

Title	Course-based Review
SOP Code	408.001
Effective Date	

Site Approvals

Name and Title	Signature	Date dd/mm/yyyy

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 Research Ethics Boards (REB) and non-REB reviewers that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members, Research Ethics staff and non-REB reviewers are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee or REB member(s) or non-REB reviewer(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

REBs should 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.

When research will be conducted by a student as part of a course, for pedagogical purposes only (e.g., to learn how to conduct research), the institution may decide that ethics review can be conducted through the delegated review procedure by an REB member or by a non-REB reviewer at the institution's department or equivalent level.

In delegating ethics review of course-based research, the REB should carefully select 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 Research Ethics staff 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, the submission is then screened against a pre-defined set of criteria for delegated review as determined by the REB. If the submission meets the delegated review criteria, it may be forwarded for course-based review.

5.2.2 For research that meets the criteria, course-based review may be conducted by an REB member or a non-REB reviewer who has the appropriate experience, expertise, training and resources as an REB member;

- 5.2.3 The non-REB reviewer 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, the non-REB reviewer may exercise all of the authorities of the REB, except that he/she may not disapprove the research; the research may be disapproved only by the REB at a Full Board meeting;
- 5.2.5 If the non-REB reviewer 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 FB review) and the outcome of the review will be recorded. The responsible Research Ethics staff 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 FB 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
SOP408.001		Original version

SOP 408.001
