

## **Attachment F**

### **Guidelines and procedures for course-based research activities involving human participants<sup>1[3]</sup>**

Some CCNM courses include class projects or activities designed to develop research skills, which might be carried out by individual students, small groups, or as a single class project. These class projects or activities might 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, if the potential exists for risk to humans who participate in these course-based projects or activities, these projects or activities should undergo ethical review.

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

- having students conduct interviews, administer standard tests, or distribute 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 taught.

#### **A. Distinguishing research from professional practice/skill development**

Students engaged in professional practice are not considered to be engaged in research. A student is engaged in professional practice when learning or doing the work of a naturopathic student. In general, professional practice for students involves the development of skills, which are considered standard practice within naturopathic medicine, and includes information-gathering processes that are typically a part of the normal relationship between a naturopath and a patient. Examples of this include patient history-taking and the provision of advice to a patient. Activities considered to be professional practice should follow the ethical standards and guidelines found within the naturopathic medical profession.

Notwithstanding the above, ethical review will be required for course research projects involving humans where research is part of professional practice and ethical review is standard practice in the naturopathic profession.

The following criteria can be used to assess whether information-gathering activities within a CCNM course are part of a research project or are intended for the teaching of professional skills (i.e., for pedagogical purposes) alone.

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 are more effective;
- the results or findings are written in a format that would be acceptable for a research journal or academic conference presentation; or

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<sup>1[3]</sup> McMaster University and Ryerson University are the sources for the guidelines upon which appendices E and F are based.

- primary data is collected and organized for analysis and distribution or dissemination/publication.

Information gathering activities are classified as **professional 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 patient;
- the intent is to develop skills which are considered standard practice within the naturopathic medical profession (e.g., observation, assessment, intervention, evaluation); or
- the information gathering processes are part of the normal relationship between the student and participants (e.g., naturopathic doctor and patient).

Instructors who are uncertain if their classroom project or activity falls within the category of research, according to the criteria outlined above, should contact the Research Department.

## **B. Criteria for student research**

If a class project falls under the definition of research described in section A above, the following guidelines and procedures may be applied.

Requests for approval of course-based research projects must comply with the following criteria.

- The research project must involve 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.
- 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, legal wards or the therapeutically dependent.
- The student project must not involve any personal, sensitive or incriminating topics or questions that could place participants or researchers at risk.
- The student project must not manipulate behaviour of participants beyond the range of "normal" classroom activity or daily life.
- The student project must not involve physically invasive contact with research participants.
- The student project must not involve deception.

If the class project falls under the definition of research described in section A above and any of the preceding criteria are not met, CCNM's **Research Ethics Board** must review the project or activity.

### **C. The application process – for a single or uniform class project**

1. The course instructor assumes the role of principal researcher and submits CCNM's *Application for Research Involving Humans* on behalf of his/her class.
2. The course instructor signs the application form and includes samples of free and informed consent forms, information letters for participants, questionnaires/surveys or other research instruments that might be used in the research project.
3. The application is submitted to the Director, Research.

### **D. The application process – for different projects within a class**

1. A separate application should be submitted for each unique research project conducted in the class. Instructors should have their students complete and submit CCNM's *Application for Research Involving Humans*.
2. The instructor should review each of these applications and ensure that they have been completed appropriately and include samples of free and informed consent forms, information letters for participants, questionnaires/surveys or other research instruments that might be used in the research project.
3. The applications are submitted to the Director, Research.

### **E. Considerations for a single class project and different projects within a class**

1. If a student project is to be carried out at another institution or agency (such as school, hospital, government agency, etc.), students should be aware that approval or permission to access the premises or obtain private information from another institution might be required. Such approval should be obtained in advance, where appropriate, for a submission for ethical review at CCNM.
2. Ethical review approval for single or uniform class projects can be maintained for three years, provided that there are no changes to the course assignments. If changes are made, a new ethical review application must be submitted. New applications for course-based research must be re-submitted every four years. All sections of the course, whether on campus or not, must follow the procedures and all instructors must ensure that these policies are followed.

<sup>1[1]</sup> The procedure outlined for expedited review is adapted from Section D1, Article 1.6, Tri-Council Policy Statement.