RE03 Research Involving Human Participants

Classification:	Research
Responsible Authority:	Director, Applied Research, Innovation and Entrepreneurship
Executive Sponsor:	Senior Vice President, Academic
Approval Authority:	Algonquin College Executive Committee
Date First Approved:	2005.02.23
Date Last Reviewed:	2021.04.07
Mandatory Review Date:	2026.04.07

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 (2018).*

SCOPE

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

a. its employees and/or students, either as researchers or participants;
b. an affiliation between the College and other institutions; and/or
c. non-College individuals or organizations using the College name or its resources to conduct research on College students and/or employees.

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
ARIE	Office of Applied Research, Innovation and Entrepreneurship
Ethics Review	Processes and guidelines by which research proposals are evaluated by the College Research Ethics Board (REB) to determine if they meet the quality and ethical principles and standards for research involving human participant, as set out in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS2 (2018).
Human Participants	An individual (living or deceased) whose data, biological materials, or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question; 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.
Research Ethics Board (REB)	A body 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.
Researcher	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).
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS2 (2018)	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 guidelines by which to conduct research involving human participants.

POLICY

1. The 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 quality and ethical standards and principles for research involving human participants.

2. All research involving human participants conducted under the auspices of the College shall comply with the standards established by the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC), known as the Tri-Council, and stipulated in its *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS2 (2018).*

3. Core Principles

3.1 All research at the College involving human participants shall be conducted in accord with the core principles guiding ethical research—Respect for Persons, Concern for Welfare, and Justice.

3.2 Respect for Persons

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.

3.3 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.

3.4 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, Indigenous and racialized groups, students, women, prisoners, those with mental health concerns and those who lack capacity for self-determination.

4. Scope of Research Ethics Review

4.1 Research Requiring REB Review

The following requires ethics review and approval by an REB before the research commences:

a) research involving living human participants;
b) research involving 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.

4.2 Research Exempt from REB Review

4.2.1 Research that relies exclusively on publicly available information does not require REB review when:

a) the information is legally accessible to the public and appropriately protected by law; or
b) the information is publicly accessible and there is no reasonable expectation of privacy.

4.2.2 Research that involves the observation of people in public places does not require REB review when:

a) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
b) individuals or groups targeted for observation have no reasonable expectation of privacy; and
c) any dissemination of research results does not allow identification of specific individuals.

4.2.3 REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

4.3 Activities Not Requiring REB Review

4.3.1 Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

4.3.2 Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

5. Research Ethics Board (REB)

5.1 Authority of the Research Ethics Board

5.1.1 The College shall maintain a Research Ethics Board (REB) that meets or exceeds the requirements set out in the TCPS2. The President has mandated the REB 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, using the considerations set forth in this Policy as the minimum standard.

5.1.2 As a formal cross-college committee, the President shall ensure that the Research Ethics Board has the appropriate moral, financial and administrative independence to fulfill its primary duties.

5.1.3 For the integrity of the research ethics review process, and to safeguard public trust in that process, the President shall ensure that the REB is able to operate effectively and independently in its decision-making.

5.1.4 The College shall respect the authority delegated to the REB, and may not override an REB decision to reject a research proposal. An appeal of the REB decision to reject a research proposal can only be brought in accordance with 6.6 of this policy.

5.2 Chair of the REB

5.2.1 The Chair of the REB is appointed by and reports directly to the President.

5.2.2 The Chair of the REB is selected from among nominations brought forward by the Director, Applied Research and Innovation, on the recommendation of the REB members.

5.2.3 The REB Chair is responsible for ensuring that the REB process conforms to the requirements of the TCPS2.

5.2.4 The REB Chair shall provide annual status reports to the President as a measure of good governance.

5.3 Membership of the REB

5.3.1 The REB shall consist of at least five members, with a diverse gender representation, of whom at least:

a) two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
b) one member is knowledgeable in ethics;
c) one member is knowledgeable in the relevant law. That member shall not be the College's legal counsel or risk manager. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and
d) one member has no affiliation with the College, but is recruited from the community served by the College.

5.3.2 Membership may be added in order to:

a) ensure an adequate and thorough review of research proposals;
b) adequately reflect the ethical views of society, or of particular groups or communities;
c) address specific research disciplines or legal issues.

5.3.3 To ensure the independence of REB decision making, College senior administrators/executive staff shall not serve on the REB.

5.3.4 To maintain effective community representation, the number of community representatives shall be commensurate with the size of the REB and should increase as the size of the REB increases.

