

UVic Guidelines for Ethical Review of Course-Based Research Involving Human Participants

The following guidelines pertain to the application for Ethical Review of Course-based Research Assignments Involving Human Participants.

The procedures outlined in this document are limited to course-based research activities, not larger-scale projects required to fulfill the requirements for a graduate degree or an undergraduate honours thesis. In these cases students must complete either a full ethics application or an application for a waiver. Also excluded from this process are course-based research activities in which students work on a larger-scale project, such as their instructor's or another faculty member's own research program. In these cases, students must be identified as research assistants or co-investigators on the ethics application for the larger research project.

As part of their teaching strategies related to research, many instructors assign class projects and activities in which students must collect data from human participants. These projects may be carried out by individual students, small groups, or as a single class project. Course-based research assignments vary in scope, but may include: students conducting interviews, administering standard tests, or distributing questionnaires outside the class to hone their interviewing or questionnaire-design skills; students conducting "mini" research projects where they pose research questions, gather data from human participants, and analyze the data for class presentations or reports; other activities considered research within the discipline in which the course is taught.

Course-based research projects may not fit the standard definition of research in that the results are not intended for publication or generalization to other situations, however the potential for risks to participants requires that the protocols and consent processes of course-based research be reviewed by the Human Research Ethics Board (HREB). Rather than require individual students to complete and submit individual applications for ethical approval of their projects, instructors may be able to complete an application for *Ethical Review of Course-based Research Assignments Involving Human Participants* for all of the research assignments planned for the course.

Excluded from this process are course activities that are not conducted within the context of, or embedded within research. For example, professional schools often have students conduct interviews as part of their skill development or individual knowledge acquisition within their professions. These types of information gathering projects are not subject to HREB review, however they must comply with the applicable professional standards and codes of conduct and follow any review processes required by the related department.

Distinguishing Research from Professional Skill Development

The following criteria may be used to assess whether information gathering activities within a university course are considered to be research or to be for the purpose of teaching professional skills. Course-based assignments are considered **research** and are subject to ethics review when:

- the intent is to educate students on research processes used to explore and expand existing theories and conceptual knowledge;

- students compare new techniques, practices, 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.

Course-based assignments are considered **skill development** and not subject to HREB review when:

- the intent is to use the information to provide advice, diagnosis, identification of appropriate interventions, or general advice for a client,
- the intent is to develop skills which are considered standard practice within a profession (e.g., observation, assessment, intervention, evaluation, auditing); or
- the information gathering process is part of the normal relationship between the student and the participants (e.g., teacher and students, nurse and patient, lawyer and client),

If instructors are unsure whether a learning activity or project falls outside the scope of the procedures outlined in this document, they should contact the Human Research Ethics Coordinator (hrethics@uvic.ca), or the Chair of the Human Research Ethics Board (ethics@uvic.ca).

General Conditions

The application for *Ethical Review of Course-based Research Assignments Involving Human Participants* must be signed by the instructor and the Departmental Chair or Director. These signatures attest to the fact that the learning activities described in the application have received the approval of the department's curriculum committee and that they conform to the ethical principles outlined in the University of Victoria *Human Research Ethics Board Guidelines* and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*. If the academic unit is also bound by other professional codes of ethics or conduct, the signatures attest to adherence to those codes as well.

Ethical approval of course-based research assignments will be granted for one year and must be renewed annually providing that there are no changes. If there is a change in the course instructor, a modification form must be submitted with the new instructor's name and contact information. If there are any substantive changes to the course, a new application must be submitted.

Minimal Risk Research Assignments

Ethical approval of course-based research assignments involving human participants is limited to those types of assignments that pose **minimal** risk to participants, as defined in the *Tri-Council Policy Statement*:

"if potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research."

Examples of minimal risk:

- Participants are competent adults, youth or children;
- Participants live freely in the community (i.e., are not captive, e.g., in prison or hospital);
- The topics are non-controversial and carry little or no risk to the participants;
- The methods are non-invasive, such as the use of questionnaires or interviews;

- The projects do not involve deception.

Instructor's Responsibility

1. The instructor will take the role of the principal investigator and submit a single completed application for *Ethical Review of Course-based Research Assignments Involving Human Participants* to cover all of the research assignments for the course.
2. The instructor will prepare students to undertake the research assignment(s) for this course, in compliance with the ethical standards set out in the University of Victoria ethical guidelines and policies, including:
 - ✓ Explaining the nature and purpose of the research project to participants.
 - ✓ Recommending recruitment strategies (e.g., by letter; through an organisation; presentation to a group; etc.), and safeguards to ensure that no coercion is used if there is the potential of a relationship between the students and the participants.
 - ✓ Obtaining free and informed consent from participants.
 - ✓ Explaining the voluntary nature of participation and the participants' right to withdraw at any time without consequences.
 - ✓ Assessing any potential risks and/or benefits related to the study and explaining them to participants (research assignments must be minimal risk).
 - ✓ Describing compensation offered to subjects (if applicable).
 - ✓ Addressing anonymity with participants (i.e., protection of the identity of participants along a continuum, from complete to no protection, as appropriate and as agreed to by participants).
 - ✓ Addressing confidentiality issues with participants (i.e., identity as well as data, including secure storage of, and controlled access to the data and personal information).
 - ✓ Explaining how the results will be reported.
 - ✓ Explaining how and when the data will be destroyed.
 - ✓ Making it clear that permission must be obtained from all outside agencies that will be involved in the study (e.g., companies; community agencies; School Districts; VIHA; Aboriginal Governments, etc.) prior to undertaking the research.
 - ✓ Explaining any other procedures relevant to complying with the ethical guidelines and policies of the University of Victoria.
3. The instructor will provide a sample of a completed Participant Consent Form for the students to follow in developing their own consent forms for their research assignments. Students will submit a draft Participant Consent Form to the instructor for review and feedback. (A template of a Participant Consent Form is provided on the [ORS website](#); and a checklist is provided with the [Course-based application form](#).)
4. All documents related to approving the ethical acceptability of each student's research assignment must be retained by the instructor for a period of three years.
5. For each separate research assignment, students will submit to the instructor, a completed *Application for Ethical Approval of Human Participant Research* (this form and the guidelines are available on the [ORS website](#)). One form is required for each project (thus, group projects only

