
POLICY

All research involving human subjects that is conducted at or undertaken by members of the Aurora College (“the College”) community as part of their employment or studies with the College will be reviewed and approved by the Aurora College Research Ethics Committee (REC) before research begins.

Note: This policy does not apply to ongoing information gathering activities deemed to be of minimum risk that are sanctioned by the College, are in accordance with its core mandate, and are directly related to the normal administration, evaluation, or improvement of an operation, program, service or activity within the College. Commonly, such activities include, but are not limited to, quality assurance studies, performance reviews or testing within normal educational requirements.

PRINCIPLES

Aurora College has an important and unique role in research in the Northwest Territories. As such, Aurora College is committed to:

1. Safeguarding the rights and well-being of human subjects involved in all research activities in which its community members participate;
2. Supporting and encouraging research and scholarship that reflect its core ethical values of integrity, excellence, accountability and respect; and
3. Adhering to the current *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS).¹

DEFINITIONS

Research Subject

For the purposes of Policy I.04 *Ethical Conduct for Research Involving Human Subjects*, Research Subject is defined as an individual, living or deceased, about whom an investigator conducting *research* obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (e.g. bodily fluid collection) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

¹ Tri-Council refers to the three federal research funding agencies consisting of the Canadian Institutes of Health Research (CIHR); the Natural Sciences and Engineering Research Council of Canada (NSERC); and the Social Sciences and Humanities Research Council of Canada (SSHRC). The terms Tri-Council and Tri-Agency are interchangeable.

Private information includes information about behaviour that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. a medical or school record). In general, private information is considered to be individually identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person could ascertain the identities of individuals.

A Research Subject includes any form of human biological material, including human embryos, foetuses, foetal tissue, reproductive material and stem cells.

PROCEDURES

1.0 CREATING AN ETHICAL ENVIRONMENT

It is the primary responsibility of all members of the College community participating in research involving human subjects to adhere to the principles and guidelines stated in this policy and to maintain high standards of ethical conduct throughout the project.

Aurora College will establish a Research Ethics Committee with the responsibility to evaluate and monitor the quality and ethical standards and principles of College research activities that involve human subjects, as well as non-College research activities that involve human subjects and are referred to it via the licensing process or the *Health Information Act*.

1.1 Responsibilities of the President (or designee)

The President (or designee):

- Establishes the Research Ethics Committee (REC), appoints its Chair and Vice Chair, approves its Terms of Reference, and enables its appropriate independence so that it can fulfill its mandate.
- Appeals any decision of the REC if he or she disagrees with the REC's decision regarding the ethicality of the proposed research.
- Maintains overall responsibility for the authorization of whether or not a proposed research project may proceed even if the REC has approved the ethicality of the project. For example, the President may not authorize any research he or she feels does not address the mandate of the College or poses a risk to the College community, regardless of the REC's decision.

1.2 Responsibilities of the Principal Investigator

The Principal Investigator:

- Seeks appropriate levels of approval from the College for research activities and resource commitment prior to engaging in any research activity;

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- Submits an application to the REC, before starting research that needs an ethics review (see section 2.0);
 - Submits an application far enough in advance to allow for revisions to the protocol (not less than 8 weeks before anticipated start date);
 - Informs the REC of any changes in methodology or unforeseen events;
 - Informs and updates the REC of any changes to the approved protocol;
 - Submits any reports required by the REC (e.g. annual reports, renewal requests, end of study reports);
 - Undertakes and directs research that adheres to the relevant ethical requirements and maintains the sanctity of human life; and
 - Protects the reputation of the College when undertaking research activities.

1.3 Responsibilities of all Researchers Using Human Subjects

All researchers using human subjects will:

- Undertake research that adheres to the relevant ethical requirements and maintains the sanctity of human life;
- Disclose any real, potential or perceived conflicts of interest to the REC;
- Report any concerns or misconduct regarding the ethical conduct within the research project to the REC; and
- Protect the reputation of the College when undertaking research activities.

All researchers who conduct Tri-Agency funded research using human subjects will provide proof to the Research Ethics Committee that they have completed the TCPS 2 Tutorial Course on Research Ethics (CORE) within the last 5 years.

1.4 Responsibilities of the Research Ethics Committee (REC)

The College and the College's Research Ethics Committee are jointly responsible for helping safeguard the rights and well-being of human subjects in research activities in which the College is involved.

