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 REB based on the general principle that the more invasive or harmful the proposed research, the greater the care in assessing the research. Full 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 do not exceed the benefits. While all research must be reviewed adequately, proportionate review is intended to reserve most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research projects.

The HSREB utilizes two levels of review. Full review at a convened REB meeting, 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 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 review by the convened HSREB 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 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:

- Categories of research that are expected to involve minimal risk;
- Minimal-risk changes to previously approved research;
- Annual renewals of approved minimal risk research;
- Annual renewals of more than minimal risk research where the researcher will no longer involve new interventions to current participants, renewal does not involve the recruitment of new participants, and the remaining research activities are limited to data analysis;
- Evidence that conditions or other requirements laid down by the REB in an initial review have been met;
- All others are at the discretion of the chair (TCPS2 Article 6.14).

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 who has been delegated by the HSREB Chair;

5.2.2. The delegated reviewers can not reject a research project, this can only be done after a full review by the convened HSREB;

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 on a delegated project, the delegated reviewers reviewing the project will contact the Chair or the EO to request this. The consultant 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 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;

5.3.4. Delegated review may be used for review procedures proposed to the 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.

5.4. **Serious Adverse Events and Safety Updates**

5.4.1. Delegated review procedures for reports of unanticipated problems (including serious adverse events) and safety updates such as reports from Data Safety Monitoring Committees may be used by the HSREB Chair or designee;

5.4.2. If the HSREB Chair or designee subsequently considers that actions are needed to protect the safety of the research participants, he/she 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.

5.5. **Additional Items**

5.5.1. Delegated review may be used by the HSREB Chair or designee for other types of minor changes to previously approved items such as the following:

- Participant recruitment materials such as posters, scripts, advertisements;
- Participant instruments such as diaries, validated questionnaires;
- Participant materials such as clinical trial identification / wallet cards;
- Protocol deviations;
- Translation of English documents previously-approved by the REB;
- Correspondence from the investigator;
- REB minutes contingently approved by the convened HSREB.

5.6. **Notification of the REB**

5.6.1. 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.

5.7. **Documentation**

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

5.7.2. 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 2010 (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/yyy
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