

 DALHOUSIE UNIVERSITY Policy on Ethical Conduct for Research Involving Humans	<i>Policy Sponsor:</i> Senate	<i>Approval Date:</i> May 12, 2008
	<i>Responsible Unit:</i> Office of the Vice-President Research and Innovation	<i>Amendments:</i> May 14, 2012 April 8, 2024

Dalhousie University is located in Mi'kma'ki, the ancestral and unceded territory of the Mi'kmaq. We are all Treaty people.

A. Purpose & Background:

Dalhousie University is committed to promoting the responsible conduct of research involving humans and communities that values human dignity through the application of the ethical principles of respect for persons, concern for welfare, and justice.

The purpose of this policy is to support the conduct of ethical and respectful research, by:

1. Ensuring that all individuals conducting research involving humans under the University's auspices or jurisdiction are doing so with appropriate ethical oversight by a research ethics board and consistent with the principles and guidance of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*;
2. Establishing an independent ethics review structure;
3. Describing the mandate, authority and responsibilities of researchers, the research ethics boards, and the University in ensuring that research involving humans is ethically acceptable.

As a signatory to *Agreement on the Administration of Agency Grants and Awards by Research Institutions* between Dalhousie University and the Canadian Institutes of Health Research; the Natural Sciences and Engineering Research Council of Canada; and the Social Sciences and Humanities Research Council of Canada, the University must comply with its obligations under this agreement. With respect to research involving humans, the primary policy document is the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.

In September of 1999, the University Senate adopted a preliminary set of administrative guidelines – *Administration of the Policy on the Ethical Conduct for Research Involving Humans at Dalhousie University* – with the intent of reviewing and revising them after an initial period of implementation. The *Dalhousie University Policy on the Ethical Conduct of Research Involving Humans* was approved by Senate on May 12, 2008 (2008:62) and May 14, 2012 (2012:045). This policy is revised to be consistent

with the University *Policy on Policies* (2017) and to incorporate University and Tri-Agency policies and statements regarding research involving Indigenous people and other distinct communities.

B. Application:

This policy applies to all research involving humans conducted by researchers and/or using resources that are under the University's auspices or jurisdiction, meeting either of the following criteria:

1. is research conducted by members of the University, or those employed by members of the University, acting in their university capacity. Members of the University include: faculty (full-time, part-time or emeritus), staff, students, medical residents, fellows, research associates, visiting or adjunct scholars, or any others associated with research at the University;
2. is research conducted using University resources that are not generally available to the public, including but not limited to facilities, human data, and human biological materials (including data or biologicals that are in the custody of the University or members of the University).

C. Definitions:

Definitions of terms are provided in Appendix A of this Policy. When terms are defined in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, they are not duplicated here.

D. Policy:

1. All researchers conducting research involving humans under the auspices or jurisdiction of Dalhousie University must receive research ethics board approval before undertaking such research. Acceptable research ethics board approval includes:
 - 1.1 Research ethics board approval from the Dalhousie University Health Sciences Research Ethics Board, Dalhousie University Social Sciences and Humanities Research Ethics Board, or any other Dalhousie research ethics board established or recognized by the University;
 - 1.2 Dalhousie University research ethics board acknowledgement of a board of record from another Canadian research ethics board that the University has authorized Dalhousie research ethics boards to accept;
 - 1.3 Research ethics board approval from other institutions with which Dalhousie University has an official agreement (such as Horizon Health Network, IWK Health Centre, and Nova Scotia Health).
2. Research involving humans must be conducted in a way that is consistent with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and any other applicable regulations, legislation, principles (such as the First Nations Information Governance Centre's principles of Ownership, Control, Access and Possession), statements (such as the Social Sciences and Humanities Indigenous Research Statement of Principles) and strategies, as relevant and appropriate.

3. Dalhousie University, through the Vice-President of Research and Innovation, will establish its research ethics boards in accordance with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* with the authority to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving humans under its auspices or jurisdiction.

E. Administrative Structure

1. Authority: This policy falls under the authority of the Dalhousie University Senate.
2. Responsible Executive: The responsible executive is the Vice President Research and Innovation or delegate.
3. Policy Review: This policy will be reviewed in accordance with the Dalhousie University *Policy on Policies*.
4. Roles and Responsibilities

4.1 Researchers

- a. Researchers undertaking research involving humans have the primary responsibility to ensure that the research is carried out in an ethical manner.
- b. Researchers must be familiar with the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* and conduct research consistent with its guidance.
- c. Researchers are responsible to obtain research ethics board approval prior to conducting research involving humans, as stipulated in this policy, and by the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* and described in the guidance documents that relate to the ethical review process. Responsibilities include: conducting REB-approved research in accordance with any instructions from the research ethics board that has approved and continues to oversee the research; and complying with, and maintaining in good standing, any ethics approval issued by the research ethics board.
- d. The lead researcher must ensure that members of a team under their supervision are aware of these responsibilities and that all researchers and research team members have adequate training, competence, and oversight to carry out their duties. All members of a research team, including those who conduct research under the supervision of others, are also responsible for the ethical conduct of the research.

4.2 Supervisors of Students

- a. Supervisors of students are professionally responsible for the ethical conduct of their students' research, even when the student is the lead researcher. Where students are engaged in course-based (non-thesis) research, supervisory responsibility rests with course instructors.
- b. Supervisors of students are responsible to provide adequate training in the methodology and in the ethical principles and policies that must be observed during the conduct of the

research.