5.3.5 The REB should have provision for consulting ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal.

5.3.6 Under certain circumstances the College may wish to seek the assistance and cooperation of other local REBs in the region.

5.3.7 At a minimum, the REB shall have members appointed in one capacity only for each of the membership categories (a-d). Where the size of the REB exceeds the minimum requirements, additional members may fulfill more than one capacity. In any case, REB members can contribute to the review based on their experience, expertise or knowledge in more than one of the categories above.

5.3.8 Members will be recruited from across the college, with each School sponsoring membership of at least one member. No School will be required to sponsor more than one member concurrently unless it is a requirement to maintain representation that is proportional to the fields of research being reviewed.

5.4 Terms of Appointment

5.4.1 The term of appointment shall be for three years.

5.4.2 At the completion of a term of appointment, membership shall rotate among staff to ensure diversity of opinion and the opportunity to spread knowledge and experience gained from REB membership throughout the College.

5.4.3 Vacancies shall be filled in accordance with 5.3 as new appointments to the REB.

5.5 Number of REBs within Algonquin

5.5.1 The College shall maintain a single Research Ethics Board covering as broad a range of research as is consistent with manageable workloads.

6. REB Review

6.1 A Proportionate Approach to Ethics Review

6.1.1 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: the lower the level of risk, the lower the level of scrutiny; the higher the level of risk, the higher the level of scrutiny. A proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research.

6.1.2 Two levels of research ethics review may apply:
a) Full REB review, carried out by all members of the REB;
b) Delegated REB review of minimal risk research, carried out by one or more members of the REB.

6.1.3 A full review by the REB shall be the default requirement for all research involving human participants.

6.1.4 Delegated REB review can be adopted for proposed research if any one of the following conditions applies:
a) the proposed research protocol confidently involves no more than minimal risk;

b) minimal risk changes to approved research;
c) annual renewal of approved minimal risk research;
d) annual renewals of more than minimal risk research where the research will no longer involve new interventions to current participants, renewal does not involve the recruitment of new participants, and the remaining research activities are limited to data analysis; or
e) the proposed research is student course-based research, in which case the review can be delegated to the department, faculty or equivalent

6.1.5 The REB should establish written procedures and set out criteria for determining which categories of student course-based research proposals may be eligible for delegated reviews per 6.1.4.e, and specify who is responsible for implementing and overseeing the approval mechanisms.

6.1.6 Delegated reviewers are free to ask for assistance from other REB members, and can request a full REB review of proposed research that they believe requires a full review.

6.2 Meetings and Attendance

6.2.1 The REB shall hold regular, face to face, REB Research Review Meetings in order to discharge their responsibilities and review proposed research that is not assigned to delegated review.

6.2.2 The REB shall meet a minimum of 8 times in any given calendar year.

6.2.3 REB Research Review Meeting and Application Submission Deadline dates shall be posted on the College website at least one month in advance of the scheduled meeting date.

6.2.4 When meeting face to face to review research proposals requiring full REB review, the REB shall maintain a quorum 80% of current membership. Quorum for full-board reviews shall be sufficient attendance to meet the minimum requirements of REB membership as outlined in the TCPS 2 (2018), Article 6.4. Motions and decisions shall be carried with a majority of 50% of membership + 1 in agreement.

6.2.5 The REB may also meet to take advantage of educational opportunities that may benefit the overall operation of the REB, discuss any general issues arising out of the REB's activities or revise policies.

6.2.6 REB members are expected to attend all meetings in order to ensure proper functioning of the ethics review process. Where a member is frequently absent, the REB should have some mechanism for reviewing whether that member should continue to serve on the REB.

6.2.7 The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but researchers will not be present when the REB is making its decision. When the REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

6.3 Submission of Applications for Ethics Review

6.3.1 Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, access to data, or collection of human biological materials.

6.3.2 Applications must be submitted using the current REB approved Application for Ethics Review of Research form located on the Algonquin College website.

6.3.3 Applications may be submitted at any time via the Algonquin College REB approved submission process, and will be reviewed at the REB Research Review Meeting following the next Application Submission Deadline as posted on the College website.

6.3.4 Researchers shall submit sufficient details to enable the REB to make an informed review of the ethical acceptability of the research. The REB may reasonably reject applications solely on the basis of lack of information.

6.4 Record Keeping

Comprehensive records of all REB meetings shall be prepared and maintained by the REB and shall include: all documentation related to the projects submitted to the REB for review; attendance at all REB meetings; and accurate minutes reflecting REB decisions. The minutes shall clearly document the REB's decisions and any dissents, and the reasons for them. The minutes must be accessible to authorized representatives of the College, researchers and funding agencies.

