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Effective date: January 1, 2004	ETHICS REVIEW OF UNDERGRADUATE COURSE-BASED RESEARCH PROJECTS INVOLVING HUMANS		

1) Introduction

Many undergraduate 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. The University of Western Ontario wishes to encourage learning of research methodologies and techniques by undergraduate students. Class exercises may not fit the standard definition of research in the sense that the results are not intended for publication or for generalization to other situations. However, the potential for risk to subjects who participate in research class exercises requires the protocol and consent information be reviewed by a research ethics board (REB).

Undergraduate research activities vary in scope, but may include:

- having students conduct interviews, administer standard tests, or distribute questionnaires to develop interview or questionnaire design skills;
- conduct '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.

All questions and clarifications concerning the interpretation of these guidelines should be directed to the Office of Research Ethics, 661-3036, ethics@uwo.ca. All forms and guidelines referred to in this document may be found on the Office of Research Ethics web site <http://www.uwo.ca/research/ethics/>.

2) Distinguishing Research from Case/Professional Skill Development

In some class situations the information gathering procedures and practices students are expected to use are exclusively required for pedagogic purposes. They are not conducted within the context of, or embedded within, a research framework. For example, professional faculties have students 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 or are for the teaching of professional skills or pedagogic purposes.

a) Information gathering activities are classified as research 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.

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b) 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,
- 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 processes are part of the normal relationship between the student and the participants (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 the criteria outlined in this document should contact the Office of Research Ethics at 661-3036, or ethics@uwo.ca

3) Criteria for Undergraduate Student Research

If an Undergraduate project falls under the definition of research as described above, the following Guidelines and Procedures will be applied. Requests for approval of Undergraduate research projects must comply with **all** the following criteria.

- a) The research projects must be no more than **minimal risk**. The standard of minimal risk is defined as follows:

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 subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk.

- b) The research participants must be drawn from the general adult population, capable of giving free and informed consent, and may not include vulnerable subjects such as children, persons who are not legally competent to consent, mentally incompetent persons, prisoners, legal wards or the therapeutically dependent. *Some exceptions may be made in the case of children if the research carries absolutely no risk.*
- c) The student projects must not involve any personal, sensitive or incriminating topics or questions which could place participants at risk.
- d) The student projects must not manipulate behaviour of participants beyond the range of “normal” classroom activity or daily life;
- e) The student projects must not involve physically invasive contact with the research participants.
- f) The projects should not withhold key information that could influence a participant’s decision to participate in the research.
- g) The projects should not involve the kind of deception that had a participant known about it in advance they likely would not have agreed to participate.

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- h) Projects should not be a direct extension of the course instructor's research that would normally be submitted to a main or Sub- REB under the instructor's own name;
- i) Projects should not be applicable to a Ph.D. or Masters student's own work that would normally be submitted to a main or Sub-REB under the Ph.D. or Masters student's own name.

4) The Application & Approval Process

- a) The Instructor for the course takes on the role of principal investigator for the purposes of the application and is responsible for overseeing the conduct of his or her individual students' research. It is the Instructor's responsibility to submit a **Request for Approval of Undergraduate Course-based Research Projects** form for the course. This form is to be signed by the Course Instructor. The following must be attached to the request form: a course outline, a sample consent form or letter of information that will be used as a model for the students, and a copy of the questions, questionnaire, survey or other research instrument etc if appropriate.
- b) Three (3) copies of the **Request for Approval of Undergraduate Research Projects** form and appended documents should be submitted to the appropriate Departmental or Faculty Sub-REB or to the Health Sciences or Non-Medical REB if there is no Departmental or Faculty Sub-REB.
- c) The REB will review the materials provided and if deemed acceptable will provide a formal REB approval notice to the Instructor. If the submission is approved by a Departmental or Faculty Sub-REB, that Sub-REB will send a copy of the Approval Notice to the Office of Research Ethics.
- d) Ethical approval for undergraduate class projects is valid for up to three (3) years, provided that there are no changes to the course assignments. If changes are made, the Course Instructor must write to the REB or Sub-REB that approved the original submission outlining the proposed changes. New course applications must be re-submitted every four (4) years. All sections of the course, whether on campus or not, must follow the procedures and all Instructors must ensure that these policies are complied with. One submission may suffice for all sections of a course as long as each section conducts its research projects in the same manner.
- e) Once the submission has been approved by the REB, the Instructor must have the students complete a outline for each separate research 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. A research project outline has been developed to aid instructors and students.

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- f) If the student projects are to be carried out at other institutions or agencies, (such as schools, hospitals, government agencies etc.), written evidence of approval from that agency or institution granting permission to carry out the study(ies) must be obtained and retained in the Instructor's files.
- g) The Letter of Information/Consent form to research participants must comply with the Information and Consent Documentation Guidelines of the relevant main REB. A sample template can be found at on the Office of Research Ethics website.
- h) The Letter of Information/Consent form to research participants should contain the following phrase in addition to the required statements dealing with participant rights and voluntary participation.

“This project is an opportunity to give students experience in doing research, it is a training and teaching exercise. Please note that if you decide not to participate or to withdraw from the study at any time, my grade in the course will not be affected.”

- i) The Instructor's name and contact information must be included in the Letter of Information to the research participants.
- j) All forms related to approving the ethical acceptability of each student's project must be retained by the Instructor for a period of two years after the completion of the project.
- k) Notify the Office of Research Ethics immediately if a research participant is harmed.

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APPENDIX 1

Some examples of Student projects that require ethics approval

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

APPENDIX 2

Some examples of student projects that *do not* require Ethics approval

1. 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;
2. Projects involving the use of naturalistic observation where the participants are seeking public visibility and participant confidentiality and anonymity are ensured;
3. Practicums or job training projects where students are fully integrated into the organization’s operational practices and are not conducting research;
4. Projects where the intent is to use the information to provide advice, diagnosis, identification of appropriate interventions or general advice for a client;
5. Projects where the intent is to develop skills which are standard practice within a profession (e.g. observation, assessment, intervention, evaluation, auditing); or
6. Projects where the information gathering processes are part of the normal relationship between the student and the participants.