by an REB is the default requirement for all research projects involving human participants unless the Health Sciences Research Ethics Board (HRSEB) decides to authorize delegated review. Delegated review is based primarily on the principle that the harms that are expected to arise from the research are likely minimal and do not exceed the expected benefits. While all research must be reviewed adequately, requirements for proportionate review allow the REB to provide a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research.

The HSREB utilizes two levels of review. Full Board review at a convened REB meeting and Delegated review by one or more experienced HSREB members designated by the HSREB Chair, Vice-Chair(s), or designee.

3. RESPONSIBILITY

This SOP applies to all HSREB members including the HSREB Chair and Vice-Chair(s) and to all Office of Human Research Ethics (OHRE) staff.

The HSREB Chair, or designee, is responsible for determining if research is eligible for Delegated review. If the HSREB Chair delegates this task to an OHRE staff member, the responsibility for oversight remains with the Chair.

The HSREB Chair, designee, or delegated HSREB members are responsible for conducting the delegated review.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Determinations of Qualification for Delegated Review

5.1.1. Full Board review is the default for research involving human participants, however, some research may be eligible for Delegated HSREB review;

5.1.2. Where it is determined that the research is of minimal risk, the HSREB Chair or designee may authorize Delegated ethics review;

5.1.3. When a research project is submitted for Delegated review, the Ethics Officer (EO) will perform an initial assessment of the research to confirm the project qualifies for Delegated review;

5.1.4. If a question arises as to whether delegated review can be carried out, the HSREB Chair or designee will make the final determination;

5.1.5. Examples of research that may be eligible for Delegated HSREB review are as follows:

- Research projects that involve no more than minimal risk;
- Minor or minimal-risk changes to approved research;
- Continuing review of approved minimal risk research;
- Continuing review of research that is more than minimal risk research for which enrolment is closed permanently and all research related interventions for all participants are complete and the only remaining research activities are post-intervention activities or follow-up of participants; or, where the remaining research activities are limited to data analysis; or, where no participants have been enrolled and no additional risks have been identified;
- Continuing review of research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to or other ethical implications for participants since the initial review by the full REB; if permissible under all applicable governing Regulations;
- The submission by the Researcher in response to the REB review as a condition of approval, as authorized by the Board;
- Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures,
- Reportable events, including adverse events and safety updates such as reports from Data and Safety Monitoring Boards (DSMB);
    - If the HSREB Chair or designee subsequently considers that actions are needed to protect the safety of the research participants, they may take such action and/or request that the full REB or designated subcommittee review reports of unanticipated problems or safety updates to determine what further action, if any, is required.
- All others are at the discretion of the Chair.

5.1.6. The REB Chair or designee may use delegated review procedures for the review of other types of minor changes including, but not limited to, the following:

- Participant materials such as: recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards,
- Authorized translations of English versions of documents previously approved by the REB;

5.1.7. The REB Chair or designee may be authorized by the Full Board to use Delegated review procedures for the review of miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a Full Board meeting;

5.1.8. When determining if initial review of research or modifications to previously approved research are eligible for Delegated review, the REB Chair or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, and all regulatory and ethics guidance requirements as applicable

5.2. **Authority of Delegated Reviewer(s)**

5.2.1. For research meeting the criteria for delegated review, the review may be conducted by the HSREB Chair, Vice-Chair(s), or one of the members of the HSREB and an Ethics Office who has been delegated by the HSREB Chair;

5.2.2. In reviewing the research under delegated procedures, the delegated reviewers may exercise all of the authorities of the REB, except that they may not disapprove the research; the research may be disapproved only after it has been reviewed by the REB at a Full Board meeting;

5.2.3. The delegated reviewers who review the delegated project must not have any conflicts of interest for the research;

5.2.4. If expert consultation is needed (i.e., an *ad hoc* advisor) on a delegated project, the delegated reviewers reviewing the project will contact the Chair or the EO to request this. The *ad hoc* advisor cannot participate in the final decision regarding the approval of the research;

5.2.5. Final approval must be signed off by the HSREB Chair, Vice-Chair(s), or authorized signatory.

5.3. **Continuing Review: Proposed Revisions to the Approved Protocol and/or Letter of Information and Consent, Supporting Documentation, Renewals**

5.3.1. Research that was previously approved by the Delegated review procedure may be reviewed at the time of continuing review using the same Delegated review procedures;

5.3.2. Research that was previously approved by the convened Full HSREB may be reviewed at the time of continuing review using Delegated review procedures when there are only minimal-risk changes or no changes to the previously approved research;

5.3.3. If the risk of the previously approved study is now more than minimal, the HSREB Chair or designee should refer the study for Full Board review at a convened HSREB meeting;

5.4. **Notification of the REB**

5.4.1. The HSREB is informed at the next convened meeting of new research submissions or revisions that were approved using the Delegated review procedures through attachments to the meeting package.

5.5. **Documentation**

5.5.1. The type of HSREB review conducted (i.e., full or delegated) will be noted in the review and approval letters sent to the Investigator;

5.5.2. The HSREB minutes and or attachments will include documentation (list) of research that was approved using Delegated review procedures.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) Chapter 1 section C; Chapter 2 section B; Article 6.12;

6.2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;

6.3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.102, 46.110;

6.4. US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.102, 56.110;

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
402.001	Original	01/21/2014
402.002	Minor administrative corrections for clarity	05/22/2014
402.003	Minor administrative corrections for clarity	05/10/2016
402.004	Minor Administrative Changes and updates to provide additional clarifications	01/27/2022