6.5 Reconsideration Following an REB Decision

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

6.6 Appeals

6.6.1 In cases when researchers and REBs cannot reach agreement through the reconsideration process, a Research Appeal Board shall review the decision.

6.6.2 A decision of the Research Appeal Board shall be provided in writing to the researcher no later than one calendar month from the date that the appeal was requested.

6.6.3 In order to ensure a just and timely appeal process the College shall either:
a) Maintain an ongoing agreement with another institution to use their REB as its official Research Appeal Board; or
b) Maintain an internal Research Appeal Board comprised of individuals per section 5.3.

6.6.4 The Research Appeal Board may approve, reject or request modifications to the research proposal. Its decision on behalf of the College shall be final.

6.6.5 Current members of the REB may not serve on the Research Appeal Board.

6.7 Continuing Research Ethics Review

6.7.1 The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review.

6.7.2 At a minimum, continuing review shall be based on an annual status report submitted by the researcher to the REB (for multi-year research projects), and an end-of-study report (projects lasting less than one year).

6.7.3 As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project.

6.7.4 The REB shall be promptly notified when the project concludes.

6.8 Review of Multi-Institutional or Multi-Jurisdictional Research

6.8.1 Researchers shall identify other REBs reviewing the research proposal in their application to the Algonquin College REB.

6.8.2 For multi-institutional and multi-jurisdictional research, the Algonquin College REB shall review the research proposal as per its normal review procedures.

6.8.3 The REB may coordinate its review of multi-institutional projects with other REBs reviewing the same project to better communicate any concerns that they may have with the project.

6.9 Review of Research in Other Jurisdictions or Countries

6.9.1 Research to be performed outside the jurisdiction or country of the institution which employs the researcher shall undergo ethics review both by:
a) the REB within the researcher's institution; and
b) the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research, or parts thereof, is to be conducted.

6.10 Requests for Changes to Approved Research

6.10.1 Researchers shall submit to their REBs in a timely manner requests for substantive changes to their originally approved research. REBs shall decide on the ethical acceptability of those changes to the research in accordance with a proportionate approach to research ethics review.

6.11 Reports of Unanticipated Issues or Events

6.11.1 Researchers shall report immediately to the REB any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare.

7. CONFLICTS OF INTEREST

7.1 Institutions and Conflicts of Interest

7.1.1 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 moneys that conflict with the College's obligations to protect and respect

human dignity as characterized by 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.

7.1.2 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 of interest.

7.2 REB Members and Conflicts of interest

7.2.1 If the REB is reviewing proposed research in which a member of the REB has an actual, potential or perceived interest (e.g., as a researcher or co-investigator, as an entrepreneur, or as a relation to the researcher(s)), conflict of interest principles require that the member disclose the conflict of interest and not be present when the REB is discussing or making its decision.

7.2.2 The REB member who is in a conflict of interest may offer evidence to the REB in its deliberations, provided the conflict is fully disclosed, and the researcher has the right to hear the evidence and to offer a rebuttal.

7.2.3 College senior administrators (e.g., a vice-president of research or business development) should not serve on an REB, or directly or indirectly influence REB decision-making processes. The mere presence of a College senior administrator at REB meetings may undermine the independence of the REB by unduly influencing REB deliberations and decisions.

7.3 Researchers and Conflicts of Interest

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

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

7.3.3 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.

8. FREE, INFORMED, AND ONGOING CONSENT

8.1 General Principles

8.1.1 Consent Shall Be Given Voluntarily

a) The voluntariness of consent is important because it respects human dignity and means that individuals have chosen to participate in research according to their own values, preferences and wishes.
b) The REB shall ensure that proposed research is designed so that:
    i) Consent is sought from all prospective participants in a way that voluntariness is not undermined by: undue influence or manipulation of prospective participants; coercion of prospective participants; and incentives offered to participants as compensation for participation;
    ii) Consent can be withdrawn by any and all participants prior to, or at any time during, the research process, and that no reason is required from the participants for withdrawal;
    iii) If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials from the research.
c) The REB shall ensure that the proposed consent form sets out any circumstances that do not allow for the withdrawal of data or human biological materials once collected.
d) Where the terms of the research do not allow for withdrawal of their data or human biological materials, the identity of the participants shall be protected at all times during the project and after its completion
e) Participants shall also be informed, as part of the consent process, that it is difficult, if not impossible, to withdraw results once they have been published or otherwise disseminated.