The REC:

- Provides a fair and impartial hearing to the researchers involved and provides appropriately reasoned and documented opinions and decisions in a timely manner.
- Reviews and approves, rejects, or proposes modifications to any research project that falls under the scope of this policy.
- Ensures all researchers and support personnel affiliated with the College are familiar with and understand the ethical issues, principles, standards, policies and procedures to which they must adhere.
- Monitors all human research protocols for conformity with the principles established by the Tri-Agency, the Association of Canadian Universities for Northern Studies, and other funding agencies.
- Terminates any research that causes undue stress or distress to the human subject(s).

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- Suspends or terminates any research that deviates from the approved proposal.
 - Suspends any research that begins without the required approval, or which deviates from the approved protocol.
 - Ensures that there is no infringement on the academic freedom² of any researcher as identified under the ethics review process.

1.5 Conflict of Interest

The REC will adhere to the conflict of interest guidelines outlined in the current edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.

1.6 Authority of the REC

- The College will respect the authority it has delegated to the REC.
- The College will not override negative REC decisions reached on grounds of ethics without a formal appeal.
- The College may, however, refuse to allow certain research, even though the REC has found it ethically acceptable.

2.0 DETERMINING IF RESEARCH REQUIRES AN ETHICS REVIEW

2.1 Research Studies Requiring an Ethics Review

Research studies that require an ethics review include:

- Studies involving human subjects including but not limited to: behavioural and social sciences studies (investigations on individual and group behaviour, mental processes, or social constructs), clinical investigations (including research to increase scientific understanding about normal or abnormal physiology, disease states or development, and research to evaluate the safety, effectiveness or usefulness of a medical product, procedure, or intervention), epidemiological studies (investigations on health outcomes, interventions, disease states and conclusions about cost-effectiveness, efficacy, efficiency, interventions, or delivery of services to affected populations) and research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses.
- Studies involving the secondary use of data collected by researchers where the identity of subjects could be determined.
- Methodologies that commonly require an ethics review are: surveys, interviews, observations, studies of existing records, and experimental designs involving exposure to some type of stimulus or environmental intervention.

² **Academic Freedom** – includes freedom of inquiry, the right to disseminate the results of that inquiry, freedom to challenge conventional thought, freedom to express one's opinion about the institution, its administration or the system in which one works, and freedom from institutional censorship.

2.2 Research Studies That Do Not Require an Ethics Review

Research studies that do not require an ethics review include:

- Research into a living individual involved in the public arena or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers.
- Research that relies solely on publicly available information that is publicly accessible and appropriately protected by law.
- Research that relies solely on publicly available information and there is no reasonable expectation of privacy regarding that information.
- Quality assurance studies, performance reviews or testing within normal educational requirements.
- Repository and database research if the investigator cannot readily ascertain the identity of the subject from whom the data or materials originated (i.e. the data is stripped of identifying information, or coded and the investigator does not have access to the key).
- Naturalistic observation of participants at public or publicly visible events where it can reasonably be expected that the participants are seeking public visibility and any dissemination of research results does not allow for identification of specific individuals.
- Research on institutions or social processes when the intent or focus of the research is to gain knowledge of the institution or social process (e.g. a political party, labour negotiations) and the research is not intended to produce generalized knowledge about any particular individual or group of individuals.

2.3 Uncertainty about the Need for REC Review

If the Principal Investigator is uncertain whether his/her proposed research requires an REC review, it is his/her responsibility to consult with the Manager, Research Ethics and Regional Programs.

2.4 Multi-Centred Research Review

The Principal Investigator is responsible for ensuring that multi-centred research is reviewed in accordance with *TCPS 2*, Chapter 8.

With multi-centred research, the REC may share and consider documents and findings with other institutions and/or review documents and findings from other institutions as part of its ethics review.

2.5 Review of Research to be Conducted in Other Jurisdictions

Regardless of the location where the research will be conducted, Aurora College is responsible for the ethical conduct of research undertaken by members of the Aurora College community.

2.6 Research Involving Indigenous People

When conducting research that involves Indigenous people, all members of the Aurora College community participating in the research will be mindful of the guidelines for conducting research involving Indigenous people as outlined in the current *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and *CIHR Guidelines for Health Research Involving Aboriginal People*.

3.0 THE ETHICS REVIEW PROCESS

As per TCPS guidelines, each research protocol submitted to the REC for review will include explanations of:

- The type of data to be collected;
- The purpose for which the data will be used;
- Limits on the use, disclosure and retention of the data;
- Appropriate safeguards for security and confidentiality (see Chapter 5 of *TCPS 2*);
- How voluntary and continuing free and informed consent will be obtained (see Chapter 3 of *TCPS 2*);
- Any modes of observation (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that allow identification of particular subjects;
- Any anticipated secondary uses of identifiable data from the research;
- Any anticipated linkage of data gathered in the research with other data about subjects, whether those data are contained in public or personal records; and
- Provisions for confidentiality of data resulting from the research.

