

Title	Determination of Ethics Review Procedure
SOP Code	401.01
Effective Date	September 2023

Site Approvals

Name and Title (typed or printed)	Signature	Date
Dr. Craig Kuziemsky Associate Vice-President, Research	<i>Original signed</i>	October 2020
Dr. Craig Kuziemsky, AVPR	<i>Original signed</i>	September 2023

1.0 PURPOSE

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

2.0 SCOPE

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

All REB members and delegated reviewers are responsible for ensuring that research entering the delegated review procedure meets the criteria as described and, if not, is escalated to Full Board.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REB shall adopt a proportionate approach to ethics review based on the general principle that the more invasive or risky the proposed and ongoing research, the greater the care in its assessment. Full Board review by the REB shall be the default requirement for all research involving human participants unless the REB decides to authorize delegated review based primarily on foreseeable risks of harm anticipated to arise from the research. While all research must be reviewed adequately, provisions for proportionate review allow the REB to reserve a higher level of scrutiny, and correspondingly more protection, for the more ethically challenging research.

In practice, the proportionate review implies different levels of REB review for different research projects. The two levels typically 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 new research projects submitted to the REB, unless the research meets the criteria 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 recruitment is complete and all research-related interventions for all participants are complete and the only remaining research activities are post-intervention activities, follow-up of participants; or, data analysis;
- 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;
- Revised submission by the Researcher in response to the REB review comments, as determined by the Board,

- Changes to consent documents that do not affect the rights and welfare of research participants, do not involve increased risk, affect data integrity, or require significant changes in research procedures,
- Unanticipated and adverse event reports.

5.1.3 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;

5.1.4 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 ethics policy requirements as applicable.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
401.00	October 8 2020	Original version
401.01	September 2023	Reviewed, no revisions needed