require a single application that lists all members of the group as co-investigators). Alternatively, instructors may develop their own form or format for students to follow in developing their research proposals for ethical review, however the format must include all elements on the standard application form and must be approved by the HREB (please attach to this application any alternative forms or formats you may wish to use instead of the standard application).¹

6. Instructors must ensure that students' applications meet the basic requirements for ethical approval as outlined in the checklist below.

Checklist

Students must provide the instructor with information pertaining to each of the following:

- ☐ A copy of the informed consent form, that will be read and signed by the participants (see the template on the [ORS website](#) or the checklist in the [Course-based application form](#));
- ☐ A brief description of the project in lay language that can be understood by the participants and that clearly identifies that this is a course-based project and includes the course name and number, and the instructor's name and telephone number;
- ☐ A full description of all data collection procedures and instruments, as well as expectations regarding the amount of time required for participation (copies of any questionnaires must be provided for the instructor's approval);
- ☐ Whether any risks or benefits are likely to arise from participation in the project (these must be minimal risk research projects);
- ☐ The names of all persons involved in collecting data for the project;
- ☐ Details of any compensation offered to subjects (if applicable);
- ☐ An explanation to participants that will ensure they understand that participation is entirely voluntary and that they can withdraw at any time, without explanation or consequences (i.e., that participation, nonparticipation, nor withdrawal will have any effect on, for example, grades, class standing, or employment - as applicable);
- ☐ The means by which participants' anonymity will be protected;
- ☐ The means by which the data will be kept confidential, including details of secure storage, who will have access;
- ☐ Permission to audio tape or video tape the participants (if applicable);
- ☐ How the raw data, including tapes, notes and other types of data will be disposed of at the end of the project;
- ☐ The way in which the results will be presented and/or dissemination;
- ☐ A Reminder: All students must provide written evidence from outside agencies (e.g., school boards, VIHA) granting approval to carry out research that involve such agencies. A copy must be sent to the ORS and will be kept on file with the instructor's application.

Informed Consent

¹ Assisting students to complete an *Application for Ethical Approval of Human Participant Research* provides an opportunity to teach students about research ethics and serves as a mechanism by which instructors can evaluate the ethical acceptability of each student's research assignment.

All prospective participants, or their authorized third party, have the right to be given the opportunity to voluntarily provide free and informed consent both prior to, and during, their participation in the study. Please refer to the [University of Victoria Human Research Ethics Board Guidelines](#) and the [TCPS](#) for more information regarding the consent process, particularly with regard to particular groups of participants (competency issues, ethnicity, age etc.). The [Forms](#) section of the Ethics website includes a checklist regarding the content of the consent form.

Waiver of Requirement for Ethical Approval

The TCPS has designated some forms of human research as not requiring ethical review or approval. Please read through section C of the [Waiver Application from a Full Ethical Review](#) for the five categories of research that qualify for a waiver. In cases where a student's research assignments fits one of the five categories for a waiver, the student should submit an [Application for a Waiver from a Full Ethical Review of Research Involving Human Participants](#) to the instructor before the research is begun.

When to Forward a Student's Application to the Human Research Ethics Board

All course-based research assignments must involve procedures that pose minimal risk and that can be reviewed comfortably by the instructor. On occasion, you may receive an application that raises issues you are unsure of. In that case, you may forward the application to the Human Research Ethics Coordinator or the Human Research Ethics Board Chair for review. In addition, you should automatically reject applications containing the following:

- Any indication of potential for more than minimal risk to the participants, whether psychological, emotional, physical, economic, etc.
- Any use of deception;
- Any questions about intimate or sensitive aspects of the participants' behaviour or life history (e.g., sexual behavior or childhood abuse).
- Excessive inducements to participate that may compromise voluntary participation. This may include excessive compensation or the suggestion that participants will benefit later on (e.g., primary-school student whose study habits will improve via participation).

The above list does not anticipate all possible situations. If you are unsure about a particular student project or procedure, please contact the Human Research Ethics Coordinator (hrethics@uvic.ca), or forward the student's application to the Human Research Ethics Office for review.