

TYPE:	Administrative
TITLE:	Ethical Conduct for Research Involving Humans
NO.:	ADMIN-231
RESPONSIBILITY:	President
APPROVED BY:	Durham College Leadership Team
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1. Introduction

Durham College (DC) is committed to advancing and safeguarding high-quality academic and ethical standards in all its activities. Research, at times, requires collaboration between human participants and researchers and may require the active involvement of participants. It is understood that research involving humans often entails risks that can be trivial or profound, physical or psychological, individual or social. Attention to the ethical and legal implications of research is an accepted and inherent part of good research practice.

2. Purpose

This policy and procedure establish the framework for DC's research ethical standards that will guide the actions of researchers, and which the College's Research Ethics Board (REB) will use to review the ethical merit of studies involving humans.

3. Definitions

Refer to [Durham College's Standard Definitions](#).

4. Policy statements

- 4.1. All research conducted under the auspices of the College that involves human participants, regardless of where the research is conducted or its funding source, must be approved in writing by the REB prior to beginning such research. Research must be done in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2022 (TCPS2-2022).
- 4.2. Requirements for conducting research on human participants are available through the Office of Research Services, Innovation and Entrepreneurship (ORSIE) in its ORSIE Procedures Manual.

4.3. Respect for Human Dignity

Respect for human dignity is an underlying value in research ethics and as such, research is conducted in a manner that is sensitive to the inherent worth of all human beings and safeguards their interests. Research that benefits society and advances knowledge will be guided by the following three complementary and interdependent core principles:

4.3.1. Respect for Persons

Respect for persons recognizes the intrinsic value of human beings and respects their ability to deliberate about a decision and to give due deference to a person's judgement. Aspects include:

- a) respect for free, informed and ongoing consent, including complete disclosure of the nature of the research so that the individual can provide free and informed consent with respect to their participation.
- b) respect for vulnerable persons, including the high ethical obligations and special protection against abuse, exploitation, or discrimination towards vulnerable persons whose capacity to make informed decisions is diminished.

4.3.2. Concern for Welfare

Concern for welfare is caring about the quality of a person's experience of life in all aspects. Aspects include:

- a) respect for privacy and confidentiality, meaning the protection of access, control, and dissemination of personal information to ensure confidentiality and anonymity unless there is consent to disclose.
- b) protection from harm, entailing a duty to ensure participants are not exposed to unnecessary risks and avoiding, preventing, or minimizing harm to research participants.

4.3.3. Justice

Justice is the obligation to treat people fairly and equitably. As such:

- a) fairness entails treating all people with equal respect and concern and that the ethics review process ensures no segment of the population will be unfairly burdened with the harm of research. There will not be any neglect or discrimination against individuals or groups that may benefit from the research.

- b) individuals or groups whose circumstances may make them vulnerable in the context of research may need to be afforded special attention in order to be treated justly in research.

Researchers must strive to achieve an appropriate balance between potential harms and benefits. Harm should not outweigh the anticipated benefits. Researchers must also strive to maximize benefits to the participants and society as a whole by providing access to the research findings.

4.4. Freedom of Inquiry

To maximize the benefits of research, researchers will have the freedom of inquiry and the right to disseminate the results of that inquiry, freedom to challenge conventional thought, and freedom from institutional censorship.

4.5. Research Ethics Board

- 4.5.1 DC will maintain an REB. The REB is accountable to the President of the College and is vested with the authority to review and decide as to whether to approve, reject, or recommend modifications to any proposed and ongoing research involving human participants that is conducted at DC.
- 4.5.2 The REB shall make decisions independently and be accountable for the integrity of the process of ethics review. To maintain its decision-making independence, the REB shall be provided with appropriate administrative and financial resources. To avoid the perception of undue influence, DC administrative staff shall not serve as members of the REB, nor attend REB meetings.
- 4.5.3 While it is not necessary for the REB to review a research proposal before it is submitted to a funding agency, REB approval must be obtained prior to commencing the research.
- 4.5.4 The REB shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions for its review of the research. Members of the REB must disclose any real or apparent conflict of interest regarding a proposal under review.
- 4.5.5 The REB shall use a proportionate approach to ethics assessment. As a preliminary step, the REB determines the level of review based on the level of risk presented by the research. The lower the level of risk, the lower the level of scrutiny (a "Delegated Review"); the higher the level of risk, the higher the level of scrutiny (a "Full Board Review") which is also the default review. The REB will review the application by

assessing the character, magnitude, and probability of potential harms of the research from the view of the human participant.

4.5.6 The College does not engage in any research involving human biological materials from living and deceased individuals, nor fetal tissue, embryos, fetuses, reproductive materials, or stem cells.

