

## ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMAN PARTICIPANTS POLICY

This document is the parent policy for any college or Divisional procedures. Questions regarding this policy are to be directed to the identified Policy Administrator.

<b>Functional Category:</b>	Academic
<b>Approval Date:</b>	January 29, 2020
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<b>Policy Owner:</b>	Vice President, Teaching and Learning
<b>Policy Administrator:</b>	Dean, Research and Strategic Enrolment

### Objective:

The ethical conduct of research is vital to the Applied Research mandate of NorQuest College (college). It is the intent of the college, where research involving human participants is conducted under the auspices of the college, to ensure that:

- The safety, welfare, and rights of participants and their communities are protected throughout the research process;
- Researchers understand their moral and legal obligations to participants, participants' communities, the college, and the research community at large;
- Researchers are accountable and transparent in their ethical conduct;
- Researchers engage in dialogue with the college's Research Office, the college's Research Ethics Board (REB), and key project stakeholders to establish consensus on what constitutes ethical conduct with respect to the unique nature of each project and the participants and communities it will engage, while simultaneously meeting the standards set out by the Government of Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2);
- Risks and benefits are clearly identified and relayed to participants to ensure full and informed consent; and further, in the case of risk, that contingency plans are in place to reduce the possibility of harm from occurring;
- Before beginning research, the amount and kind of information that is communicated to participants is appropriate to ensure that free, full, informed, and ongoing consent can be granted;
- Participants are aware that their participation is entirely voluntary and that they have the right to withdraw from the research at any time during the course of the project without any negative consequences to themselves or others; and
- For multi-centred research projects and research under other jurisdictions, its partners provide appropriate ethical approval.

Authority to establish this policy is derived from the [NorQuest College Board of Governor's Policy No. 5](#), which delegates authority to the President and CEO to establish policies and procedures for the college's management and operation.

### Policy:

This policy governs the conduct of research involving humans. Research involving human participants at the college will be conducted, at minimum, in accordance with the most current version of the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans*.<sup>1</sup>

<sup>1</sup> <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>

### Guiding Ethical Principles

Researchers contribute to human welfare by acquiring knowledge and applying it to address problems humanity faces. Ethical research with human participants is guided by three overarching principles: respect for persons, concern for welfare, and justice. These can be broken down into more specific areas of concern:

- **Respect for human dignity.** This is the cardinal principle of contemporary research ethics. It requires researchers protect the multiple and interdependent interests of persons, the groups to which they belong, and their communities. This ranges from respecting participants' bodily and mental health to the integrity of a culture or community as they are affected by the research.
- **Free, informed, and ongoing consent.** Individuals are generally presumed to have the capacity and right to make informed decisions on their own behalf. Respect for persons, therefore, means respecting the exercise of individual's free and informed consent throughout the research process. As well as the right to choose to participate in research, individuals have the right to refuse to participate in a research study or to decline continued participation at any point in the research process.
- **Protection of vulnerable persons.** Respect for human dignity entails high ethical obligations towards vulnerable persons—those who have diminished competence, have diminished decision-making capacity and/or competency, and/or have limited access to "social goods," including rights, autonomy, power, privilege, and opportunities compared to the dominant social group and the researcher. On the grounds of human dignity, caring, solidarity, and fairness, those who are vulnerable are entitled to special protection against abuse, exploitation, and discrimination. Ethical obligations to vulnerable people, groups of people, or communities in the research enterprise may translate into special procedures or processes to help protect their interests.
- **Privacy and confidentiality.** Respect for human dignity also implies the principles of respect for privacy and confidentiality. Standards of privacy and confidentiality protect the access, control, and dissemination of personal information. In doing so, such standards help to protect the physical, social, and/or psychological integrity of participants and their communities.
- **Justice** connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards, and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of the benefits and burdens of research. Distributive justice requires that no segment of the population should be unfairly burdened with the harms of research and also imposes duties to neither neglect nor discriminate against individuals and groups who may benefit from advances in research.
- **Harms-benefit balance.** The analysis, balance, and distribution of harms and benefits are critical to the ethics of human research. Contemporary research ethics requires a favourable harms-benefits balance—that is, that the foreseeable harms can not outweigh the anticipated benefits. Harms-benefits analysis thus affects the welfare and rights of research participants and the informed assumption of harms and benefits. There is often uncertainty about the magnitude and kind of benefits and harms that may result from proposed research and about the balance of benefits and harms. This uncertainty imposes an obligation on researchers and their supporting institutions to conduct research at a high level of competency in order to minimize the potential harms and maximize the potential benefits of the research.
- **Necessity of human participants.** Research participants must not be subjected to unnecessary risks of harm and, further, their participation

in the research must be essential to achieving scientifically and societally important aims that cannot be realized without human participation.

