COLLEGE POLICY

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

Durham College is committed to advancing and safeguarding high-quality academic and ethical standards in all its activities. It is understood that research often entails risks that can be trivial or profound, physical or psychological, individual or social. Establishing research ethical standards involves identifying, promoting and adopting a clearly understood set of principles and procedures that will guide the actions of researchers, and which the Research Ethics Board (REB) can use to judge the ethical merit of a given research study involving humans. Attention to the ethical and legal implications of research is an accepted and inherent part of good research practice. Research will be conducted at Durham College in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2014 (TCPS2 (2014))

2. Purpose

Durham College supports research that consistently meets the highest ethical standards. Research, at times, requires collaboration between human participants and researchers and may require active involvement of participants. Therefore, the interests of both researchers and participants are central to the research and there is an overriding premise that participants must not be treated simply as objects or a means to an end. It also requires that researchers conduct their research studies with accuracy, candour, objectivity and sensitivity. The purpose of this policy and the accompanying procedure document is to articulate the principles and framework underlying the establishment of the REB (Durham College Ethical Conduct for Research Involving Humans Policy) as well as the methodology for reviewing the ethical acceptability of research proposals (Durham College Ethical Conduct for Research Involving Humans Policy).
Procedure). Together the two documents ensure the preservation of human dignity and respect when humans are involved in research activities. Research conducted under the auspices of the college will be in accordance with the policy and procedures developed to ensure proper ethical review and accountability.

3. Definitions

3.1. Research

Research is an undertaking designed to extend knowledge through a disciplined inquiry or systematic investigation. It is the advancement of knowledge through scholarly, scientific and creative activity. Research involving humans is driven by the desire for new knowledge, or for the benefit to the participants such as improved teaching and learning, improved treatment for illnesses, or for the benefit of society such as the insights into political behaviour to produce better policy, or sociological data about lifestyles to instigate social reform.

3.2. Human participation

Human participation involves individuals whose data or responses to interventions, stimuli or questions by the research are relevant to answering the research question.

Under a broad definition, the research may include human participation:

- Directly in activities through physical participation and may include both active and/or passive involvement;
- Indirectly through the provision for or access to personal data and/or biological material; or
- On behalf of others (parents/legal guardians for those without the capacity to give informed consent and supervisors of individuals under controlled environments (e.g. prisoners, students).

The nature of human participation in research will vary from one project to the next depending on the degree of involvement and an individual’s consent. It is recognized that data collected about characteristics and responses may have identifiable private information, which is confidential and must be protected by the researcher.

3.3. Research Ethics Board (REB)

The Durham College Research Ethics Board (REB) oversees ethical screening and conducts a full review of research projects involving human participants. One board has been established to evaluate all research and ensure the research is conducted in a manner that is consistent with this policy.
3.4. Conflict of interest

A conflict of interest may arise when activities or situations place a person or the college in a real, potential or perceived conflict between their duties or responsibilities related to research and their personal, institutional or other interests. Conflict of interests may occur when individuals’ judgments and actions or the college’s actions in relation to research are, or could be, affected by personal, institutional or other interests, including, but not limited to, business, commercial or financial interests pertaining to these individuals, their family members, friends, or former, current or prospective employers or professional associations.

4. Policy statements

4.1. 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 of conduct as set out in the TCPS2 (2014):

4.1.1. 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 judgment.

a) Respect free, informed and ongoing consent – complete disclosure of the nature of the research so the individual can provide a free and informed consent with respect to their participation.

b) Respect vulnerable persons – high ethical obligations and special protection against abuse, exploitation or discrimination towards vulnerable persons whose capacity to make informed decisions is diminished.

4.1.2. Concern for Welfare

Concern for Welfare is caring about the quality of a person’s experience of life in all aspects.

a) Respect privacy and confidentiality – protecting access, control and dissemination of personal information to ensure confidentiality and anonymity unless there is consent to disclose.
b) Protection from harm – there is a duty to ensure participants are not exposed to unnecessary risks and to avoid, prevent or minimize harm to research participants.