4.6 Research Involving Indigenous Peoples of Canada

Research involving Indigenous Peoples will respect the distinct world views of the First Nations, Inuit, and Métis peoples and ensure that they are represented in all aspects of planning and decision-making, following TCPS2 Chapter 9 and the respective Indigenous communities' guidelines, as applicable.

4.7. Safeguards/Research Data Management

Appropriate safeguards on research data and information will be in place to respect the privacy of participants and support researchers in fulfilling their obligations concerning confidentiality. Best practices in research data management shall be applied.

4.8. Appeals

DC will maintain an appeal mechanism in cases where the principal investigator and REB cannot reach agreement through discussion and reconsideration.

5. Procedure

5.1. Research Requiring a Review

5.1.1 All research projects under the auspices of the College involving human participants require a review by, and approval from, the REB prior to the start of the research.

5.1.2 Research under the auspices of DC includes:

- a) research conducted by a DC employee, full-time or part-time, where the employee is a principal investigator, co-investigator, or collaborator, and the employee's affiliation with DC is explicit in the research plan, regardless of where the research is conducted;
- b) research conducted by a researcher not affiliated with DC that involves DC students or employees as human participants, where the students' or employees' affiliation with DC is explicit in the research plan, regardless of where the research is conducted;

- c) research conducted by a researcher not affiliated with DC that involves the use of DC resources, including but not limited to space, class time, email distribution lists, controlled bulletin boards, internet services, computers, assistance or collaboration from staff, and the like; and
 - d) research conducted by DC students to fulfill course requirements.
- 5.1.3 A DC employee who is undertaking graduate studies at the masters or doctoral level and who plans to utilize DC resources (e.g., for recruitment or data collection) may submit an application as a principal investigator when the research is conducted to fulfill the degree requirements, and the faculty supervisor will be listed as co-investigator. In these cases, the DC employee must obtain REB approval from the university at which the employee is studying prior to seeking approval from the College's REB. In cases where this procedure is in conflict with the university's procedure, the REB will work with the researcher to establish a mutually agreeable solution for both REBs.
- 5.1.4 Whether the researcher is internal or external, the REB reserves the right to request information that demonstrates that the researcher or another member of the research team possesses the qualifications necessary to execute the research plan.
- Only in exceptional circumstances will a DC student be deemed to possess the qualifications necessary to serve as a principal investigator.
- 5.1.5 Research conducted by an external researcher who uses publicly available information or resources to recruit DC employees or students is not considered under the auspices of the College.
- 5.1.6 Research involving DC employees or students that is not connected in any way to their affiliation with the College and does not involve College resources is not considered under the auspices of DC.
- 5.1.7 Research conducted under the auspices of the College performed in whole or in part outside of Canada shall undergo a research ethics review by the DC REB and by a responsible review body at the research site.
- 5.1.8 Where there is uncertainty about whether the research requires a review, the principal investigator will request a written opinion from the REB chair as to the need for an ethics review and approval.

5.2. Institutional Permission

All researchers, whether internal or external to DC, planning to conduct research involving human participants and wishing to access DC faculty, staff, students, or resources, must first obtain institutional permission to conduct the research before applying for ethical approval from the REB. Research ethics approval does not constitute institutional permission.

5.3. Application for Ethical Approval

Researchers conducting research projects involving human participants must submit a completed Application for Ethical Review Involving Human Participants Form to the REB. Applications must receive approval prior to the start of recruitment of participants or access to data.

5.4. Ethical Review for Research with Prior REB Approval

If a researcher has obtained prior research ethics approval at another recognized Canadian institution and the study is considered minimal risk, the REB Chair has the option of conducting a Delegated Review. In this case, the researcher shall submit the application and supporting documents sent to the recognized Canadian institution and its approval certificate, as well as a completed multi-jurisdictional form. The REB may require additional information that is not included in the original package before approving the study.

5.5. Reconsideration

Principal investigators have the right to request reconsideration of decisions affecting a research protocol.

5.6. Appeals

5.6.1 If the principal investigator and REB cannot reach agreement through discussion and reconsideration, the principal investigator may request an appeal in writing to the REB Chair within thirty (30) business days.

5.6.2 Grounds for an appeal include any alleged breaches to the established research ethics review process or any elements of the REB decision that is not supported by the TCPS2-2022. The onus is on the researcher to justify the grounds on which an appeal has been requested, and to indicate any breaches of the review process.