- **Beneficence.** The principle of beneficence imposes a duty to benefit others and, in research ethics, to maximize potential research benefits. Human research is intended to produce benefits for the participants themselves and their communities, to other individuals, and to society as a whole, as well as for the advancement of knowledge.

### **Free, Informed, and Ongoing Consent**

Researchers' respect for human dignity is conveyed, in part, by adhering to the following ethical standards for free, informed, and ongoing consent that are aimed at protecting human participants.

- Research shall begin only if potential participants, or authorized third parties, have been provided the opportunity to give free, full, and informed consent about participation and their free and informed consent has been given and is maintained throughout their participation in the research.
- Free and informed consent must be voluntarily given without manipulation, undue influence, or coercion, and can be withdrawn, wholly or in part, within a time frame that has been clearly articulated by the researchers. If no time frame has been clearly communicated to participants, consent can be withdrawn at any time, including after the conclusion of the project.
- Any personal information must be collected in adherence with sections 33 and 39, as well as 33(c) and 39(1)(b) (when applicable), of the *Freedom of Information and Protection of Privacy Act*.
- Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall 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 college's Research Ethics Board (REB).
- In research studies that include randomization or blinding, such as in clinical trials, neither the research participants, nor those responsible for their care know which treatment the participants are receiving before the project begins. Such research will not be regarded as a waiver or alteration of the requirement for free, informed, and ongoing consent if the participants are informed of the probability of being randomly assigned to one part of the study or another.

### **Assent**

Researchers' respect for human dignity is conveyed through recognizing an individual's right to choose to participate in a study even if that individual is legally unable to give consent.

- Where free and informed consent is given by an authorized third party, the researchers will, to the best of their abilities, obtain assent from the research participant.
- As with free and informed consent, assent must be voluntarily given without manipulation, undue influence, or coercion and maintained throughout the research project.
- In cases where informed consent has been given by an authorized third party but assent is actively refused by the potential participant, researchers will withdraw the individual from the study.

### **Privacy and Confidentiality**

- The inherent dignity and autonomy of human research participants and the communities to which they belong is the ethical basis of the respect for research participants' privacy. Privacy is a fundamental value, perceived by many as essential for the protection and promotion of human dignity.
- Researchers will ensure confidentiality of an individual's participation in research. Where confidentiality cannot be ensured, participants must be

advised of the risk to ensure free and informed consent. The college's REB must approve any instance whereby participant confidentiality is not guaranteed, even when it is at the request of participants.

- Where participants wish to waive confidentiality and be identified, approval to do so must be given by the college's REB.
- Researchers who wish to utilize information that falls under Alberta's *Freedom of Information and Protection of Privacy Act* (FOIP Act, see especially Section 42 'Disclosure for research or statistical purposes') shall provide documentation to the college's REB of approval to access such information by the college Divisional Head responsible for the records. REB approval does not constitute FOIP approval, nor does FOIP approval constitute REB approval.

### **Fair and Inclusive Research**

- Selection of research participants and dissemination of results should ensure that, with special consideration to vulnerable participants and communities, no one individual or segment of population is unreasonably expected to bear the burdens of, nor should one individual or segment of the population receive the majority of benefits from, research activities.
- Researchers shall not exclude participants for reasons that are unrelated to the research. This includes attributes such as culture, religion, race or ethnicity, mental or physical ability, sexual orientation, gender, or age. Where explicit exclusions or inclusions are made, there must be a valid methodological and scientific reason for doing so.

### **Research Ethics Board**

The college will have its own Research Ethics Board (REB) or enter into an agreement with another Alberta post-secondary institution for it to act as its REB. The purpose of the REB is to conduct research ethics reviews for NorQuest faculty, staff, and students. In rare circumstances and at their discretion, the REB will review non-NorQuest research at the request of the college's Research Office.

Projects conducted by external researchers who have documented prior institutional ethical review board approval from outside the college and who wish to access college resources (including personnel, equipment, programs, or students) are reviewed by the college for institutional, research, administrative, and operational purposes to help ensure that local issues and values are taken into account.

### Authority of the REB

- The REB will review research conducted by college faculty, staff, and students to ensure adequate ethical consideration has been given to all research activities. The REB is to approve, reject, propose modifications to, and/or terminate any proposed or ongoing research involving human participants, which is conducted under the aegis of the college, using the Tri-Council Policy Statement as the standard. Depending on the location of the research, the nature of the research, and other parties involved additional review may be required.
- The college remains responsible for the ethical acceptability and ethical conduct of research undertaken within its jurisdiction and under its auspices irrespective of where the research is conducted.
- The college may refuse to allow certain research within its jurisdiction, even though the REB has found it ethically acceptable. As the college's Research Administrator (the Associate Dean of Research) and the Dean of Research and Strategic Enrolment may refuse projects, as may the President and Vice Presidents for any projects undertaken within their portfolios. In addition, Deans, Directors, and Senior Managers may refuse research projects which unduly burden their areas.

