

Guidance Document	REB Requirements for Student Research and Pedagogical Activities
Effective Review	NMREB and HSREB; Delegated & Full Board
Version Date	January 7, 2022

Introduction:

Many university courses include class projects and activities designed to develop research skills. These projects may be carried out by individual students, small groups or as a single class project. This guidance document provides an overview of these student activities and the associated procedures for ethical review when these activities involve human participants (incl. data and/or biological materials). If, after reviewing the below information, it is not clear if a project/assignment requires Western’s Research Ethics Board (REB) oversight, contact the Office of Human Research Ethics (OHRE) before any implementation of the project(s).

Important Note: If a project will serve a dual purpose and falls into two categories, then it must be held to the higher standard. For example:

- Data collected for course-based pedagogical (Category 2) projects cannot subsequently be used as secondary data for research purposes (Category 1); they should be treated as Category 1 from the outset.
- TCPS2 Application of Article 6.12 indicates that if course-based, pedagogical activities are used for the purposes of research, including an instructor’s own research program, then they would be subject to the regular institutional REB procedures (i.e., see Category 1 considerations).

Category 1: Research involving humans requiring REB review

The following information can be used to determine if a proposed student project is subject to standard REB oversight. If the below criteria apply, please adhere to the guidance that follows.

- The project is conceptualized as **research**, which is defined as “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation” (TCPS2 Application of Article 2.1).
- The project involves **human participants**, who are defined as “individuals whose data, biological materials, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question(s)” (TCPS2 Application of Article 2.1).
- The project does not otherwise meet the exemption criteria for research involving humans detailed in TCPS2 Chapter 2 (e.g., use of publicly available information - Article 2.2; naturalistic observation - Article 2.3; secondary use of anonymous information - Article 2.4; quality assurance/quality improvement/program evaluation projects - Article 2.5; and creative practices - Article 2.6).
- The process of data collection and analysis is systematic, rigorous and intended to generate analyzable data according to *disciplinary standards*.
- The measures to disseminate results typically include publication, thesis/dissertation, and/or other knowledge translation/mobilization strategies relevant to the discipline.
- Category 1 student projects could include:

- Class projects and activities which are intended to reflect the TCPS2 definition of research involving humans described above when disseminated outside of the classroom;
- Theses or equivalent research projects (e.g., independent study projects); and
- Student co-op work, field placements, or experiential learning projects where students reference their affiliation to Western or use any of its resources when engaging in research involving humans (see TCPS2 Application of Article 6.1).

REB Review Requirements: Subject to all existing guidelines/procedures for standard REB oversight.

Category 2: Course-based pedagogical projects

The following criteria can be used to determine if a proposed project should follow the review guidelines for a Category 2 project. If the below criteria apply, please adhere to the guidance that follows.

Criteria:

- Data collection/analysis activities are embedded within the context of a course assignment (e.g., research methods courses) and would otherwise constitute research involving humans as described above.
- Data may be collected anew from participants OR data may come from already existing datasets (i.e., secondary identifiable or non-identifiable data; see TCPS2 Article 5.5A/B).
- The course assignment is designed to teach students how to address a research question using a research framework within the field of study and involves human participants and/or their information/biological materials.
- The primary intention of the assignment is to provide students with an opportunity to learn and develop research skills with human participants and/or data (e.g., interview or survey procedures, transcription, data coding, application of analysis techniques/tools/software, etc.).
- The results of the project will form the basis of a report that is a graded class component.
- The structure of the report is determined by requirements set out by the instructor, typically in the course outline, to meet the course component.
- The data, data analysis, and report will not be used or presented as “research” as defined by TCPS2, Article 2.1. The data, data analysis, and report are intended *solely* for the purpose of meeting a course requirement, and will not be disseminated outside the classroom.
- Only the students engaging in these activities are expected to benefit (i.e., in terms of gaining experience in how research is conducted in the discipline).

REB Review Requirements:

- TCPS2 Application of Article 2.1 indicates that pedagogical, course-based research activities are subject to REB oversight “because of the possible risks to those recruited to participate in such activities, and the fact that, from their perspective, such activities may appear indistinguishable from those that meet this Policy’s definition of research.”