5.7. Ethics Review for Student Course-Based Research

- 5.7.1 To qualify as course-based research, the research cannot be an extension of the faculty member's research; it must be minimal risk; it cannot involve the collection of data that will subsequently be used towards the completion of a masters or doctoral degree; and it cannot involve Indigenous Peoples or clinical trials.
- 5.7.2 For course-based research that is not senior-level undergraduate research, the REB will delegate research ethics review to a faculty member who is deemed the faculty supervisor for the purposes of the course-based research and who is responsible for supervising students conducting course-based research projects involving humans.
- 5.7.3 For senior-level undergraduate research, including honours theses, major research projects, or final capstone projects in which students conduct independent research involving humans, students must complete the standard application form and list their faculty supervisor as a co-principal investigator or co-investigator. The REB may choose to delegate research ethics review to a faculty-level research ethics committee, in cases where volume warrants.
- 5.7.4 For senior-level undergraduate research in which the student wishes to conduct research that is more than minimal risk, or involves Indigenous Peoples or clinical trials, the faculty supervisor must first approve in principle, and the application will be reviewed by the REB and not the faculty-level research ethics committee.
- 5.7.5 Course outlines incorporating course-based research require at least one learning outcome pertaining to research skills.

5.8. Ongoing Reporting Requirements

- 5.8.1 In accordance with a proportionate approach to ethics review, the REB will make the final determination as to the nature and frequency of the continuing ethics review. At a minimum, an annual status report with sufficient details to make a judgement about the ethical acceptability of the research will be submitted to the REB Chair.
- 5.8.2 Any unanticipated issues or adverse effects suffered by the participants are to be reported immediately to the REB by the principal investigator and resolved within seven (7) business days of their occurrence.
- 5.8.3 Contemplated changes to a research protocol must be submitted to the REB through the completion of a Change Request and/or Study Renewal Form with an explanation and are subject to an ethics review and approval before the changes are implemented. The only exception

is when changes are necessary to eliminate an immediate hazard to the research participants.

5.8.4 Researchers who have completed all interactions with participants must submit a Study Completion form to the REB prior to the REB approval expiry date. Submission of the Study Completion form does not prohibit subsequent use of the data collected.

5.9. Informed Consent Procedure

An important mechanism for respecting participants' autonomy in research is the requirement to seek their free, informed, and ongoing consent. This requirement reflects the commitment that participation in research is according to their values, preferences, and wishes. Participation through the use of one's data should be a matter of choice and to be meaningful, the choice must be informed. An informed choice is one that is based on as complete an understanding as is reasonably possible of the purpose of the research, what it entails, its risks and potential benefits, both to the participant and to others.

5.10. Public Emergencies

Extraordinary events such as natural disasters or communicable disease outbreaks that arise unexpectedly and require a quick response to minimize damage create certain challenges for research ethics review. The REB will consider how official emergencies may affect research and anticipate the pressures and challenges that may arise to ensure quality, timely, proportionate research ethics review. During these extraordinary circumstances, the REB will exercise due diligence in respecting the core principles of respect for persons, concern for welfare, and justice when reviewing the ethics of research.

5. **Accessibility for Ontarians with Disabilities Act considerations**

Accessibility for Ontarians with Disabilities Act (AODA) standards have been considered in the development of this policy and procedure and it adheres to the principles outlined in the College's commitment to accessibility as demonstrated by the Multi-Year Accessibility Plan.

6. **Non-Compliance Implications**

- 6.1. Failure to comply with this policy and procedure may negatively impact the dignity, rights, and well-being of human participants in research.
- 6.2. Failure to comply with this policy and procedure may result in damage to internal and external relationships, financial loss, property damage, reputational harm, legal action, and/or a diminished ability to achieve the mission of DC.

- 6.3. Failure to comply with this policy and procedure may also affect the College's status as an institution eligible to receive funding from the Natural Sciences and Engineering Research Council of Canada, the Social Sciences and Humanities Research Council of Canada, and the Canadian Institutes for Health Research.

7. Related forms, legislation or external resources

- Application for Ethical Review Involving Human Participants Form
- Change Request and/or Study Renewal Form
- Course based – Annual Review/Change Request Form
- Course-based – Request for Ethical Approval –Form A
- Course based – Student Application to Involve human Participants - Form B
- Course based – Study Completion
- *Freedom of Information and Protection of Privacy Act*, R.S.O. 1990, c. F.31
- Multi Jurisdictional Research Form
- *Personal Health Information Protection Act*, 2004, S.O. 2004, c. 3, Schedule. A
- Researcher Institutional Permission Request Form
- Secondary Use of Data Form
- Study Completion Form
- Summary of Course-based Research
- Tri-Agency Framework: Responsible Conduct of Research
- Tri-Agency Research Data Management Policy
- Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, 2022.
- Unanticipated Issues Reporting Form