- c. Supervisors of students are responsible for the content of research ethics submissions and must ensure the adequate scholarly merit, feasibility, quality, and completeness of submissions prior to submission for research ethics board review.
- d. Supervisors of students are responsible to ensure that student research undergoes research ethics review at the appropriate level:
 - i. All research that is more than minimal risk is reviewed by a University-level research ethics board;
 - ii. Course-based (non-thesis) minimal risk research is reviewed by unit-level research ethics committees (or equivalent);
 - iii. Undergraduate minimal-risk thesis research is initially reviewed by unit-level research ethics committees (or equivalent) and is subsequently reviewed by a University research ethics board;
 - iv. All graduate thesis and any other research undertaken under academic supervision is reviewed by a University-level research ethics board.

4.3 University Research Ethics Boards

- a. The research ethics boards are mandated by the University to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving humans that is conducted under the auspices or jurisdiction of the University by applying the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.
- b. The research ethics boards are accountable to the Vice President Research and Innovation for their research ethics review processes but are independent and impartial in their ethical decision-making.
- c. Unit-level research ethics committees: Academic units and programs whose students undertake course-based (non-thesis) research involving humans are responsible to establish and maintain a standing research ethics committee (or equivalent), in consultation with the research ethics office. The responsibility of the unit-level research ethics committee is to approve, reject, propose modifications to, or terminate any proposed or ongoing minimal risk research involving humans that is conducted under the auspices or jurisdiction of the academic unit by applying the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. Unit-level research ethics committees are accountable to the University research ethics boards.
- d. Appeal board: The University research ethics appeal board is convened to review appeals from University researchers when the University research ethics board has refused ethics approval of the research. Appeals follow the process and guidance as outlined in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. The appeal board may approve, reject or request modifications to the research proposal. Its decision on behalf of the University is final. The appeal board chair and members are appointed by the Vice President Research and Innovation and may not include any members from the research ethics board whose decision is under appeal. Likewise, administrative support is provided by the Office of the Vice President Research and Innovation rather than the

research ethics office.

4.4 University Administration

- a. Vice President Research and Innovation (or delegate): The Vice President Research and Innovation is responsible for oversight of the research ethics review system for research involving humans. This includes the allocation of financial and administrative resources to support the ethics review process, and ensuring the adequate number, qualifications, expertise and education of research ethics boards, members, and staff. The Vice President Research and Innovation is responsible for the appointment of research ethics board members and chairs.
- b. Academic administrators: deans, directors, department chairs, department heads and program heads are responsible for promoting a climate for ethical conduct of research involving humans and for ensuring researchers are aware of, and compliant with, this policy and the requirement for research ethics board oversight. Where students are engaged in research, this responsibility extends to ensuring that students are adequately instructed and supervised in the principles and implementation of research ethics.
- c. Academic administrators are responsible for nominating individuals to serve as research ethics board members. The process of selection and nomination of research ethics board members is conducted collaboratively among academic administrators, the Vice President Research and Innovation, the research ethics board chairs, and the director research ethics to ensure the board membership has the necessary representation of disciplinary and methodological expertise, research experience, and reflects the diversity of the University community (considering race, ethnicity, Indigeneity, gender, ability etc.). In nominating individuals for research ethics board membership, academic administrators should be mindful to appropriately recognize the workload commitment of this University service.
- d. Academic administrators of units whose students undertake course-based (non-thesis) research involving humans are responsible to establish a standing ethics review committee (or equivalent) to review and approve course-based, minimal risk projects.

F. Related Dalhousie policies and reports:

Indigenous Strategy (2018)

Policy for the Protection of Personal Information from Access Outside Canada (President, January 12, 2007)

Policy on Conflict of Interest (Senate, June 24, 2002)

Report on Lord Dalhousie's History on Slavery and Race (2019)

Scholarly Misconduct Policy (Senate and Board of Governors, June 2016)

US Public Health Service Research Misconduct Policy (Senate March 17, 2017 and Board of Governors April 18, 2017)

Appendix A: Definitions

When terms are defined in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, they are not duplicated in this policy. Terms not defined in the *TCPS* used in this policy are defined below:

Community – see *TCPS Glossary*.

Conduct of research – includes multiple stages of the research life cycle that involve humans, including the recruitment of participants, collection of data, access to data, collection and use of human biological materials, use and analysis to address research questions, dissemination of findings that involve participants, and records management and/or management of human biological materials.

Diversity – see Dalhousie’s *Diversity and Inclusion Strategy Progress Report (2019)* or successor documents.

Good standing – status of a project in which all requirements of the research ethics board are met.

Lead researcher – the researcher responsible for the leadership of the project, including its intellectual direction, with primary ethical, administrative and/or financial responsibility for the project.

Minimal risk – see *TCPS Glossary*.

Participant (human participant) – see *TCPS Glossary*.

Research – see *TCPS Glossary*.

Research ethics board – see *TCPS Glossary*.

Research Ethics Appeal Board refers to the group which the Vice President Research and Innovation convenes for the purpose of hearing appeals by researchers of negative decisions made by a University Research Ethics Board.

Researcher – a person engaged in research.

Student – a person enrolled at a post-secondary educational institution as well as trainees working under academic supervision, such as residents and post-doctoral fellows.

Unit-level – refers to Faculties, Departments, Schools, Colleges, Programs and other academic entities that operate at the University but do not serve the whole university.

Unit-level research ethics committee (or equivalent) – the group or person responsible to review the ethical acceptability of minimal risk course-based (non-thesis) research involving humans and have experience, expertise and knowledge comparable to what is expected of a University-level research ethics board member.

The University, when used in this policy, refers to Dalhousie University.