

University of Saskatchewan Research Ethics Boards

GUIDELINES FOR ETHICS REVIEW OF COURSE-BASED RESEARCH PROJECTS

The University of Saskatchewan encourages course-based research at both the undergraduate and graduate levels for the purpose of developing research skills. These projects may be carried out by individual students, small groups or as a single class project. Although these course based research projects may not meet the standard definition of research as “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation (TCPS2, 2010)”, it is important that the ethical standards that respect and protect human participants in research are learned and practiced as students develop their research skills.

The University of Saskatchewan Human Research Ethics Policy (2013) follows the Tri-Council Policy Statement (TCPS2, 2010) and requires instructors conducting projects involving human participants to submit an application to the appropriate Research Ethics Board (REB) or Research Ethics Committee (REC) and receive ethics approval prior to undertaking the project

Course-based research activities vary in scope, but may include:

- students conducting interviews, administering standard tests, or distributing questionnaires to develop interview or questionnaire design skills;
- conducting “mini” research projects where students pose research questions, gather data from human participants, and analyse the data for presentation; or
- other activities that would be considered research within the disciplinary traditions in which the course is being taught.

1. Distinguishing Research from Professional Skill Development

In some courses the information gathering procedures and practices students learn are exclusively required for pedagogic purposes. They are not conducted within the context of, or embedded within, a research framework. For example, professional faculties train students to conduct interviews as part of skill development or individual knowledge acquisition. Information gathering projects within these situations are not subject to REB review requirements, however they must align with the appropriate professional standards or codes of conduct and review processes required by the relevant Faculty.

The following criteria can be used to assess whether information-gathering activities within a university course are part of a research project requiring Research Ethics Board review and approval or are for the teaching of professional skills or pedagogic purposes.

Information gathering activities are classified as **RESEARCH** where

- the intent is to educate students on research processes used to explore, replicate or expand existing theories and conceptual knowledge;
- students compare new techniques, practices, or programs with standard approaches to determine which is more effective;
- the results or findings are written in a format that would be acceptable for a research journal or academic conference presentation; or
- primary data is collected and organized for analysis and distribution or dissemination.

Information gathering activities are classified as **SKILL DEVELOPMENT AND NOT RESEARCH** when:

- the intent is to use the information to provide advice, diagnosis, identification of appropriate interventions, or general advice for a client to develop skills which are considered standard practice within a profession (e.g., observation, assessment, intervention, evaluation, auditing);
- the information gathering processes are part of training students in the conduct of a professional relationship with the participant (e.g., classroom teacher and students, nurse and patient, lawyer and client),

Instructors who are uncertain as to whether a learning activity or project falls outside the scope of these guidelines should contact the Research Ethics Office at 306-966-2975.

2. Options for Course Based Research Ethics Applications

a. Delegated Review of Course Based Research: *This option is limited to situations in which the course instructor designs a class research project for all students in the course. The students conduct research class sub-projects that conform to the class project and all follow the same methodology or procedure. The course instructor is delegated the authority to review individual student research projects.*

- Requests for delegated approval of course-based research projects must also comply with the following criteria
 - The research projects must be no more than minimal risk;
 - The research participants may only involve adult participants capable of giving free and informed consent and may not include vulnerable participants such as children, persons who are not legally competent to consent, mentally incompetent persons, legal wards, or persons dependent on the researcher(s) for therapeutic care or marginalized populations;
 - The research must not involve any personal, sensitive or incriminating topics or questions that could place participants at risk;
 - The research must not manipulate behaviour of participants beyond the range of “normal” classroom activity or daily life;
 - The research must not involve physically invasive contact with the research participants for example taking blood or urine samples, cortisol, muscle biopsies, tissue for genetic testing;
 - The research must not involve deception.
- The Instructor for the course takes the role of principal investigator and completes an “Application for Delegated Review of Course-Based Research” for the class that is being taught.
- The “Application for Delegated Review of Course-Based Research” form is submitted to the Departmental/College REC, or to the appropriate REB if there is no REC.
- Once the application is approved by the REB or REC, the Instructor may have their students complete an “Course Based Application To Involve Human Participants in Research” form for each research sub-project which is being undertaken in the class. The Instructor reviews each of these applications and ensures that they are complete and in compliance with the ethics review requirements of the University.

- If the student projects are to be carried out at other institutions or agencies (such as hospitals, government agencies etc.) students should be made aware that approval granting permission to access premises or to obtain private information from the other institution may be required, and should be obtained, where appropriate.
- Ethical approval for delegated review of course-based research is granted for three (3) years, provided that there are no changes to the course assignments. If changes are made, a memo indicating the changes must be submitted to the REC or REB. After 3 years, a new application must be submitted to the REB.
- An annual Status Report Form must be completed and submitted to the REC or REB.
- All sections of the course, whether on campus or not, must follow the guidelines and it is the responsibility of the Instructor to ensure compliance with the procedures.

b. Individual Student Class Project – student(s) in the course conduct diverse research class projects that are different in content, methodology or procedure.

