

Title	Course-based Review
SOP Code	408.001
Effective Date	2023-FEB-03

Site Approvals

Name and Title	Signature	Date (yyyy.mm.dd)
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1.0 PURPOSE

This standard operating procedure (SOP) describes the review procedure for research that will be conducted for pedagogical purposes as part of a student's course.

2.0 SCOPE

This SOP pertains to the Human Research Ethics Board (HREB), the Student Human Research Ethics Committee (SHREC) members, and non-REB reviewers that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

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

The SHREC Chair or designee or SHREC member(s) is responsible for conducting the course-based delegated review.

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

MRU HREB adopts 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 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.

When research activities will be conducted by a student as part of a course, for pedagogical purposes only (e.g., to learn how to conduct research), HREB delegates research ethics review of these minimal risk course-based research projects to the Student Human Research Ethics committee (SHREC) in accordance with TCPS 2 Article 6.12.

In delegating ethics review of course-based research, the HREB carefully selects REB member(s) or non-REB reviewer(s) and ensure that they have the appropriate experience, expertise, training and resources required to review the ethical acceptability of all aspects of the proposal in accordance with this Policy.

Research undergoing the course-based review procedure must meet the criteria for delegated review. Greater than minimal risk course-based research cannot use the course-based review procedure and must be reviewed by the Full Board.

5.1 Course-Based Review Process

5.2.1 REB Office Personnel will perform an initial screening of the submission. If the submission covers research activity within a recognized course (with valid course code) for a pedagogical purpose and meets the delegated review criteria, the submission is then directed to SHREC for delegated review.

5.2.2 For research that meets the criteria, course-based review will be undertaken by SHREC members who have the appropriate experience, expertise, training and resources as an REB member;

- 5.2.3 SHREC members reviewing research under course-based review must not have a conflict of interest in the research;
- 5.2.4 In reviewing the research under course-based procedures, SHREC members may exercise all of the authorities of the REB, except that they may not disapprove the research; the research may be disapproved only by the REB at a Full Board meeting;
- 5.2.5 If the SHREC member 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;
- 5.2.6 The decision regarding the designation of the research (i.e., course-based or Full Board review) and the outcome of the review will be recorded. The responsible REB Office Personnel may issue the review letter or decision.

5.3 Reporting to the REB

- 5.3.1 At minimum once per year, the REB will be informed of research that was reviewed and approved using course-based review procedures.

5.4 Documentation

- 5.4.1 The type of REB review conducted (i.e., course-based or Full Board review) is documented in the REB records and noted in the decision issued to the Researcher, where appropriate;
- 5.4.2 The REB annual report will include a list of submissions that were reviewed and approved using delegated review procedures.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 408.001	2023.02.03	Original version