# ETHICAL CONDUCT OF COURSE-BASED RESEARCH

## REVIEW AND APPROVAL

**DALHOUSIE UNIVERSITY**
FACULTY OF MANAGEMENT

Hi everyone and welcome to a tutorial focused on Research Ethics Review within the Faculty of Management. My name is Alison Brown and I am the Faculty of Management's Research Ethics Officer. In this tutorial we will cover several topics that will provide an overview of research ethics and then discuss how to apply that deeper understanding of ethical principles to our course-based research projects.

**LEARNING OUTCOMES**

By the end of this tutorial, you will be able to
- understand the importance of ethical conduct in all research
- articulate the core ethical principles in conducting research with human participants
- distinguish between research and evaluation or quality assessment
- determine which type of ethics approval is required for your research
- describe 'minimal risk' and 'vulnerable populations'
- understand the Faculty of Management's ethics review process
- implement tips for successful applications

After completion of the tutorial, you will be able to understand the importance of ethical conduct in all research, articulate the core ethical principles in conducting research with human participants, understand what kinds of projects need ethics approval and distinguish between research and evaluation or quality assessment. You will know how to determine which type of ethics approval is required for your research, describe 'minimal risk' and 'vulnerable populations', follow the Faculty of Management's ethics review process, and, finally, implement tips for successful applications.

RESEARCH ETHICS

Ethical principles and guidelines seek to advance the pursuit of knowledge while simultaneously protecting and respecting research participants.

*Figure 1*. Why researchers make such a big deal about E=ethics by Bridget Higton, 2016, retrieved from https://communicationblog06.wordpress.com/2016/04/06/why-do-researchers-make-such-a-big-deal-about-ethics/.

Research is propelled by our search for knowledge about ourselves and the world around us. We are compelled to understand and improve the world in which we live. That research often entails risks to those who participate in the research because it seeks to understand something we have yet to know or uncover. These risks can be minimal or profound, physical or psychological, individual or social. And this is where research ethics comes in. Ethical principles and guidelines seek to advance the pursuit of knowledge while simultaneously protecting and respecting research participants.

## OBJECTIVES OF AN ETHICS REVIEW AND APPROVAL

1. Protect human participants

2. Ensure research is conducted in a way that serves interests of individuals, groups and/or society as a whole

3. Examine specific research activities and projects for their ethical soundness

There are three main objectives in research ethics when people are involved as participants in research. The first and broadest objective is to protect human participants. The second objective is to ensure that research is conducted in a way that serves interests of individuals, groups and/or society as a whole. Finally, the third objective is to examine specific research activities and projects for their ethical soundness. This includes looking at things like the management of risk, protection of confidentiality and the process of informed consent.

## TRI-COUNCIL POLICY STATEMENT: ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS (TCPS 2)

Canada's Interagency Advisory Panel on Research Ethics (PRE) develops, interprets, and implements the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2).

For universities and other federal agencies in Canada, research ethics are governed by the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, known as the TCPS2. The Interagency Advisory Panel on Research Ethics (PRE) is the body of experts whose role is to advice Canadian research agencies on the evolution, interpretation, implementation and the educational needs of the TCPS 2.

As an institution that receives funding from the Tri-Council (SSHRC, NSERC, CIHR), Dalhousie is bound by the policy, and it is upheld by the university's Research Ethics Boards.

Core principles of research ethics

**Respect for Persons**
- Voluntary
- Informed decisions/consent

**Concern for Welfare**
- Privacy
- Minimize risks, maximize benefits

**Justice**
- Fairness
- Equity
- Power

The guidelines in the TCPS are based on three core, complementary, and interdependent principles which provide the compass for navigating the ethical conduct of research: respect for persons, concern for welfare, and justice.

Respect for persons highlights that people need to have sufficient information and capacity to make an informed and voluntary choice to participate in research. That is, individuals must be provided with complete information about a study and decide on their own whether to enroll. Some people in our communities may not have the capacity to make fully informed decisions about what they do or what happens to them. This could include young children or people who are very ill. In such cases, these people should be protected and only be included in research under specific circumstances.

Concern for welfare means that researchers should aim to protect the welfare of participants – that is, their physical, emotional, psychological, economic, and social well-being. Researchers must provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation in the research. Researchers are obligated to do their best to

minimize those possible risks and to maximize the benefits for individual participants and society has a whole.