- The college will accept the review of other institutions REBs constituted under the Tri-Council Policy Statement if it so wishes. The approval of such research will take place through procedures and processes established by the college's Research Office and its REB. The college reserves the right to request of any project that has received ethical review by an external organization additional review by the college's own REB.
- The college does not accept ARECCI (A pRoject Ethics Community Consensus Initiative [ARECCI]) approval as equivalent to an institutional REB approval. Researchers who obtain ARECCI approval will also need to obtain REB approval for their research projects.

### **Research Involving the First Nations, Inuit and Métis peoples of Canada**

The Guiding Ethical Principles for conducting ethical research with humans apply to research with Indigenous peoples in Canada. The interpretation and application of these principles, however, may vary and requires increased researcher sensitivity to the potential need for increased engagement, reciprocity, articulation of interconnected benefits and risks, collective welfare, and collective decision-making.

Researchers should follow the ethical guidance offered by the Indigenous peoples with whom they are working. For any research likely to affect the welfare of an Indigenous community, researchers will seek engagement with that community prior to conducting any research. This includes research conducted on First Nations, Inuit, or Métis land, studies where participant criteria specifies Indigenous identity, studies of community cultural heritage, or where research results will specifically describe Indigenous peoples, communities, practices, languages, histories, or cultures.

Some Indigenous communities have established formal research ethics review boards or research review committees. Research ethics review by community REBs does not constitute institutional REB approval. Researchers must seek approval through both the community REB and the college REB. Where conflicts arise between community REB and the college REB requirements, a dialogue will be undertaken to achieve consensus.

The TCPS 2 provides comprehensive guidelines for researchers working with First Nations, Inuit and Métis peoples in Canada (see Chapter 9). The college adheres to the Statement as the minimum standard on which to develop ethical practices with Indigenous individuals and communities.

### **Research with Indigenous Peoples as Best Practice for Research with any Community**

The principles outlined above and by the TCPS 2 are required for anyone conducting research with Indigenous people and communities. The college and TCPS 2, however, also considered them as best practices for researchers who engage any specific community.

### **Ethical Misconduct of Research**

In the event that actions are taken by researcher(s) that are contrary to this policy, other policies of the college, the funding body, another organization involved in the research, or federal policies and requirements, it will be considered ethical misconduct. Ethical misconduct is considered to be both academic misconduct and research misconduct. In the event of ethical misconduct, the college's Research Office is responsible for suspending the project and for all communications regarding the suspension to the researcher, the participants, the respective REB, any funding agencies, and the Secretariat of Responsible Conduct of Research. As per the college's *Integrity in Research and Scholarship Policy*, researchers who engage in ethical misconduct are subject to disciplinary actions ranging from warnings

## Definitions:

to dismissal by the college. Misconduct may further be subject to investigation and response by the funding agency and/or legal authorities.

**Applied Research:** the process of systematic investigation, often using established methods, to establish facts, principles, or knowledge that produce(s) practical results with actual or potential application to real world situations. Applied research often focuses on solving immediate problems faced by businesses, industry, communities, government, and society.

**Assent:** is the permission given by an individual who is legally unable to give consent to participate in a research project. Assent does not replace or negate the need for informed consent.

**Authorized third party:** "Any person with the necessary legal authority to make decisions on behalf of a prospective participant who lacks the capacity to decide whether or not to participate, or to continue to participate, in a particular research project. In other policies/guidance they are also known as 'authorized third party decision makers.'"<sup>2</sup>

**Coercion:** In research, it is considered "an extreme form of undue influence, involving a threat of harm or punishment for failure to participate in research."<sup>3</sup>

**Confidentiality:** "An ethical and/or legal responsibility of individuals or organizations to safeguard information entrusted to them, from unauthorized access, use, disclosure, modification, loss, or theft."<sup>4</sup>

**Consent:** "An indication of agreement by an individual to become a participant in a research project. Throughout this Policy, the term 'consent' means 'free (also referred to as voluntary), informed and on-going consent.'"<sup>5</sup>

**Harm:** "Anything that has a negative effect on participants' welfare, broadly construed. The nature of the harm may be social, behavioural, psychological, physical, or economic."<sup>6</sup>

**Identifiable information/personal information:** "Information that may reasonably be expected to identify an individual, alone or in combination with other available information."<sup>7</sup>

**Informed consent: (see consent)**

**Innovation:** "The process by which ideas are converted into value—in the form of new and improved products, services, and approaches. It often draws on research and development and may involve commercialization, but it is not synonymous with either. Innovation can be developments in technology, design, business models, social models, and mechanisms of

<sup>2</sup> Secretariat on Responsible Conduct of Research. (2018). *Ethical Conduct for Research Involving Humans*. Ottawa, ON: Tri-Council.

