

RE03 Research Involving Human Subjects

Classification:	Research
Responsible Authority:	Director, Applied Research
Executive Sponsor:	Senior Vice President, Academic
Approval Authority:	Algonquin College Executive Team
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PURPOSE

To establish principles and guidelines for maintaining quality and ethical standards in conducting research at the College on human participants, consistent with the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS2 \(2022\)](#).

SCOPE

All research involving human participants conducted under the auspices of the College through:

1. Its employees and/or students, either as researchers or participants;
2. An affiliation between the College and other organizations; and/or
3. Non-College individuals or organizations using the College name or its resources to conduct research on College students and/or employees.

Course-based research activities involving human participants where the primary purpose is pedagogical, such as providing students with exposure to research methods in their field of study are subject to this policy. Minimal risk course-based research activities are also subject to the provisions in policy RE08: Course-based Research Projects Involving Human Participants.

This policy does *not* apply to Institutional Research, that is, the ongoing collection of data used to facilitate the management of the College as part of its normal operations and related directly to the normal administering, evaluating, or improving of an operation, program, service or activity within the College.

DEFINITIONS

Word/Term	Definition
Applied Research Office	The Office of Applied Research, Innovation and Entrepreneurship brings Algonquin College’s talented professors and students to greater Ottawa’s businesses, industry and community organizations to collaborate on applied research projects that provide practical solutions to everyday issues and create new and innovative products and services.

Human Participant	Living human participants or human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials, and stem cells. This applies to materials derived from living and deceased individuals. Also referred to as “research participant”, “participant”, “human subject”, “subject”, and/or “research subject”.
Minimal Risk Research	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.
Research	An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.
Researcher	A researcher is any College employee, student, visiting scholar, or volunteer who conducts research, or who uses students or employees as human research participants, or any person who conducts research using Algonquin resources (whether research space, materials, or human resources).
Research Ethics Board	The Research Ethics Board is a body consisting of representatives from Algonquin College and the community with the mandate to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants, which is conducted within, or by members of the College.
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)	The joint policy of the three primary Canadian federal research funding agencies—The Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC)—which sets out the ethical requirements by which research involving human participants must follow.

POLICY

1. Algonquin College is committed to safeguarding the rights and well-being of human participants of research activities in which the College is involved by adhering to the highest ethical standards for the protection of human participants and their rights. As such, all research involving human participants carried out under the auspices of the College shall be consistent with the following:
 - Respect for human dignity
 - Requirement for free and informed consent
 - Respect for privacy and confidentiality
 - Protection of academic freedom
 - Respect for vulnerable persons and communities
 - Fair and equitable inclusion
 - Balancing of harms and benefits; maximizing benefit and minimizing harm
2. All research conducted under the auspices of the College that involves human participants shall comply with the standards established by, but not limited to, the [Tri-](#)

[Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS2 \(2022\)](#).

3. **Core Principles**

All research at the College involving human participants shall be conducted in accord with three core principles guiding ethical research as laid out in [TCPS 2 \(2022\)](#)— Respect for Persons, Concern for Welfare, and Justice.

1. *Respect for Persons*

Recognizes the intrinsic value of human beings and the respect and consideration that they are due. It encompasses the treatment of persons involved in research directly as participants and those who are participants because their data or human biological materials, which for the purposes of this policy include materials related to human reproduction, are used in research. Respect for Persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.

2. *Concern for Welfare*

The welfare of a person is the quality of that person's experience of life in all its aspects. Welfare consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances. Thus, determinants of welfare can include housing, employment, security, family life, community membership, and social participation, among other aspects of life. Other contributing factors to welfare are privacy and the control of information about the person, and the treatment of human biological materials according to the free, informed and ongoing consent of the person who was the source of the information or materials. A person's or group's welfare is also affected by the welfare of those who are important to them. Harm includes any negative effects on welfare, broadly construed. Note that, for the purposes of this policy, "group" and "community" are used in their ordinary sense.

3. *Justice*

Justice refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it.

Treating people fairly and equitably does not always mean treating people in the same way. Differences in treatment or distribution are justified when failures to take differences into account may result in the creation or reinforcement of inequities. One important difference that must be considered for fairness and equity is vulnerability. Vulnerability is often caused by limited decision-making capacity, or limited access to social goods, such as rights, opportunities and power. Individuals or groups whose circumstances may make them vulnerable in the context of research have historically included children, the elderly, students,

women, prisoners, those with mental health concerns and those with diminished capacity for self-determination.

4. Research Involving the First Nations, Inuit and Métis peoples of Canada

Algonquin College acknowledges the unique status of the Indigenous peoples of Canada (including First Nations, Inuit, and Métis peoples), and the importance of interpreting the core ethical principles of research in an Indigenous context. As such, research involving Indigenous peoples shall be conducted in collaboration and engagement with the communities to which prospective participants belong. Researchers are required to show awareness and respect for the issues of conducting research with these communities, paying particular attention to the guidelines outlined in TCPS2 (2022) Chapter 9.

5. Requirement for Research Ethics Review

1. The Algonquin College Research Ethics Board (REB) has been established with the mandate to review, approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants under the auspices of the College, based on their assessment of compliance with this policy and other ethical standards, including the TCPS 2 (2022).
2. All research involving human participants requires ethics review and approval by the REB prior to the commencement of participant involvement.