The REC will review only those research protocols received by the deadline date published on the Aurora Research Institute website.

All research proposals and activities that involve human subjects will be reviewed through a Proportionate Ethics Review process which is based on the ethical principle that, while all research involving human subjects must be reviewed adequately to ensure protection for the subjects, the greater the potential for risk or harm to the subjects, the greater the scrutiny required in reviewing the research. In accordance with this principle, research proposals will be reviewed through one of the following three levels as appropriate:

- Delegated Ethics Review of Course-Related Student Research and Projects
- Delegated Ethics Review of Student and Staff Research
- Full Ethics Review of Student and Staff Research (Note: If there is any question whether to do a delegated or full ethics review, a full ethics review will be done.)

3.1 Delegated Ethics Review of Course-Related Student Research and Projects

- Delegated reviews will only be done for research that is of minimal risk.
- The REC Chair conducts delegated reviews.
- The REC Chair may choose to do a delegated review or a full review of student research and student projects that involve human participants, are of minimal risk, and are conducted under staff supervision as part of Aurora College course requirements.
- The research will be subject to a full review if the REC Chair thinks that there is more than minimal risk to participants.
- If students are required or may be required to do research and projects involving human participants as part of a course, this will be clearly stated in the course outline and syllabus.
- The instructor will discuss the course-related research and projects with the REC Chair or designee before course delivery begins.
- The Chair of the REC will report to the REC on all delegated reviews of course-related student research and projects with six (6) weeks of receipt of the research request.

3.2 Delegated Ethics Review of Student and Staff Research

- Research that is expected to involve minimal risk will be reviewed by the REC Chair, who may decide to do either a delegated or a full review.
- The research will be subject to a full review if the REC Chair thinks that there is more than minimal risk to participants.
- The Chair of the REC will conduct a delegated review using the Research Ethics Review Form.
- The Chair of the REC will report to the REC on all delegated reviews within six (6) weeks of receipt of the research review request.

3.3 Full Ethics Review of Student and Staff Research

If there is any question whether to do a delegated or full ethics review, a full ethics review will be done using the Research Ethics Review Form.

1. The REC will review proposals using the Ethics Review Decision Criteria.
2. There are four (4) decisions that the REC can return.
 - If the members believe the proposal meets the required standards, the REC will return a decision of **Approved**. This implies the project fulfills ethical standards and guidelines.
 - If the members believe the proposal meets the required standards with minor adjustments, the REC will return a decision of **Provisionally Approved**. This means specific problems have been noted and changes are required. Resubmission of the amended Research Ethics Review Form is required.

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- If the members believe a decision cannot be made due to lack of information, the REC will return a decision of **Deferred** and ask for additional information to be submitted and, if need be, an amended Research Ethics Review Form.
 - If the members believe the proposal does not meet the required standards, the REC will return a decision of **Denied**. This means the project cannot be resubmitted without major methodological and procedural changes.
3. If a minority within the REC membership considers a research project unethical, even though it is acceptable to a majority of members, an effort will be made to reach consensus. Consultation with the Principal Investigator, external advice, and/or further reflection by the REC will be considered, as appropriate and necessary. While a unanimous decision by the REC is desirable, a majority decision is acceptable. Each REC member will vote; no member may abstain from voting.
 4. The REC will notify the Principal Investigator in writing of its decision regarding his/her proposed research activity. If a proposal is not approved for ethical reasons, the notification will include the reasons for the decision and the Principal Investigator will be given an opportunity to respond in writing or in person.
 5. The Chair will monitor the REC's decisions for consistency, ensure that these decisions are recorded accurately, and ensure that the Principal Investigators are provided with written communication of the REC's decisions as soon as possible.
 6. Ethics approval is given for only one year. For multi-year projects, the Principal Investigator must submit a year end status report and renewal request to the REC Chair one month before the Approval Certificate is due to expire. Upon receipt and satisfactory review of this report, an Approval Certificate will be issued for another year.
 7. The REC will also:
 - Monitor ongoing research projects;
 - Conduct yearly reviews of ongoing research for compliance with the terms of the approved proposal;
 - Terminate any ongoing research that ceases to meet ethical standards; and
 - Promote ethics education within the College for those involved in research activities.

3.4 The Use of Other REC recommendations

The Aurora College REC may choose to accept the reviews of other research ethics review boards constituted under the Tri-Council Policy Statement.