<sup>3</sup> Secretariat on Responsible Conduct of Research. (2018). *Ethical Conduct for Research Involving Humans*. Ottawa, ON: Tri-Council.

<sup>4</sup> Secretariat on Responsible Conduct of Research. (2018). *Ethical Conduct for Research Involving Humans*. Ottawa, ON: Tri-Council.

<sup>5</sup> Secretariat on Responsible Conduct of Research. (2018). *Ethical Conduct for Research Involving Humans*. Ottawa, ON: Tri-Council.

<sup>6</sup> Secretariat on Responsible Conduct of Research. (2018). *Ethical Conduct for Research Involving Humans*. Ottawa, ON: Tri-Council.

<sup>7</sup> Secretariat on Responsible Conduct of Research. (2018). *Ethical Conduct for Research Involving Humans*. Ottawa, ON: Tri-Council.

	<p>service delivery.”<sup>8</sup> Innovation is often conceived as a new way of doing something that adds value and contributes to the existing knowledge store of an organization.</p> <p><b>Privacy:</b> “An individual’s right to be free from intrusion or interference by others.”<sup>9</sup></p> <p><b>Research:</b> “The process of systematic investigation used to advance knowledge. Research explores underlying principles and mechanisms which provide an understanding of the world in which we live, discovers new ideas, and is the foundation for addressing long-term challenges.”<sup>10</sup></p> <p><b>Research Data:</b> “Data that are used as primary sources to support technical or scientific enquiry, research, scholarship, or artistic activity, and that are used as evidence in the research process or are commonly accepted in the research community as necessary to validate research findings and results. All other digital and non-digital content have the potential of becoming research data.”<sup>11</sup></p> <p><b>Risk:</b> The possibility of the occurrence of harm. The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties.<sup>12</sup></p> <p><b>Vulnerability:</b> “A diminished ability to fully safeguard one’s own interests in the context of a specific research project. This may be caused by limited decision-making capacity or limited access to social goods, such as rights, opportunities, and power. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances.”<sup>13</sup></p>
<b>Related NorQuest College Information:</b>	<ul style="list-style-type: none"> <li>• <a href="#">Academic Freedom Policy</a></li> <li>• <a href="#">Applied Research and the Promotion of Innovation Policy</a></li> <li>• <a href="#">Code of Conduct Policy</a></li> <li>• <a href="#">Ethical Conduct for Research Involving Human Participants Procedure</a></li> <li>• <a href="#">Freedom of Information and Protection of Privacy (FOIP) Act Policy</a></li> <li>• <a href="#">Integrity in Research and Scholarship Policy</a></li> </ul>
<b>Related External Information:</b>	<ul style="list-style-type: none"> <li>• <a href="#">Freedom of Information and Protection of Privacy Act</a></li> <li>• <a href="#">Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Human Participants</a></li> </ul>
<b>Next Review Date:</b>	December 2024

<sup>8</sup> Alberta Research and Innovation Framework

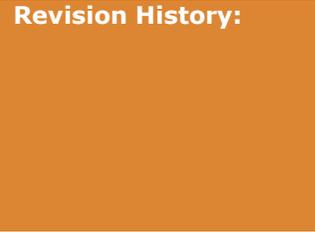
<sup>9</sup> Secretariat on Responsible Conduct of Research. (2018). *Ethical Conduct for Research Involving Humans*. Ottawa, ON: Tri-Council.

<sup>10</sup> Alberta Research and Innovation Framework

<sup>11</sup> Tri-Council Research Data Management Policy. (2018). Retrieved from <https://www.science.gc.ca > eic > site > 063.nsf > eng>

<sup>12</sup> Secretariat on Responsible Conduct of Research. (2018). *Ethical Conduct for Research Involving Humans*. Ottawa, ON: Tri-Council.

<sup>13</sup> Secretariat on Responsible Conduct of Research. (2018). *Ethical Conduct for Research Involving Humans*. Ottawa, ON: Tri-Council.



**Revision History:**

January 2013: new

August 2013: updated for document links and branding

November: 2014: updated for change in policy administrator and document links

June 2017: updated

August 2019: Compliance Office template & reorganization update

January 2020: updated to reflect new federal requirements and document links