- The Application for Behavioural Ethics Review or the Application for Biomedical Ethics Review form is submitted to the Departmental/College REC, or to the appropriate REB if there is no REC.

3. Recommended Educational Resources and Help with Completing this Form

- The Research Ethics Office (REO) website has templates and samples that comply with ethics requirements and can be customized to the specific requirements of your students' projects.
- The REO highly recommends Canada's Panel on Research Ethics' CORE tutorial for all students and course instructors: <http://pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>
- The Research Ethics Facilitators are available for help and consultation on your research ethics application. They are also available to make a presentation in your class about research ethics and the review process. Please contact them at 966-2975 to make an appointment.
- The following is sample wording instructors can include in course syllabi on research ethics clearance requirements:

The research activity involving human participants outlined in this course syllabus has been reviewed by the University of Saskatchewan _____ (Bio/Beh REB or relevant REC) and received ethics clearance. If you have any concerns or questions about the way this research activity is conducted, please contact: University of Saskatchewan Research Ethics Office, Telephone: (306) 966-2975; toll free 1-888-966-2975: ethicsoffice@usask.ca

These guidelines have been adapted by permission from McMaster University Research Ethics Board Request for Ethics Clearance of Course-Based Research Projects Guidelines.

APPENDIX I : Examples of Projects and Activities and the Review Procedures

1. Projects with the following characteristics are eligible for Course-Based Research review and approval.

- Projects where primary data is being collected and organized for analysis and distribution or dissemination;
- Projects designed to answer research questions;
- Projects involving a risk of disclosure, publication, or use of data outside the classroom or outside the organization being studied;
- Projects where students are asked to sign a non-disclosure or confidentiality agreement;
- Projects where students require consent to use individual identifiers in reports or classroom presentations because of confidentiality or privacy concerns;
- Projects where “ownership of information” or “product development” as a result of a project may become an issue;

2. Projects that require regular REB approval:

- Projects that are a direct extension of the course instructor’s research;
- Projects involving more than minimal risk as defined by the Tri-Council Policy Statement;
- Projects applicable to an honours, Master’s or Ph.D. thesis;
- Projects where the participants are not capable of giving free and informed consent and which include vulnerable participants such as children, persons who are not legally competent to consent, mentally incompetent persons, legal wards or persons dependent on the researcher(s) for therapeutic care;
- Projects which involve any personal, sensitive or incriminating topics or questions which could put the participants or the researcher(s) at risk;
- Projects which involve deception;
- Projects which involve manipulation of the behaviour of participants beyond the range of “normal” classroom activity or daily life;
- Projects which involve physically invasive contact with the research participants.

3. Projects that do not require REB review and approval:

- Projects where students are conducting the research on themselves during class time;
- Projects involving the use of records or information that is in the public domain, including the use of anonymous secondary data and surveys or questionnaires that have already been published;
- Projects involving the use of naturalistic observation where the participants are seeking public visibility and participant confidentiality and anonymity are ensured;
- Practicum or job training projects where students are fully integrated into the organization’s operational practices and are not conducting research;
- Projects where the intent is to use the information to provide advice, diagnosis, identification of appropriate interventions or general advice for a client;
- Projects where the intent is to develop skills which are standard practice within a profession (e.g. observation, assessment, intervention, evaluation, auditing); or
- Projects where the information gathering processes are part of the normal professional relationship between the student and the participants.

APPENDIX II: Reviewers' Checklist: Student Protocols

1. Research Methodology

- a) Is the research question clearly stated and is the research design appropriate to the research question?
- b) Is there some educational value in the project which justifies the involvement of human participants?

2. Data Collection Tools

- a) Are the data collection tools (interviews, questionnaires, surveys, etc) described in enough detail for you to assess their appropriateness and utility?
- b) Do the data collection tools involve any personal, sensitive or incriminating topics or questions?

3. Recruitment of Participants

- a) Are the criteria for the choice of participant population equitable? (*i.e. no unjustified exclusions based on race, gender, culture, religion, sexual orientation, etc.*)
- b) Are there any concerns about inappropriate inducement?
- c) Does the recruitment process violate the participant's privacy in any way?

4. Benefits and Harms

- a) Does the research meet the criteria for student projects as outlined in the guidelines for ethics review of course-based research projects?

5. Consent Form/Letter of Information

- a) Do the consent form and/or letter of information adequately address the following:
 - The nature and purpose of the research;
 - What participation in the research means for the participant;
 - That they will be free to withdraw from participation at any time with no adverse consequences;
 - How the data will be stored, and whether or not confidentiality and/or anonymity are assured;
 - Who can answer questions about the research, including student and instructor contact information
- b) Is the consent form/letter of information in layperson's language and devoid of technical jargon?

6. Privacy and Confidentiality

- a) Will the data be kept secure?
- b) How will confidentiality and/or anonymity be assured?

7. Feedback

- a) How will the participants be advised of the results of the project?