8.1.2 Consent Shall Be Informed

a) Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.
b) The REB shall ensure that the following information is provided to prospective participants, or authorized third parties, as part of the informed consent process:
    i) information that the individual is being invited to participate in a research project;
    ii) a statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
    iii) a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;
    iv) an assurance that prospective participants:
        a. are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
        b. will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and
        c. will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;
    v) information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
    vi) the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
    vii) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;

viii) the identity and contact information of the Algonquin College REB Chair, whom participants may contact regarding possible ethical issues in the research;

ix) an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected, a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;

x) information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;

xi) a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and

xii) in clinical trials, information on stopping rules and when researchers may remove participants from trial.

c) Researchers wishing to exclude any of the elements listed in i-xii must provide a rationale to the REB, and it is up to the REB to determine if the excluded information must be included.

d) The REB can require that additional information be included as part of the informed consent process.

e) For consent to be informed, prospective participants shall be given adequate time and opportunity to assimilate the information provided, pose any questions they may have, and discuss and consider whether they will participate. The time required for this initial phase of the consent process will depend on such factors as the magnitude and probability of harms, the complexity of the information conveyed, and the setting where the information is given.

8.1.3 Consent Shall Be an Ongoing Process

a) Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants and the REB with all information relevant to participants' ongoing consent to participate in the research.

8.1.4 Incidental Findings

a) Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research. "Incidental findings" is a term that describes unanticipated discoveries made in the course of research but that are outside the scope of the research. Material incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological or social.

b) If researchers are unsure of the most appropriate method for disclosing material incidental findings to participants, they should consult with their REB or with colleagues.

c) Researchers should exercise caution in disclosing incidental findings that may cause needless concern to participants, and should consult the REB in cases of uncertainty.

8.1.5 Consent Shall Precede Collection of, or Access to, Research Data

a) Research shall begin only after the participants, or their authorized third parties, have provided their consent.

8.1.6 Critical Inquiry

a) Permission is not required from an organization in order to conduct research on that organization. If a researcher engages the participation of members of an organization without the organization's permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation.
b) REBs should not prohibit research simply because the research is unpopular or looked upon with disfavor by a community or organization, in Canada or abroad.
c) REBs should not veto research on the grounds that the government in place or its agents have not given approval for the research project, or have expressed a dislike for the researchers.

8.2 Departures from General Principles of Consent

8.2.1 Alteration of Consent in Minimal Risk Research

a) The REB may approve research without requiring that the researcher obtain the participant's consent in accordance with 8.1 to 8.5 where the REB is satisfied, and documents, that ALL of the following apply:
   i) the research involves no more than minimal risk to the participants;
   ii) the lack of the participant's consent is unlikely to adversely affect the welfare of the participant;
   iii) it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
   iv) whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with Articles 8.2 and 8.4, at which point they will have the opportunity to refuse consent in accordance with Article 8.1; and
   v) the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.
b) The REB must ensure that in studies involving partial disclosure or deception in which an alteration to the requirement for prior consent has been allowed, participants must nevertheless be able to indicate their consent or their refusal at the conclusion of the project, following debriefing.

8.2.2 Consent for Research in Individual Medical Emergencies

a) This section addresses the exception to consent in situations where an individual who requires urgent medical care is unable to provide consent for research due to loss of consciousness or capacity – and the delay to seek authorized third party consent could seriously compromise that individual's health. Certain types of medical emergency practices can be evaluated only when they occur, hence the need for this exception.
b) Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves medical emergencies to be carried out without the consent of participants, or of their authorized third party, if ALL of the following apply:

   i) a serious threat to the prospective participant requires immediate intervention;
   ii) either no standard efficacious care exists or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care;

iii) either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant;
iv) the prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project;
v) third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
vi) no relevant prior directive by the participant is known to exist.

c) When a previously incapacitated participant regains capacity, or when an authorized third party is found, consent shall be sought promptly for continuation in the project, and for subsequent examinations or tests related to the research project.

8.3 Capacity

8.3.1 Capacity refers to the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate. This ability may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the point in time at which consent is sought. The determination of capacity to participate in research, then, is not a static determination. It is a process that may change over time, depending on the nature of the decision the prospective participant needs to make, and on any changes in the participant's condition. Assessing capacity is a question of determining, at a particular point in time, whether a participant (or prospective participant) sufficiently understands the nature of a particular research project, and the risks, consequences and potential benefits associated with it.

8.3.2 For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:

a) the researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;
b) the researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;
c) the authorized third party is not the researcher or any other member of the research team;
d) the researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research; and
e) when authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

8.3.3 The decision of authorized third parties should be based on their knowledge of the prospective participants, and on consideration of the prospective participants' welfare.