4.1.3. Justice

Justice is the obligation to treat people fairly and equitably.

a) Fairness entails treating all people with equal respect and concern. That the ethics review process ensures no segment of the population will be unfairly burdened with the harm of research. Nor will there be any neglect or discrimination against individuals or a group that may benefit from the research.

b) Vulnerable or marginalized people 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.

4.2. 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.

4.3. Research Ethics Board

4.3.1. Durham College will establish and maintain one REB to provide ethical review and approval of research involving humans, prior to the start of the research. Policies specific to the REB are identified below.

4.3.2. 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.

4.3.3. The REB shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions of its review of the research.

4.3.4. 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 (Delegated Review); the higher the level of risk, the higher the level of scrutiny (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.

4.4. Aboriginal research

Aboriginal research will respect the distinct world views of the First Nations, Inuit and Métis peoples and ensure they are represented in planning and decision-making from the earliest stages of project design through to analysis and dissemination of results.

4.5. Safeguards

There will be appropriate safeguards on research information that respects the privacy of participants and supports researchers in fulfilling their confidentiality obligations.

4.6. Appeals

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

5. Research Ethics Board

5.1. Purpose

The REB is accountable to the president of Durham College and is vested with the authority to review and make a decision as to whether to approve, reject or recommend modifications to any proposed and ongoing research involving human participants that is conducted at Durham College. The REB will also monitor all research involving human participants through notices of change to research protocol, annual renewal of research projects and notices of research completion. It will suspend or terminate ongoing research that does not comply with this policy and with the TCPS2 (2014).

5.2. Independence

The REB shall make decisions independently and be accountable for the process of ethics review as identified in the Durham College Ethical Conduct for Research Involving Humans Procedure. In order to maintain its decision-making independence and operate at arm’s length from administrative and programmatic research structures, the REB shall be provided with appropriate administrative and financial resources and will be supported by the Office of Research Services, Innovation and Entrepreneurship (ORSIE). Senior administrators may not attend REB meetings as they may be perceived as unduly influencing REB deliberations and decisions. The REB must have independence to conduct ethics reviews, free of inappropriate influence, including situations of real, potential or perceived conflict of interests.
5.3. Composition of the board

5.3.1. The membership requirements are designed to ensure the board has the necessary basic background, expertise, perspectives and independence to conduct an informed independent reflection and a competent research ethics review. The REB shall consist of at least five members of whom:

a) At least two have broad expertise in the methods or areas of scientific methodology and research;

b) At least one is knowledgeable in ethics to assist with ethical issues and options;

c) At least one is from the community and has no affiliation to Durham College. This will broaden the perspective and value base of the board; and

d) At least one knowledgeable in relevant law so the member can alert the board to possible legal issues and their implications. The member must not be the college’s legal counsel.

5.3.2. Although an REB member may be qualified to fulfill more than one of the above roles, the individual may fulfill only one designated role during the term of appointment.

5.3.3. In addition to the above, the REB will have adequate gender representation and may be expanded to include a representative with legal expertise in biomedicine, if required, to specifically provide insight into biomedical research issues. Should additional representation be added to the board for the purpose of an adequate and thorough review, the community representation will also be increased to maintain a 20 per cent representation on the board, based on the TCPS2 (2014). Where possible, former research participants will be appointed to the REB to provide an experiential perspective.

5.3.4. Ad hoc appointments by the REB chair may be made to provide specific expertise and knowledge not present on the REB. However these appointees do not have voting privilege nor can they be counted to establish quorum.

5.3.5. Members for the REB will be selected based on the following criteria:

a) Main responsibility is in teaching or research (with the exception of the community member);
b) Commitment to ethics and willingness to expand knowledge;

c) Regular attendance at meetings and able to contribute to sound decisions;

d) Adherence to ethical practice in research;

e) Desire to foster ethical research practice within the college; and

f) Adherence to college policies and procedures.

5.3.6. Records related to REB membership, qualifications, and research ethics training will be maintained by ORSIE for a period of seven years.

5.4. Terms

Members of the REB will be nominated by the vice-president, Academic and appointed by the president for a period of up to three (3) years, renewable with staggered appointments of no more than one-third being replaced each year to maintain continuity. New members will receive orientation and training on ethics review including the principles, policies, legal and regulatory requirements to understand their role and responsibility on the REB.

