

SOP Title	200: REB Operations
Number Version	REB SOP 205 The Full Review Process
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1.0 PURPOSE

This section describes the REB full review process.

2.0 GENERAL PROCEDURE STATEMENT

All research involving human participants must be submitted for REB review according to the specified application format and process, otherwise the investigator will be notified that the REB will not review the research activity until all required elements are submitted. No intervention or interaction with human participants in research, including recruitment, may begin until the REB has reviewed and approved the TCPS certificate of completion, research protocol, consent documentation and recruitment materials.

There are four possible decision outcomes are: Approved, Clarifications Required, Deferred (Major Clarifications, Re-submission), or Rejected. Except when the delegated review procedure is used, these actions will be taken by a vote of a majority of the members present, except for those members present but unable to vote in accordance with REB's conflict of interest policies. The decision will reflect the majority vote. In cases where a minority disagree with the vote, their position may be communicated to the researcher in the decision letter.

When reviewed via delegated review, the REB Chair or his/her designate can take any of the actions outlined below, except to reject a study.

3.0 RESPONSIBILITY AND AUTHORITY

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

4.0 SPECIFIC PROCEDURES

4.1 Application Process

REB staff will review each application for completeness. If there are elements missing, the investigator will be notified.

Review Procedures

Initial applications are pre-screened for completeness and assessment of the level of risk. If the application does not meet the criteria for delegated review, it will be reviewed by the Research Ethics Board in accordance with the following procedures:

- The REB office will assign the study to one primary reviewer who will review the study and the application and all relevant documentation in detail. If the study involves a medical intervention, a medical doctor must also provide a review.
- The protocol may also be assigned to an additional expert (external reviewer) who is not a member of the REB if the nature of the protocol warrants the need for additional expertise.
- All materials and relevant documents are accessible by all REB members. The primary reviewers will receive notification of their assignments via e-mail approximately one week prior to the REB meeting at which the study is scheduled to be reviewed.
- For projects reviewed by the full REB, the Principal Investigator may be requested to attend the meeting of the Research Ethics Board and if so, he/she will be given an appointment time. If the Principal Investigator is requested to attend but cannot represent the project on the specified date and cannot delegate this responsibility to a co-investigator, the project may be deferred to the next scheduled REB meeting.
- Discussion of the Protocol at the REB meeting is led by the primary reviewer. In accordance with SOP 101 Article 4.6, the REB may make any of the determinations outlined below in article 4.2.

4.2 REB Determinations

The REB may make one of the four following determinations as a result of its review of research submitted for initial or continuing review: Approval, Clarifications Required, Deferral, or Rejected.

- A. **Approvals:** The protocol and accompanying documents are approved as submitted. Research may begin as soon as the Principal Investigator receives a Certificate of Approval to proceed from the REB Chair or designate. Once the Certificate of Approval has been issued, the research may begin provided that all other Institutional requirements have been met. The one-year period of approval will commence on the day the study is approved by an action of the convened REB or the REB Chair or his/her designate.
- B. **Clarifications Required:** The Board may decide that a Protocol may be approved provided that certain conditions are met or required changes are made. A written explanation of the conditions and/or modifications is sent to the Investigator by the Chair of the REB through the REB administration. When appropriate, the communication will include written reasons for the required modifications. When the Principal Investigator provides the Research Ethics Board with proof that the conditions have been met and the documents have been amended, (as confirmed by Research Ethics Administrative Staff or the REB Chair), the Certificate of approval will be sent to the Investigator.
- C. **Deferral:** The REB may defer a decision on any submitted research application if it does not have sufficient information to arrive at a determination, or if the REB requires extensive

revisions to any part of the research. The application will be brought back before the full Board for consideration after the additional information or revisions are received.

- D. Rejection: The REB may reject any protocol which does not meet its standards for ethical or scientific review and where revision is unlikely to enable the REB to reach a positive determination. No other UOIT Institutional official or other REB may approve a study which has been previously rejected by the UOIT REB. A researcher may request reconsideration of a decision made by the REB and has the right to appeal the REB's decision to the appeals board (Trent University REB). The decision rendered by the appeals board is final.