This principle of justice is about the obligation to deal with people fairly and equitably, with respect and concern. Equity involves the duty of the researcher to ensure that no segment of the population is unduly burdened by or denied the benefits of participation in research and that imbalance of power between the researcher and participants is acknowledged and mitigated. Finally, individuals or groups whose circumstances cause them to be marginalized may need to be afforded special attention in order to be treated justly in research.

WHAT KIND OF PROJECTS NEED ETHICS APPROVAL*?

**Generally**
All research that involves living human subjects requires review and approval

**Do not**
Individuals with whom you interact in order to obtain factual information, but who are not themselves the "subject" of the study

**Do**
Individuals from whom you seek opinions, or whom you observe in their work or other non-public settings

**Unless**
The project is not considered 'research'

*With thanks to Dr. Karen Beazley

So, what kind of projects or studies require research ethics approval? It all depends on what questions you are asking, the information you need to answer these questions, and where you will get this information. The Tri-Council Policy states that "... all research that involves living human subjects requires review and approval..." Therefore, studies that use surveys, interviews or participant observations usually need approval.

There are nuances, however. For example, individuals with whom you interact in order to obtain factual information, but who are not themselves the "subject" of the study, are not considered to be research participants, and thus ethics review is not required. On the other hand, individuals from whom you seek opinions, or whom you observe in their work, are considered research "subjects", and thus ethics review is required.

There is also a distinction related to the setting: is it public or private? You may use

information collected from individuals who share their opinions in a public forum, such as public meetings, without ethics review. This is because the individual should have no expectation of privacy in such a situation.

These distinctions between factual and opinion-based questions and public and private settings seem relatively clear. But there is another nuance. Even if it is an opinion-based inquiry in a private setting, the study may not need ethics approval. This is the case if it is not considered 'research' as defined by the Tri-Council Policy.

How does the TCPS2 define 'research'?

**Generally**

All studies that involve human subjects

**Except**

Program evaluation and quality assurance and improvement

So, what does the Tri-Council Policy mean by 'research'? Generally, it is all studies that involve human subjects except Program evaluation and Quality assurance and improvement. For example, the Ratings of Instruction you complete for your courses, are not considered 'research', per se. Instead, they are intended to evaluate instruction for improvement purposes. You are not the 'subjects' of 'research', and thus ethics approval is not required.

**DIFFERENTIATING RESEARCH, PROGRAM EVALUATION & QUALITY IMPROVEMENT**

Distinction hinges on the design, purpose, generalizability and intended beneficiaries

Research projects
- typically designed and based on theory
- results often meant to be generalizable/transferable
- contribute to the knowledge base

Program evaluation or quality improvement
- tend to focus on organisational goals
- typically not meant to test or develop more generalizable findings
- designed to assess and/or improve a particular practice
- outcomes are most relevant for the organisation or unit being evaluated

**Guidelines for Differentiating Among Research, Program Evaluation and Quality Improvement**

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Program evaluation and quality assurance activities are exempt from research ethics review (as per TCPS 2.5). It is often difficult to determine what is research from what is program evaluation or quality improvement. Dalhousie's Research Ethics boards have developed Guidelines for Differentiating Among Research, Program Evaluation and Quality Improvement. The link to that document is here. It includes a 12-item table, designed to help you make the distinction. The table is worth considering carefully as you design your projects.

Generally, the distinction hinges on the design, purpose, generalizability and intended beneficiaries of the project. Research projects are typically designed and based on theory, they often test a hypothesis, the results are often meant to be generalizable or transferable and the findings are meant to contribute to the knowledge base of a particular discipline.

Program evaluation or quality improvement, on the other hand, tend to focus on organisational goals as opposed to investigative goals, are typically not meant to test or develop more generalizable findings, are designed to assess or improve a particular practice or program, and the findings are most useful to the organisation or

unit being evaluated.

## COURSE-BASED RESEARCH ACTIVITIES

The TCPS2 specifically states that university **course-based research activities require** ethics review and approval.

Dalhousie University's *Policy on the Ethical Conduct of Research Involving Humans* (section 5.2.4) states that students engaged in course-based (non-thesis) research of minimal risk are eligible for faculty-level research ethics review.