8.3.4 The third parties should not be in a position of conflict of interest when making their decision.

8.3.5 Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants' expression of dissent or signs suggesting they do not wish to participate must be respected and shall preclude their participation.

8.3.6 Research Directives

a) Where individuals have signed a research directive indicating their preferences about future participation in research in the event that they lose capacity or upon death, researchers and authorized third parties should be guided by these directives during the consent process.

8.4 Consent Shall Be Documented

Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent.

9. FAIRNESS AND EQUITY IN RESEARCH

9.1 Appropriate Inclusion

Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion.

9.2 Inappropriate Exclusion

9.2.1 Research Involving Women

a) Women shall not be inappropriately excluded from research solely on the basis of gender or sex.
b) Women shall not be inappropriately excluded from research solely on the basis of their reproductive capacity, or because they are pregnant or breastfeeding.

9.2.2 Research Involving Children

Children shall not be inappropriately excluded from research solely on the basis of their age or developmental stage.

9.2.3 Research Involving the Elderly

Elderly people shall not be inappropriately excluded from research solely on the basis of their age.

9.2.4 Research Involving Indigenous Peoples

Indigenous participants shall not be inappropriately excluded from research based solely on their identification.

9.2.5 Research Involving People Who Lack the Capacity to Consent for Themselves

Subject to applicable legal requirements, individuals who lack capacity to consent to participate in research shall not be inappropriately excluded from research. Where a researcher seeks to involve individuals in research who do not have capacity to consent for themselves, the researcher shall, in addition to fulfilling the conditions in 8.3, satisfy the REB that:

a) the research question can be addressed only with participants within the identified group; and
b) the research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or
c) where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

9.2.6 Participants' Vulnerability and Research

Individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances.

9.2.7 Equitable Distribution of Research Benefits

a) Researchers should consider ways to ensure the equitable distribution of any benefits of participation in research.
b) Researchers should normally provide copies of publications, or other research reports or products, arising from the research to the institution or organization—normally the host institution—that is best suited to act as a repository and disseminator of the results within the participating communities.

10. PRIVACY AND CONFIDENTIALITY

10.1 Ethical Duty of Confidentiality

10.1.1 Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. The College shall support researchers in maintaining promises of confidentiality.

10.1.2 Researchers shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements:

a) in application materials they submit to the REB; and
b) during the consent process with prospective participants.

10.2 Safeguarding Information

10.2.1 Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal.

10.2.2 Factors relevant to the REB's assessment of the adequacy of the researchers' proposed measures for safeguarding information include:

a) the type of information to be collected;
b) the purpose for which the information will be used, and the purpose of any secondary use of identifiable information;
c) limits on the use, disclosure and retention of the information;
d) risks to participants should the security of the data be breached, including risks of re-identification of individuals;
e) appropriate security safeguards for the full life cycle of information;
f) any recording of observations (e.g., photographs, videos, sound recordings) in the research that may allow identification of particular participants;
g) any anticipated uses of personal information from the research; and
h) any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records

10.3 Consent and Secondary Use of Identifiable Information for Research Purposes

10.3.1 Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:

a) identifiable information is essential to the research;
b) the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and
f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

10.3.2 If a researcher satisfies all the conditions in 10.3.1.a to f, the REB may approve the research without requiring consent from the individuals to whom the information relates.

10.3.3 When secondary use of identifiable information without the requirement to seek consent has been approved under 10.3.1, researchers who propose to contact individuals for additional information shall, prior to contact, seek REB approval of the plan for making contact.

10.4 Data Linkage

10.4.1 Researchers who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information as discussed in 4.3.1. The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage.

10.4.2 Where data linkage involves or is likely to produce identifiable information, researchers shall satisfy the REB that:

a) the data linkage is essential to the research; and
b) appropriate security measures will be implemented to safeguard information.

10.5 Privacy Legislation

10.5.1 Researchers shall comply with all applicable privacy legislation of the jurisdiction(s) in which the research takes place.

11. RESEARCH INVOLVING THE FIRST NATIONS, INUIT AND MÉTIS PEOPLES OF CANADA

11.1 Where the research is likely to affect the welfare of an Indigenous community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community. The conditions under which engagement is required include, but are not limited to:
a) research conducted on First Nations, Inuit or Métis lands;
b) recruitment criteria that include Indigenous identity as a factor for the entire study or for a subgroup in the study;
c) research that seeks input from participants regarding a community's cultural heritage, artifacts, traditional knowledge or unique characteristics;
d) research in which Indigenous identity or membership in an Indigenous community is used as a variable for the purpose of analysis of the research data; and
e) interpretation of research results that will refer to Indigenous communities, peoples, language, history or culture.