3.5 Meetings and Attendance

The REC may invite Principal Investigators to speak to the REC about their proposals at REC meetings. Principal Investigators will not be present during the decision making process.

3.6 Record Keeping

Minutes will be kept from the meetings and stored securely at the Aurora Research Institute in accordance with GNWT policies and legislation.

3.7 REC Reporting

The Vice President, Research in consultation with the REC Chair will submit an annual activity report to the President, Aurora College and the Research Advisory Council by the end of June each year.

4.0 GUIDELINES FOR RESEARCH INVOLVING EMERGENCY HEALTH SITUATIONS

4.1 Research in Individual Medical Emergencies

Subject to all applicable legislative and regulatory requirements, research involving emergency health situations will be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REC.

The REC may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party **only if ALL** of the following apply:

- A serious threat to the prospective subject requires immediate intervention;
- Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care;
- Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject;
- The prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research;
- Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
- No relevant prior directive by the subject is known to exist.

When a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent will be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

5.0 COMPLIANCE

The REC will try to resolve apparent instances of non-compliance. If the researcher is intentionally non-compliant or the non-compliance is serious or repeated, the REC may suspend the research and/or make an allegation of misconduct in research (see Aurora College policy I.03 *Integrity in Research and Scholarship*).

6.0 RECONSIDERATION AND APPEALS

6.1 Reconsideration of REC Decisions

1. Researchers have the right to request, and the REC has the obligation to provide, prompt reconsideration of decisions affecting a research project.
2. Requests for reconsideration of REC decisions should be made in writing by the Principal Investigator as soon as possible after being notified that his/her research proposal has not been approved. The written request should be submitted to the Chair of the REC.
3. The onus is on researchers to clarify and justify the grounds on which they request reconsideration by the REC and to indicate any alleged breaches to the established research ethics review process, or any elements of the REC decision that are not supported by this policy.
4. Researchers will be given an opportunity to clarify the proposal and/or provide more information to the REC.
5. Researchers and the REC should make every effort to resolve disagreements they may have through deliberation, consultation or advice. If a disagreement between the researcher and the REC cannot be resolved through reconsideration, the researcher will have the option of appealing the REC decisions through the established appeal mechanism (see 6.2 below).

6.2 Appeal of REC Decisions

1. Aurora College will establish agreements with other Canadian colleges that have Tri-Council accredited research ethics committees whereby Aurora College research proposals may receive a second review.
2. The Principal Investigator will notify the Vice President, Research in writing of his/her intent to appeal within 30 working days of the original REC decision to deny approval of the research proposal.

3. The Vice President, Research will send the application and all relevant documents to the Tri-Council accredited research ethics committee at one of the colleges with which Aurora College has an agreement (see above) for review. Notes from the original review and a copy of the Aurora College Research Ethics Committee decision will be included.
4. The College and the Principal Investigator will respect the determination of the external review committee, except as provided for in sections 1.1 and 1.6 above.

PROCEDURES, FORMS, AND RULES

The Vice President, Research (or designee) is responsible for managing the supporting procedures, forms, and rules for this policy.

Forms are available on SharePoint and at <http://www.nwtresearch.com>.

RELATED POLICIES

- F.04 Conflict of Interest
- I.02 Research Administration
- I.03 Integrity in Research and Scholarship
- I.05 Care of Animals in Teaching and Research
- I.06 Intellectual Property
- I.07 Research Associate Program

RELATED AURORA COLLEGE BYLAWS

- Bylaw #1 – Student Conduct
- Bylaw #3 – Student Loss of Privileges, Penalties, Sanctions, and Appeals

FACT SHEET**DATES:**

2011-05	New policy issued. Board of Governors Motion BG#27-2011. Implemented July 1, 2011.
2011-06	Implementation date rescinded by Board of Governors fax poll pending legal review and approval of policies I.03 and I.06.
2013-06-11	Implementation date recommended. Policy and Planning Committee Motion #PP09-2013. Board of Governors Motion #BG13-2013 Implemented July 1, 2013.
2014-04-15	Amended title of Bylaw #3
2014-09-19	Amended 2.3 and last bullet in 3.1
2014-12-15	Released with final versions of pdf fillable forms.
2018-06-08	Policy revised; <i>Research Ethics Committee Terms of Reference</i> and <i>Research Ethics Committee Ethics Review Decision Criteria</i> documents removed from policy to be standalone documents. Approved by Public Administrator Ref.#Admin-26-2018. Implemented July 1, 2018
2021	Next scheduled review