5.5. Meetings

5.5.1. Meetings will normally be held monthly from September to June, and at least three times per academic year as required to review research applications. The REB shall normally meet face-to-face to review proposed research that is not assigned to delegated review, for adequate discussion and decision-making. In the event that an REB member cannot attend in person, the member may attend by teleconference or video conference, if the REB chair agrees and if the appropriate technology exists in the meeting room. A meeting schedule will be publicly available.

5.5.2. A quorum for a full board review shall consist of at least five (5) members who reflect the range of backgrounds and expertise required for the specific protocols under review at the meeting. The community member and the legal member must be present at each meeting at which full board reviews will take place.

5.5.3. Protocols will only be approved if sufficient and appropriate expertise is available at the meeting.
5.5.4. At least two meetings per year will include administrative matters, with the director, Research Services attending the administrative portion of the agenda.

5.6. Conflict of Interest

Members of the REB must disclose any real or apparent conflict of interest regarding a proposal under review. They may explain the conflict of interest and offer evidence to the REB and the proposer of the research who has the right to hear the evidence and offer a rebuttal. The REB member may not be present for the discussion where there is the perception the member has a vested interest and the member may not participate in the decision process.

5.7. Decision-making

Each REB member will make a decision based only on the ethical acceptability of the research, as defined by the TCPS2 (2014). For full board reviews, REB members will normally make decisions on each application by consensus. In cases where one or more members have concerns, the REB will work together to identify needed revisions that will make a project ethically acceptable. The REB chair may consult with the director, Research Services, other REB chairs, or the Secretariat on Responsible Conduct of Research. If disagreement persists, the majority position will stand, and the minority position will be communicated to the researcher in writing by the REB chair.

5.8. Professional Development

REB members will have regular opportunities to participate in professional development, including events hosted by the national association, that address identified needs of the REB. In addition, ORSI will periodically arrange for guest speakers, training, TCPS2 (2014) case studies or interpretations, or other similar opportunities that enhance the effectiveness of the REB.

6. Scope

6.1. All research conducted under the auspices of Durham College that involves human participants must be approved in writing by the REB, prior to beginning such research. The college does not currently engage in any research involving human biological materials from living and deceased individuals, nor fetal tissue, embryos, fetuses, reproductive materials or stem cells. In the event that research of this nature is undertaken, written approval of the REB will be obtained.

6.2. All college employees involved in research involving humans must ensure that they are familiar with the principles in this policy and incorporate these principles into the research design and implementation of the project.
6.3. Research on public policy issues, modern history, or creative practice activities does not require an REB review unless the participant is to be approached directly for interviews or private papers are to be accessed.

7. Accessibility for Ontarians with Disabilities Act (AODA) considerations

Durham College’s commitment to accessibility and AODA standards has been considered in the development of this policy and it adheres to the principles outlined in the AODA standards and Durham College Accessibility Policy (ADMIN-203).

8. Roles and responsibilities

8.1. Responsibilities of the president

As required by the TCPS2 (2014), it is the responsibility of the president, as the highest authority for establishing an REB, to ensure that the Ethical Conduct for Research Involving Humans policy is fully implemented.

8.2. Responsibilities of all individuals associated with Durham College

All individuals associated with Durham College in any capacity and conducting research involving human participants must comply with this policy. This includes individuals not associated with Durham College who approach faculty, staff or students or seek approval or endorsement from the college, or use college resources for research involving human participants.

8.3. Responsibilities of the REB

Responsibility for ethical review and for consideration of ethical research is vested in the REB, which ensures that ethical procedures are implemented and regularly reviewed in the college.