11.2 The nature and extent of community engagement in a project shall be determined jointly by the researcher and the relevant community, and shall be appropriate to community characteristics and the nature of the research.

11.3 Where a proposed research project is to be conducted on lands under the jurisdiction of a First Nations, Inuit or Métis authority, researchers shall seek the engagement of formal leaders of the community, except as provided under 11.5, 11.6 and 11.7. Research ethics review by the REB and any responsible community body recognized by the First Nations, Inuit or Métis authority (see 11.9 and 11.11) is required in advance of recruiting and securing consent of individuals.

11.4 For the purposes of community engagement and collaboration in research undertakings, researchers and REBs shall recognize Indigenous organizations, including First Nations, Inuit and Métis representative bodies, and service organizations and communities of interest, as communities. They shall also recognize these groups through representation of their members on ethical review and oversight of projects, where appropriate.

11.5 Where alternatives to securing the agreement of formal leadership are proposed for research on First Nations, Inuit or Métis lands or in organizational communities, researchers should engage community processes and document measures taken, to enable the REB to review the proposal with due consideration of complex community authority structures.

11.6 In engaging territorial or organizational communities, researchers should ensure, to the extent possible, that they take into consideration the views of all relevant sectors – including individuals and subgroups who may not have a voice in the formal leadership. Groups or individuals whose

circumstances make them vulnerable may need or desire special measures to ensure their safety in the context of a specific research project. Those who have been excluded from participation in the past may need special measures to ensure their inclusion in research.

11.7 Research involving Indigenous peoples that critically examines the conduct of public institutions, First Nations, Inuit and Métis governments, institutions or organizations or persons exercising authority over First Nations, Inuit or Métis individuals may be conducted ethically, notwithstanding the usual requirement of engaging community leaders.

11.8 Researchers have an obligation to become informed about, and to respect, the relevant customs and codes of research practice that apply in the particular community or communities affected by their research. Inconsistencies between community custom and this Policy should be identified and addressed in advance of initiating the research, or as they arise.

11.9 Research ethics review by community REBs or other responsible bodies at the research site will not be a substitute for research ethics review by the Algonquin College REB, and will not exempt researchers affiliated with the College from seeking Algonquin College REB approval. Prospective research and secondary use of data and human biological materials for research purposes is subject to research ethics review.

11.10 When proposing research expected to involve First Nations, Inuit or Métis participants, researchers shall advise the REB how they have engaged, or intend to engage, the relevant community. Alternatively, researchers may seek REB approval for an exception to the requirement for community engagement, on the basis of an acceptable rationale.

11.11 Where a community has formally engaged with a researcher or research team through a designated representative, the terms and undertakings of both the researcher and the community should be set out in a research agreement before participants are recruited.

11.12 As part of the community engagement process, researchers and communities should consider applying a collaborative and participatory approach as appropriate to the nature of the research, and the level of ongoing engagement desired by the community.

11.13 Where the form of community engagement and the nature of the research make it possible, research should be relevant to community needs and priorities. The research should benefit the participating community (e.g., training, local hiring, recognition of contributors, return of results), as well as extend the boundaries of knowledge.

11.14 Research projects should support capacity building through enhancement of the skills of community personnel in research methods, project management, and ethical review and oversight.

11.15 Researchers should engage the community in identifying Elders or other recognized knowledge holders to participate in the design and execution of research, and the interpretation of findings in the context of cultural norms and traditional knowledge. Community advice should also be sought to determine appropriate recognition for the unique advisory role fulfilled by these persons.

11.16 Researchers and community partners shall address privacy and confidentiality for communities and individuals early on in the community engagement process. The extent to which limited or full disclosure of personal information related to the research is to be disclosed to community partners shall be addressed in research agreements where these exist. Researchers shall not disclose personal information to community partners without the participant's consent, as set out in Article 8.1.2.b.ix.

11.17 Researchers should afford community representatives engaged in collaborative research an opportunity to participate in the interpretation of the data and the review of research findings before the completion of the final report, and before finalizing all relevant publications resulting from the research.

11.18 In collaborative research, intellectual property rights should be discussed by researchers, communities and the College. The assignment of rights, or the grant of licenses and interests in material that may flow from the research, should be specified in a research agreement (as appropriate) before the research is conducted.

