

Title	Delegated Review
SOP Code	404.01
Effective Date	September 2023

Site Approvals

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

1.0 PURPOSE

This standard operating procedure (SOP) describes the review procedure for research that meets the criteria for delegated review.

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 or REB member(s) is (are) responsible for conducting the delegated review.

The REB Chair or designee is responsible for oversight of the research undergoing delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REBs 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 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 REB members, as determined by the REB Chair or designee.

5.1 Delegated Review Process

- 5.2.1 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 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 they may not reject the research; the research may be rejected only 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.

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 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
404.00	October 8 2020	Original Version
404.01	September 2023	Reviewed, no revisions needed