6. Exemption from Ethics Review

The following activities do not require review and approval by the REB:

- Research that relies exclusively on the secondary use of anonymous information or on publicly available information that is legally accessible to the public, so long as the process of collection, dissemination and linkage of data do not generate identifiable information.
- Research that involves the observation of people in public places, where there is no reasonable expectation of privacy, there is no intervention or direct interaction with the individuals or groups, and the dissemination of research results does not allow identification of specific individuals.
- Activities intended exclusively to assess, manage, and improve the performance of the College, an affiliated institution, or its employees or students, within the mandate of the organization, or according to the terms and conditions of employment (e.g. quality assurance and improvement studies; testing within normal educational requirements; performance evaluations).
- Data gathering related to professional skills development within a discipline, conducted as part of the regular activities within that discipline (e.g. interviewing individuals for news gathering; measuring or collecting health data as part of a clinical assessment).

7. Roles and Responsibilities for Ethics Review

1. The College

1. The College shall maintain, reporting to the President, a single Research Ethics Board covering as broad a range of research as is consistent with manageable workloads; and that, at minimum, meets the requirements established in the TCPS 2 (2022).
2. The President shall ensure that the REB has the appropriate moral, financial and administrative independence to fulfil its mandate.

3. The College shall ensure appropriate financial and administrative resources for the REB to support effective and efficient operation, including the provision of research ethics training opportunities to REB members, researchers, and students.
4. The College shall respect the independence and authority delegated to the REB by the President and may not override a decision by the REB to prohibit research on ethical grounds. An appeal of a REB decision can only be brought in accordance with section 8 of this policy.

2. *Research Ethics Board*

1. The REB will ensure all decisions are made impartially, all applications receive a fair hearing, and that a documented explanation of any decision is provided to the researcher(s).
2. The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research. A proportionate approach to assessing the ethical acceptability of the research involves consideration of the magnitude and probability of foreseeable risks, the potential benefits and the ethical implications of the research.
3. Ongoing research is subject to continuous ethics review. The REB shall make the determination as to the nature and frequency on continuing review in accordance with the proportionate approach. At minimum, this consists of submitting an annual renewal form (for multi-year research), a change of protocol request (for any substantive changes to approved research), or an end-of-study report (at project conclusion).
4. The REB will react to and investigate any concerns, complaints or comments it receives concerning the ethical conduct of research involving human participants.

3. *Researcher*

1. Researchers are responsible for submitting, in a timely manner, all applicable forms and supporting documents to the REB for initial and continuing review. Research must not commence or continue until approval by the REB is granted.
2. Researchers shall report immediately to the REB any unanticipated issue or adverse event that may increase the level of risk to participants or has other ethical implications that may affect participants' welfare.
3. All researchers, whether internal or external to Algonquin College, who wish to collect information from members of the College (e.g. students, employees, staff, volunteers, etc.) must obtain institutional approval to conduct their research, in addition to receiving REB approval. REB approval does not constitute institutional approval and vice versa.

8. **Reconsideration and Appeals**

Researchers have the right to request, and the REB has an obligation to provide, reconsideration of decisions affecting a research protocol.

In cases where a researcher and the REB cannot reach agreement through discussion and reconsideration, the researcher may appeal the REB's decision using a Research

Ethics Appeals Board.

9. **Conflicts of Interest**

Potential, perceived, and/or actual conflicts of interest must be assessed when conducting research, as they may jeopardize the integrity of the research and the protection offered to participants. Conflicts that create divided loyalties may distract researchers, REBs, and institutions from concern for the welfare of participants and are contrary to the core principles on which this policy is based. Failure to disclose and manage conflicts may impede the informed and autonomous choices of individuals to participate in research.

The College may have financial or reputational interests including, but not limited to, the provision of education, the promotion of research, the securing of donor contributions, and the securing and spending of research grant funds that conflict with the College's obligations to prioritize the core principles of this policy. An institutional conflict of interest involves a conflict between at least two substantial College obligations that cannot be adequately fulfilled without compromising one or both obligations. The College has an obligation to ensure that the ethical conduct of research is not compromised by actual, potential or perceived conflicts of interest, and must notify the REB of any such conflicts.

Conflicts of interest for researchers may arise from an individual's dual or multiple roles within or outside the College; interpersonal relationships (e.g., family or community relationships); financial partnerships; other economic interests (e.g., companies in which researchers have stakes or private contracts), academic interests or any other incentives that may compromise integrity or respect for the core principles of this Policy.

Researchers shall inform the REB of any actual, potential or perceived conflicts of interest that exists in relation to the proposed research.

While it may not be possible to eliminate all conflicts of interest, researchers are expected to identify, minimize or otherwise manage their individual conflicts in a manner that is satisfactory to the REB.

10. **Research Ethics Review during Publicly Declared Emergencies**

Research ethics review during publicly declared emergencies may follow modified procedures and practices. The Algonquin College REB will establish an emergency preparedness plan that will take into account the pressures, time constraints, priorities and logistical challenges that may arise in order to ensure quality, timely, proportionate and appropriate ethics review when modifying procedures. Such modifications will cease as soon as is feasible after the end of the publicly declared emergency.

11. **Non-compliance Implications**

Non-compliance with this policy, including failure to obtain REB approval or failure to comply with the conditions of approval, constitutes research misconduct and is subject to the appropriate sanctions established in RE02 Integrity in Research and Scholarly Activities. This may include suspension of research, financial loss, reputational and relationship damages, and/or legal action.

RELATED POLICIES

AA35 Confidentiality of Student Records

AD02 Freedom of Information and Protection of Privacy

HR12 Conflict of Interest
RE01 Research Administration
RE02 Integrity in Research and Scholarly Activities
RE05 Intellectual Property
RE07 Academic Freedom Rights and Responsibilities

RELATED MATERIALS

[TRI-Council Policy Statement: Ethical Conduct for Research Involving Humans \(2022\)](#)

[Tri-Agency Framework: Responsible Conduct of Research \(2021\)](#)

[Tri-Agency Research Data Management Policy](#)

[Agreement on the Administration of Agency Grants and Awards by Research Institutions](#)

[Algonquin College Research Ethics Board](#)