11.19 As part of community engagement, researchers shall address and specify in the research agreement the rights and proprietary interests of individuals and communities, to the extent such exist, in human biological materials and associated data to be collected, stored and used in the course of the research.

11.19.1 Researchers and communities should address and specify in the research agreement:

a) the objectives for collection, use and storage of human biological materials;
b) the roles and responsibilities regarding custodianship of the data and the human biological materials; and
c) any future use of these human biological materials and associated data, including material transfer agreements to third parties, and any subsequent requirements for community engagement.

11.19.2 Researchers must seek consent from individuals who are invited to donate their biological materials.

11.20 Secondary use of data and human biological material identifiable as originating from an Indigenous community or peoples is subject to REB review.

11.20.1 Researchers shall engage the community from which the data or human biological materials and associated identifiable information originate, prior to initiating secondary use where:

a) secondary use has not been addressed in a research agreement and has not been authorized by the participants in their original individual consent; or
b) there is no research agreement; and
c) the data are not publicly available or legally accessible.

11.21 Where research relies only on publicly available information, or on legally accessible information, community engagement is not required. Where the information can be identified as originating from a specific community or a segment of the Indigenous community at large, seeking culturally informed advice may assist in identifying risks and potential benefits for the source community.

11.22 REB review is required where the researcher seeks data linkage of two or more anonymous datasets or data associated with human biological materials and there is a reasonable prospect that this could generate information identifiable as originating from a specific Indigenous community or a segment of the Indigenous community at large.

12. QUALITATIVE RESEARCH

12.1 Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, or access to data. Subject to the exceptions in Article 12.3, REB review is not required for the initial exploratory phase (often involving contact with individuals or communities) intended to discuss the feasibility of the research, establish research partnerships, or the design of a research proposal.

12.2 In research involving observation in natural environments or virtual settings where people have a reasonable or limited expectation of privacy, the researcher shall explain the need for an exception to the general requirement for consent. The REB may approve research without requiring that the researcher obtain consent from individuals being observed on the basis of the justification provided by the researcher and appropriate privacy protection.

12. In studies using emergent design in data collection, researchers shall provide the REB with all the available information to assist in the review and approval of the general procedure for data collection. Researchers shall consult with the REB when, during the conduct of the research, changes to the data collection procedures may present ethical implications and associated risks to the participants.

13. HUMAN BIOLOGICAL MATERIALS

<u>13.1 General Considerations</u>

13.1.1 Ethical considerations raised by research involving human biological materials center on acceptable access to, and use of, the materials, potential privacy concerns arising from the handling of information derived from such materials, and the special status some individuals and groups accord to the human body and its parts. Because the significance of biological materials varies among individuals and groups, it is important to assess the ethics of research involving such materials with an awareness of and sensitivity to the known values, beliefs and attitudes of those from whom the materials originated.

13.1.2 For the purposes of this Policy, human biological materials include tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva and other body fluids, human pluripotent stem cells, animal-human hybrids and chimeras.

13.1.3 An individual whose data and/or biological materials are used in research becomes a participant. In regard to human biological materials, individuals may become participants by agreeing to provide a biological sample for use in a particular project. Individuals may also choose to donate organs, tissue or their entire body for research that occurs after their death. In this way, they become participants through their donation.

13.2 Collection of Human Biological Materials

13.2.1 Human Biological Materials may be obtained in different ways:

a) they may be collected expressly for a specific research purpose;
b) they may be collected incidentally to medical or diagnostic procedures with no initial intent to be used in research; or
c) they may be collected for research or medical or diagnostic purposes with some expectation that they may, or will, also be used in future research, although the precise research project(s) may not be known at the time.

13.2.2 Research involving collection and use of human biological materials requires REB review and:
a) consent of the participant who will donate biological materials; or
b) consent of an authorized third party on behalf of a participant who lacks capacity, taking into account any research directive that applies to the participant; or
c) consent of a deceased participant through a donation decision made prior to death, or by an authorized third party.

13.2.3 To seek consent for use of human biological materials in research, researchers shall provide to prospective participants or authorized third parties, applicable information as set out in 8.1.2 as well as the following details:

a) the type and amount of biological materials to be taken;
b) the manner in which biological materials will be taken, and the safety and invasiveness of the procedures for acquisition;
c) the intended uses of the biological materials, including any commercial use;
d) the measures employed to protect the privacy of and minimize risks to participants;
e) the length of time the biological materials will be kept, how they will be preserved, location of storage (e.g., in Canada, outside Canada), and process for disposal, if applicable;
f) any anticipated linkage of biological materials with information about the participant; and
g) the researchers' plan for handling results and findings, including clinically relevant information and incidental findings.