Articles 2.1 and 6.12 of TCPS2 specifically state that university course-based **research activities require** ethics review. Dalhousie University's *Policy on the Ethical Conduct of Research Involving Humans* (section 5.2.4) states that students engaged in course-based (non-thesis) research may implement faculty-level research ethics review of minimal risk. This means, certain research projects are eligible to be assessed for ethics approval at the Faculty of Management level, rather than having to secure approval from the larger Dalhousie University Research Ethics Board.

## ELIGIBILITY FOR ASSESSMENT OF ETHICAL REVIEW AT THE FACULTY LEVEL (RATHER THAN UNIVERSITY REB)

❑ Enrolled in a course in the Faculty of Management

❑ Not conducting the research in your capacity as a faculty member, a post-doctoral fellow, a research assistant, or a staff person

❑ Research project is required for a course in the Faculty of Management

❑ Research project is neither thesis nor Research Assistant work

❑ Research is being undertaken for pedagogical purposes and not for purposes of academic publication

❑ Research project involves minimal risk to participants

❑ Research project does not involve a vulnerable population

To be eligible for faculty-level ethics review, your project must meet ALL of these criteria:

- You are a student enrolled in a course in the Faculty of Management

- You are not conducting the research in your capacity as a full or part-time faculty member, a post-doctoral fellow, a research assistant, or a staff person

- Your research project is required for a course in the Faculty of Management

- Your research project is not solely part of a thesis and it is not Research Assistant work

- Your research is being undertaken for pedagogical purposes and not for purposes of academic publication.

- Your research project involves minimal risk to participants

- Your project does not involve a vulnerable population

## MINIMAL RISK

"potential subjects 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" *(Tri Council Policy Statement on Ethical Conduct for Research Involving Humans, p. 194)*

## VULNERABLE POPULATIONS

"A diminished ability to fully safeguard one's own interests in the context of a specific research project. This may be caused by limited capacity or limited access to… rights, opportunities and power. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances" *(Tri Council Policy Statement on Ethical Conduct for Research Involving Humans, p. 197)*

A note here about minimal risk and vulnerable populations. As just mentioned, the TCPS2 states that research projects that meet minimal risk criteria and do not involve or engage vulnerable populations are eligible for faculty-level review. "Minimal risk" research is defined by the policy as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research. So, the extent and likelihood of experiencing physical, psychological, and/or social harms must be taken into account. You need to consider whether participation in the research might involve things like emotional discomfort, loss of reputation, experiences of pain – beyond which they could reasonably be expected to encounter day to day.

Further, the TCPS2 states that individuals or groups whose circumstances make them vulnerable should not be inappropriately included or automatically excluded from participation in research.  Research involving vulnerable persons, which may include children, persons with developmental or cognitive disabilities, persons who are institutionalized, the homeless or those without legal status, raises

unique ethical issues and need to be considered at the university-level Research Ethics Board.

In the Faculty of Management, most student research is social-science research that includes human participants who are surveyed or interviewed or participate in focus groups or some form of user test. This research, in general, falls into the category of minimal risk. If you are uncertain, consult your supervisor or the Research Ethics Officer.

CORNERSTONES OF THE ETHICAL REVIEW PROCESS AT THE FACULTY OF MANAGEMENT

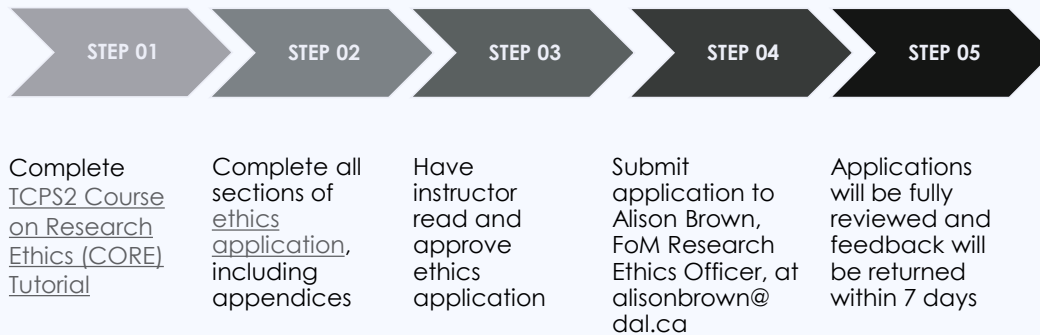Informed Consent        Minimal Risk        Protected Identities

The cornerstones of the ethical review process at the Faculty of Management level ensure that:

- Informed consent will be obtained from the participants

- There is minimal risk and participants will be informed about any potential risk, however small

- Participants will be respected and their identities will be protected unless otherwise warranted by the research methodology

By carefully reviewing students' ethics review applications, the Research Ethics Officer's goal is to help students ensure that all research study participants will be protected and respected.

**FACULTY OF MANAGEMENT ETHICS REVIEW PROCESS**

| STEP 01 | STEP 02 | STEP 03 | STEP 04 | STEP 05 |
|---|---|---|---|---|
| Complete TCPS2 Course on Research Ethics (CORE) Tutorial | Complete all sections of ethics application, including appendices | Have instructor read and approve ethics application | Submit application to Alison Brown, FoM Research Ethics Officer, at alisonbrown@dal.ca | Applications will be fully reviewed and feedback will be returned within 7 days |

*Alison Brown, Faculty of Management's Research Ethics Officer is available to answer questions and to support the development of applications at any time.*

This slide outlines the process you will undertake to secure ethics approval for your course-based, non-thesis, minimal risk research project. First, you must complete the TCPS2 Course on Research Ethics tutorial. It covers in more detail the issues we've addressed in this tutorial. You will need to include your certificate of completion with your ethics application.

Next, you need to carefully review and complete the Faculty of Management's Ethics Review Application. This will involve consideration and assessment of the research project's background, methodology – including data collection instruments, participants, recruitment, risks and benefits, privacy and confidentiality, compensation, conflicts of interest, and informed consent.

Your course instructor will need to review and approve your application. Then, you will submit the application, together with all the appendices to the Research Ethics Officer. Typically, the application will be reviewed and returned with feedback within seven days.

## TOP TIPS FOR SUCCESSFUL APPLICATIONS

➤ **Plan ahead** to ensure you have plenty of time.

➤ **Read and follow the submission instructions and guidelines**.

➤ Follow the **consent form guidance [template](#)** to avoid missing information.

➤ Provide a detailed description of what a participant will be asked to do from the **participant's perspective**.

➤ Provide a step-by-step description of how the **recruitment** and **informed consent process** will be handled.

➤ Avoid over/understated **risk/benefit assessment**.

➤ **Proofread** your submission and avoid inconsistencies.

This is a list of things you should keep in mind and consider for a successful ethics review application. First, **plan ahead** to ensure you have plenty of time to prepare your submission and go through one or more rounds of review. The majority of submissions require at least one set of revisions/clarifications. Incorporate this into your work plan for the term.

**Read and follow the submission instructions and guidelines**. Failure to do so commonly results in incomplete applications, missing signatures, insufficient information in the appropriate sections, missing appendices (e.g. copies of recruitment material, screening material, scripts, study instruments).

Follow the **consent form guidance template** provided by the Faculty (it's linked here) to avoid missing information. Ensure that consent forms and all documents that go to potential participants are grammatically correct and written in clear, concise, easy to understand language with no jargon.

Provide a detailed description of what a participant will be asked to do from the **participant's perspective**. Be sure that you plan to only collect information you need to conduct your study and answer your research questions.

Provide a step-by-step description of how the **recruitment** and **informed consent process** will be handled (including initial and on-going consent). Who, what, when, where and how, should all be addressed. Do not simply refer to an attached consent form (although that will be required too).

Avoid over/understated **risk/benefit assessment**. Cite "minimal risk" rather than "no risk"; identify risks and describe what you will do to mitigate the risk. Be realistic in your description of the benefits of research.

And finally**, proofread** your submission. Avoid providing inconsistent information in various sections of the submission (e.g. protocol details that are contradicted in consent documents). If the ethics officer isn't clear on the proposed research plan, they will need clarification before approval can be granted.

## Questions?

We are eager to address issues of interest to you. Please tell us what ethics topics you would like to see addressed in future tutorials.

Don't hesitate to reach out with any questions or concerns.

**Alison Brown,** Faculty of Management Research Ethics Officer, **alisonbrown@dal.ca**

Thanks for taking the time to complete this tutorial and best of luck with your research projects and ethics applications. We are eager to address issues of interest to you. Let us know if there are ethics topics you would like to see addressed in future tutorials. And don't hesitate to reach out with any ethics-related questions or concerns.