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RESEARCH INVOLVING HUMANS POLICY

CONTENTS

1.0 PURPOSE STATEMENT

North Island College (NIC, or the College) shall regulate and monitor all research involving humans conducted at or under the auspices of North Island College. Review and approval of ethics applications for research involving humans – including human participants, human biological material, human/ancestral remains, and research on cultural heritage – shall be the responsibility of the Research Ethics Board (REB). See 3.1 for additional information on research areas subject to review.

NIC recognizes the importance of research to educational progress and affirms that the welfare of the individual or collective must prevail over the researcher's use of humans for that purpose. The College has a responsibility to ensure that the activities it supports respect the rights of the public it serves. NIC affirms its support for ethical research by providing the REB with necessary and sufficient ongoing financial and administrative resources to fulfill its duties.

The REB is guided by ethical principles regarding all research involving human participants based on the Tri-Council Policy Statement and on specific policies and laws related to First Nations, Métis, and Inuit peoples, including the Declaration on the Rights of Indigenous Peoples Act (DRIPA) and emerging legal frameworks and applied best-practices related to its implementation (see section 5.4 below).

General guiding principles include the following concerns:

- Respect for Persons
    - Recognize the intrinsic value of humans and the respect and consideration they are due, and
    - Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.
- Concern for Welfare
    - Aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks,
    - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation, and
    - Ensure that participants are not exposed to unnecessary risks.
- Justice
    - Obligation to treat people fairly with equal respect and concern, and
    - Vulnerable or marginalized people may need to be afforded special attention.

This policy delineates North Island College's position on research involving humans. The procedural guidelines and the REB's responsibilities outlined below will assist the REB and the researcher in determining whether contemplated research requires ethical review.

This policy will also guide the REB and Delegated Ethics Review Panels (see 2.3 below) in avoiding any adverse consequences that could arise from research involving human subjects.

Where research activities involving human participants are carried out under the purview of North Island College, it is the intention of the College to ensure that

- the safety, welfare and rights of research participant(s) (including individuals, groups and/or communities) are adequately protected;
- information communicated with participants ensures their informed consent is obtained;
- participants are made aware that their participation is voluntary and that they have the right to withdraw from the research or study at any time;
- sufficient steps are taken to ensure confidentiality and anonymity; and

- there is no coercion, constraint, or undue inducement to participate.

For specific definitions of terms and concepts in this document, refer to the glossary in the most current Tri-Council Policy Statement guiding the ethical conduct for research involving humans.

2.0 RESEARCH ETHICS BOARD'S AUTHORITY, RESPONSIBILITIES, AND MEMBERSHIP

2.1 Authority and Responsibilities of the REB

The Research Ethics Board (REB) derives its authority from the President of North Island College.

The Vice-President, Academic exercises the authority of the President for administrative and operational aspects of the REB.

The REB, following the current Tri-Council Policy Statement on research ethics, has the following authority and responsibilities:

- All research involving humans must receive prior ethical review and approval by the REB or, if the research is minimal risk and delegated by the REB, one of the Delegated Ethics Review Panels at the College. The type and rigour of the review shall be proportionate to the level of risk and vulnerability of the participant(s).
- The REB will establish guidelines for the procedures of Delegated Ethics Review Panels (DERPs) to review and adjudicate students' course-based research ethics applications. The REB must review the stated procedures of each DERP on a bi-annual basis.
- The REB will review, at its discretion, on-going projects (through meetings, phone calls, and/or email communication with investigators) to ensure that approved research is being conducted according to Policy 1-12. Ongoing research shall be subject to continuing review.
- The REB will refer reports of non-compliance with this policy and procedures to administrators responsible for professional and/or academic integrity for investigation under NIC Policy #3-27 Integrity in Research and Scholarship.
- The REB will monitor research ethics policies and act as a contact point and resource center for researchers.
- The REB will maintain and retain records, including (but not limited to):
    - Minutes of meetings,
    - Copies of all applications for research approval,
    - A list of all active projects approved by the REB and DERPs,
    - Any notifications of changes to approved procedures,
    - Written reasons regarding the acceptance or rejection of applications, and
    - Records of investigation of complaints or reports of non-compliance with this policy and procedure
- The REB will maintain and retain records according to provincial privacy legislation requirements.
- The REB will promote awareness of the highest ethical standards throughout North Island College by offering symposia, by providing resources, and by meeting with departments, schools, and faculties and with administrators, instructors, and students.

