

Title	Delegated Review
SOP Code	401.002
Effective Date	01-July-2016

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/mmm/yyyy
Karine Morin Executive Director, Platforms	<i>original signed</i>	effective 01-July-2016

1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for determining when research meets the criteria for delegated ethics review and the associated delegated review procedures.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for determining if research is eligible for delegated review. In some circumstances, the REB Chair or designee may delegate this task to qualified REB Office Personnel; however, the responsibility for oversight remains with the REB Chair or designee.

The REB Chair or designee or qualified REB member(s) is responsible for conducting the delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REBs should adopt a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. Full Board review by an REB should be the default requirement for all research involving human participants unless the REB decides to authorize delegated review based primarily on the harms that are expected to arise from the research. 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.

In practice, the proportionate review implies different levels of REB review for different research projects. The two levels typical used by REBs are Full Board review or delegated review by one or more experienced REB members, as determined by the REB Chair or designee.

5.1 Determination of Qualification for Delegated Review

5.1.1 Full Board review is the default for most new research projects submitted to the REB; however, some research may be eligible for delegated review;

5.1.2 Submissions that meet the following criteria may be eligible for delegated review:

- 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 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);

5.1.3 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;

5.1.4 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;

5.1.5 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 Delegated Review Process

5.2.1 Qualified REB Office Personnel will perform an initial screening of the submission. Those submissions that meet a pre-defined set of criteria for delegated review as determined by the REB may be forwarded for delegated review. For all other submissions, the REB Chair or designee will make the determination of whether the submission meets the criteria for delegated review;

5.2.2 For research that meets the criteria, delegated review may be conducted by the REB Chair, or by one or more qualified REB members as designated by the REB Chair or designee;

5.2.3 The REB Chair or designee reviewing research under delegated review must not have a conflict of interest in the research;

- 5.2.4 In reviewing the research under delegated procedures, the REB Chair or designee may exercise all of the authorities of the REB, except that he/she may not disapprove the research; the research may be disapproved only after it has been reviewed by the REB at a Full Board meeting;
- 5.2.5 REB member(s) conducting a delegated review will contact the REB Chair or designee to request the expertise of an ad hoc advisor, if applicable. Ad hoc advisors may not participate in the final decision regarding approval of the research;
- 5.2.6 If the REB Chair or designee subsequently determines that the level of risk for the submission is greater than minimal, the submission will be referred to a Full Board meeting for review;
- 5.2.7 The REB Chair or designee will record the decision regarding the designation of the research (i.e., either requiring FB or delegated review) and the outcome of the review. The responsible REB Office Personnel may issue the review or decision letter.

5.3 Notification of the REB

- 5.3.1 At its next Full Board meeting the REB will be informed of research that was reviewed and approved using delegated review procedures.

5.4 Documentation

- 5.4.1 The type of REB review conducted (i.e., Full Board or delegated) is documented in the REB records and noted in the decision letter issued to the Researcher, where appropriate;
- 5.4.2 The REB meeting agendas and minutes will include a list of submissions that were reviewed and approved using delegated review procedures from the time that the agenda for the previous REB meeting was issued.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP401.001	01 July 2016	Original version
SOP401.002	01 July 2016	Version 2 - no changes