13.3 Consent and Secondary Use of Identifiable Human Biological Materials for Research Purposes

13.3.1 Secondary use refers to the use in research of human biological materials originally collected for a purpose other than the current research purpose. A researcher may seek to use human biological materials left over from a diagnostic examination or surgical procedure, or materials that were collected for an earlier project. Reasons to conduct secondary analyses include: avoidance of duplication in primary collection and the associated reduction of burdens on participants; corroboration or criticism of the conclusions of the original research; comparison of change in a research sample over time; application of new tests of hypotheses that were not available at the time of original collection; and confirmation that the data or materials are authentic. Privacy concerns and questions about the need to seek consent arise, however, when human biological materials provided for secondary use in research can be linked to individuals, and when the possibility exists that individuals can be identified in published reports, or through linkage of human biological materials with other data.

13.3.2 Researchers who have not obtained consent from participants for secondary use of identifiable human biological materials shall only use such material for these purposes if the REB is satisfied that:

a) identifiable human biological materials are essential to the research;
b) the use of identifiable human biological materials without the participant's consent is unlikely to adversely affect the welfare of individuals from whom the materials were collected;
c) the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable human biological materials;
d) the researchers will comply with any known preferences previously expressed by individuals about any use of their biological materials;
e) it is impossible or impracticable to seek consent from individuals from whom the materials were collected; and
f) the researchers have obtained any other necessary permission for secondary use of human biological materials for research purposes.

13.3.3 If a researcher satisfies all the conditions in Article 13.3.2.a to f, the REB may approve the research without requiring consent from the individuals from whom the biological materials were collected.

13.3.4 When secondary use of identifiable human biological materials without the requirement to seek consent has been approved under Article 13.3.2, researchers who propose to contact individuals for additional biological materials or information shall, prior to contact, seek REB approval of the plan for making contact.

PROCEDURE

	Action	Responsibility
1.	**Research Ethics Board (REB)**	
1.1	Invite researchers from the College and the community to submit applications to sit on the REB when a vacancy becomes available.	Director, ARIE
1.2	Submit a resume indicating an interest to sit on REB to the REB Chair.	Interested researchers
1.3	Review applications and retain those that meet the REB membership requirements found in the Policy section 5.3.	REB Chair
1.4	Bring forward membership recommendations for consideration and appointment by the President.	REB Chair
1.5	Recommend a candidate to serve as the REB Chair to the President for approval, based on the recommendation of the REB.	Director, ARIE
2.	**Review of Research Proposals**	

2.1	Submit research proposal for review and approval to the REB using the College's standard application for ethics review, and according to the application submission process outlined on the Algonquin College REB website.	Researcher
2.2	Determine whether a full or delegated REB review is required.	REB Chair
2.3	Review the application at the next scheduled REB meeting.	REB
2.4	Report the REB decision regarding the review, whether delegated or not, within seven (7) working days of the REB meeting to the researcher.	REB Chair
2.5	If necessary, respond to REB comments and/or requests for information.	Researcher
2.6	If necessary, finalise decision to approve/deny application and notify Director, ARIE and researcher.	REB Chair
3.	**Review of Ongoing Research**	
3.1	Submit an annual report at least once a year, or as requested by the REB, for a review.	Researcher
3.2	Notify the REB within ten (10) working days of the research project being concluded.	Researcher
4.	**Conflicts of Interest**	
4.1	Disclose any real, potential, and perceived conflicts of interest to the REB as part of the REB application process.	Researcher
4.2	Notify the REB of any real, potential, or perceived conflicts of interest that might affect the ability to carry out proposed or ongoing research in a manner consistent with the core principles of this Policy.	All College Employees, REB Members, Researcher(s)
4.3	Assess the nature of the conflict of interest and determine the appropriate action(s) required to eliminate, minimize, or otherwise manage the conflicts of interest.	REB

SUPPORTING DOCUMENTATION

None

RELATED POLICIES

AD02 Freedom of Information and Protection of Privacy
AA16 Academic Dishonesty and Discipline
AA35 Confidentiality of Student Records

SA07 Student Conduct
RE01 Research Administration
RE02 Integrity in Research and Scholarly Activities
RE04 Use of Animals in Research, Teaching and Other Activities
RE05 Intellectual Property
RE06 Use of Biohazardous and Radioactive Materials in Research and Education
RE07 Academic Freedom Rights and Responsibilities
HR12 Conflict of Interest

RELATED MATERIALS

TRI-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018)
https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf