

SOP Title	200: REB Operations
Number. Version	REB SOP 204 Delegated Review
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Approved By	REB
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1.0 PURPOSE

This procedure describes the research that can be reviewed by the REB chair or designate and outlines the process to determine if the research meets criteria for delegated review.

2.0 GENERAL PROCEDURE STATEMENT

A delegated review procedure consists of a review of research by two voting REB members, one of whom will be the Chair or Vice-Chair.

The REB will use a proportionate approach to the review of research. Research that may be reviewed by the REB through a delegated review procedure includes research activities that present no more than minimal risk to human participants and minor changes in approved research. This SOP pertains to both initial and continuing REB review of research.

The reduced level of scrutiny associated with delegated review does not imply that a lower standard will be applied. The intention of delegated review is to ensure adequate protection of participants while reducing unnecessary impediments to ethical research. This approach is in keeping with the need to respect academic freedom.

3.0 RESPONSIBILITY AND AUTHORITY

The Chair, Vice-Chair and the REB Administration are responsible for executing this SOP.

3.1. Authority of the Reviewer

The REB Chair or designate may exercise all of the authorities of the REB, except that he/she may not reject the application. A research proposal may be rejected only after review by the full REB. The REB Chair (or designate) may refer a study to the full Board at his/her discretion.

3.2. Notification of the Board

When the delegated review process is used, all members shall be informed of REB activities at the next convened meeting.

3.3. Additional Items that May be Reviewed

3.3.1 Missing Documents or Unclear Proposals

This may prompt a request by a reviewer for further information before continuing their review.

3.3.2. Approvals with Clarifications Required

The REB Chair or designate will review clarifications submitted by investigators.

3.3.3. Continuing Review / Renewals

The REB Chair, Vice-Chair or designate may use the delegated review procedure to review minor changes in previously approved research during the period for which approval is authorized. Changes to informed consent documents that do not involve increased risk or significant changes in study procedures may be reviewed by the REB Chair or his/her designate.

Any protocol revision that entails a significant change to the original approval, as determined by the Chair or designate, may be sent for delegated or full board review. The researcher may be asked to complete a full application if the changes are substantive.

3.3.4. Serious Adverse Event Reports and Safety Updates

When serious adverse events, unanticipated problems, and/or safety updates are reported, the REB Chair will assess the situation to determine the potential risks to participants. The Chair may suspend the research during this assessment. In addition, the Chair may convene a subcommittee (comprised of the Vice-Chair and Research Ethics Coordinator) of the REB to determine how to mitigate risks.

3.4. The outcome of the first review of the application through delegated review will be one of the following three decisions:

- a. Approval,
- b. Clarifications Required, or
- c. Referral to the Full Board