The REB is responsible for the following:

8.3.1. Ensuring that all research proposals involving human participants meet the highest standards of scientific rigour and ethics;

8.3.2. Recommending procedures regarding ethical issues relating to the use of human participants in research;

8.3.3. Assessing the design of the research project that poses more than minimal risk to ensure it is capable of addressing the questions being asked;

8.3.4. Reviewing protocols involving human participants to verify there is a favourable risk/benefit ratio for research participants, that it is respectful of the rights, dignity and autonomy of human participants, and that it equally distributes the benefits and burdens of research;
8.3.5. Reviewing annually all REB protocols to ensure they reflect current changes in an evolving ethics environment;

8.3.6. Ensuring that all applications that involve human participants, regardless of funding source, receive a thorough review and fair hearing in a timely fashion;

8.3.7. Rendering a reasoned decision about a research project, maintaining records of the process and documenting the opinions expressed;

8.3.8. Monitoring an approved research project in an appropriate manner to ensure that ethical standards and protocols are maintained throughout the course of the investigation;

8.3.9. Ensuring there is a mechanism in place for reporting and reviewing all adverse events associated with research projects;

8.3.10. Preparing an annual report on activities for inclusion in the ORSI annual report with assistance from ORSI; and

8.3.11. Acting as a resource and participating in professional development on matters relating to research ethics and the use of human participants.

8.4. Responsibilities of the REB Chair

The REB chair will be appointed by the vice-president, Academic, taking into consideration the recommendation of the director, Research Services. With the support of ORSIE, the REB chair will provide leadership for the REB, and will be responsible to:

8.4.1. Call and preside over meetings;

8.4.2. Ask for declarations of conflict of interest at each meeting and resolve any that arise;

8.4.3. Ensure there is quorum at each meeting during which decisions will be made;

8.4.4. Ensure there is appropriate expertise to deal with issues before the REB;

8.4.5. Approve the agendas, as prepared by the Finance and Ethics Compliance Coordinator;

8.4.6. Ensure that protocols are available to REB members for review;

8.4.7. Issue requests to researchers for additional information;

8.4.8. Oversee the revision and approval process for applications;
8.4.9. Oversee/approve the minutes, as prepared by the Finance and Ethics Compliance Coordinator;

8.4.10. Monitor all decisions, dissents and reasons for consistency; and

8.4.11. Identify opportunities for professional development and initiate training where appropriate.

The REB chair will meet regularly with the director, Research Services regarding training needs and administrative matters.

8.5. Responsibilities of the REB Vice-Chair

Depending on workload and other commitments, the REB may request the appointment of an REB vice-chair, who will assume the responsibilities of the REB chair, in the absence of the REB chair.

8.6. Responsibilities of REB Members

8.6.1. All members of the REB, including the REB chair and REB vice-chair if there is one, must complete the Tri-Council online tutorial Course on Research Ethics (CORE) and submit the Certificate of Completion to ORSI, and sign a confidentiality agreement before commencing responsibilities with the REB.

8.6.2. All members are responsible for impartially assessing each applicant’s project for compliance with TCPS2 (2014) standards and ethical acceptability. Specifically, members will review applications before each meeting, attend meetings prepared, participate in the delegated review process as requested by the REB Chair, offer feedback during meetings and delegated reviews as appropriate, request revisions as required, and approve or deny approval of protocols.

8.6.3. Members are expected to attend all scheduled meetings. In the case of illness or emergency, members will notify the finance and ethics compliance coordinator and the REB chair as soon as possible before the meeting. Members may be replaced if they are absent for two scheduled full board review meetings in an academic year.

8.6.4. Other specific staff roles and responsibilities are outlined in the related procedure document, Ethical Conduct for Research Involving Humans, ADMIN 231.1.

9. Non-compliance implications

Failure to comply with this policy 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 Durham College. Failure to comply with this
policy may also affect the college’s status as an institution eligible to receive funding from the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada.

10. Communications plan

A message will be posted on ICE alerting employees when new or revised policies and procedures are added to ICE. A message will be posted on MyCampus alerting students when new or revised policies and procedures are added.

11. Related policies, procedures and directives

- Durham College Conflict of Interest Policy (EMPL-303);
- Durham College Ethical Conduct for Research Involving Humans Procedure (ADMIN-231.1)
- Durham College Research Ethics Board Protocols
- Durham College Freedom of Information and Protection of Privacy Policy (ADMIN-222) and Procedures (ADMIN-222.1) and ADMIN-222.2)
- Durham College Intellectual Property Policy (EMPL-306);
- Durham College Responsible Conduct of Research Policy (ACAD-116) and Procedure (ACAD-116.1)