- Additionally, Western’s REBs acknowledge that part of the pedagogical objective of teaching research methods within the context of a course should include providing students with the relevant research ethics training to conduct research in that discipline.
- TCPS2 Article 6.12 indicates that when these projects are *minimal risk*, they can be delegated to non-REB members with “experience, expertise and knowledge comparable to what is expected of an REB member” (80), and that these projects must be reported to the REB.

REB Delegation:

- Western’s REBs delegate review and approval of individual student projects to the *course instructor*.
 - o Note: The course instructor is expected to be PI-eligible and have completed the TCPS2 CORE Tutorial. If the course instructor is not PI-eligible (according to Research Western’s PI eligibility criteria), the OHRE will accept department chair confirmation that the instructor can assume the PI role and they have completed the TCPS2 CORE Tutorial or equivalent human ethics training.
- The PI/course instructor must submit a Pedagogical Initial Application via WREM for review and acknowledgment prior to initiating the assignment.
- The REBs delegate review and acknowledgment of Pedagogical Initial Applications to staff in the OHRE (e.g., *ethics officer/coordinator*). As part of the review process, PIs/course instructors may receive feedback from the OHRE requesting updates to the application and/or project documents to ensure compliance with applicable guidelines and regulations. Acknowledgment is issued for one year.

Pedagogical Initial Application Requirements:

- a. Course code and title;
- b. Name and role of the PI/course instructor and any additional instructors (incl. TAs) involved in the course/assignment.
- c. Description of the course assignment that will include research-like activities (e.g., as described in the course outline/syllabus);
- d. Overview of parameters to ensure individual student projects are conducted in an ethical way (e.g., protocol/research plan, voluntary and informed recruitment/consent, privacy/confidentiality protections, guidelines regarding topic sensitivity and participant vulnerability, etc.); and
- e. Process for instructor to ensure appropriate conduct of project (e.g., instructor ‘sign-off’ on topic/documents prior to project initiation, periodical supervision/interim report, etc.).

If changes are needed to the pedagogical research assignment after initial acknowledgment:

- A Pedagogical Amendment Application must be submitted by the course instructor for review and acknowledgment by the OHRE, prior to the implementation of such changes.
- Note: The expiry date noted upon initial acknowledgment remains the same upon acknowledgment of an amendment (i.e., amendment acknowledgments do not extend the project beyond the originally specified one-year period).

To continue the pedagogical research assignment in the following year:

- If this course will be offered more than one year in a row, the instructor must submit a Pedagogical Continuing Ethics Review application via WREM for OHRE acknowledgment, indicating:
 - o The number of students who took part in this project in the previous term/year; and
 - o Any problems that arose during the students' projects that previous term/year.
- The course instructor will receive acknowledgment for an additional year, which can be subsequently be renewed again the following year if applicable.

To report the end of a pedagogical research assignment:

- If the course (or the specific assignment) will no longer be offered (including those courses that are only intended to be offered for 1 term/year), the instructor must submit a Pedagogical Study Closure Form application via WREM for OHRE acknowledgment, indicating:
 - o The number of students who took part in this project in the previous term/year; and
 - o Any problems that arose during the students' projects that previous term/year.

Category 3: Professional Skill Development

The following are examples of student projects involving human interaction that do not meet the definitions of Category 1 or 2, as their primary purpose is not research-related.

- Vocational skill development or job-related training within standard educational interactions and activities (e.g., student-to-student, nurse-to-patient, etc.).
- May include techniques commonly used in research, but they are not being carried out for research purposes.
 - o Example: Students may administer a clinical or educational assessment (e.g., via standardized questionnaires, interviews and/or observations) to gain experience in how the assessment should be performed in the specific field of study. Any data/information generated in such training exercises will not be used or analyzed for research purposes.
- Only the students engaging in these activities are expected to benefit in terms of gaining experience in how professional activities are conducted in the discipline.

Review Requirements: No REB oversight required.