2.1.1 Meetings of the REB, Quorum and Votes

The REB shall meet formally at least once a year and as often as necessary to fulfill its responsibilities.

The Chair of the REB shall ensure that REB members have at least two (2) weeks' notice of any meeting and that copies of all documents to be considered at the meeting are provided with the notice.

A quorum of the REB will be at least three (3) members. The Chair can count as a member. If the quorum deviates significantly from the range of expertise reflected in the membership, the members in attendance may defer review and decision-making. Every effort will be made to reach a decision by consensus. All decisions will be recorded in the minutes, which shall clearly document both the Board's decisions and any dissents and the reasons for them. Minutes are to be accessible to authorized representatives of the institution, researchers, and funding agencies.

The REB's review of research proposals shall be based on detailed research proposals or, where applicable, progress reports.

The REB shall aspire to function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions.

When the REB is considering a negative decision, it shall provide the researcher(s) with all the reasons for doing so and provide the researcher(s) an opportunity to reply and make revisions prior to a final decision by the REB.

Every effort will be made to review proposals at face-to-face meetings. However, if necessary, the REB may make decisions via email, video-conferencing, or other technology as organized by the Chair, provided that

- adequate time is allowed for review,
- all REB members receive copies of all relevant documentation, and
- at least three members vote.

Telephone, email, or a similar text-based technology will typically only be used for expedited, minimal-risk applications, and decisions will be noted on the agenda and included in the minutes of the next formal meeting.

For purposes of clarification, the REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals; however, researchers are not to be present when the REB is making its decision.

2.1.2 Independence and Accountability

The REB acts independently and at arm's-length from the administration of North Island College, thereby maintaining its autonomy over ethical questions and review, even when the institution has a strong interest in seeing a project approved or not approved.

REB approval relates to the ethical acceptability of proposed research and **does not** constitute authorization for the research to proceed, which may need further institutional, professional, and/or legal approval.

The REB will provide the Vice-President, Academic an annual report that summarizes its activity for the year.

NIC may conduct a quality-assurance review of the REB based on current public-sector best practices.

2.2 REB Membership and Chair

2.2.1 REB Membership

NIC's REB will seek to foster and encourage a diverse membership while meeting current TCPS guidance on number of members and composition. As part of this diverse membership, the REB will seek to include at least one (1) member and preferably more who is/are Indigenous and possess/es Indigenous knowledge and recognized relationships with one or more Indigenous communities. In addition, the REB will include

- at least two members who have expertise in the methods or areas of research commonly reviewed by the REB,
- at least one member who is knowledgeable in ethics,
- at least one member knowledgeable in the relevant law, and
- at least one member who has no affiliation with North Island College drawn from the North Island College region.

All appointments must be discussed, in relation to the criteria, and approved by the Board via vote, if no consensus is reached through discussion. The Chair will make a recommendation on behalf of the Board for appointment to the Vice-President, Academic; appointments are made by the Vice-President, Academic. The Vice-President, Academic will convey in writing to the Chair why an appointment has not been offered where a recommendation has been made.

2.2.2 REB Chair

REB members will nominate and elect a current member as Chair. Any NIC REB member seeking the Chair position must be a regular faculty member at NIC. The Chair will serve a two-year term at which time an election will take place or, if no other NIC REB member has expressed interest in the Chair role, the Chair may serve another two-year term. Based on the result of the election, the Vice-President, Academic will appoint the member as the Chair of the REB.

The role of the REB Chair is to provide overall leadership for the REB and to facilitate the REB review process, based on this policy and the Tri-council Policy Statement. The Chair monitors the REB's decisions for consistency and ensures that these decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible. The REB Chair or designee is responsible for ensuring that the composition of the REB meets the applicable regulatory requirements. The REB Chair or designee monitors the REB membership composition for appropriate membership in relation to the nature and volume of research submissions.

2.2.3 Ad Hoc Advisors

The REB Chair or designee may, in consultation with Board members, invite individuals with expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB.

The ad hoc advisor may be asked to participate in the REB meeting to lend the advisor's expertise to the discussions. The ad hoc advisor may not contribute directly to the REB's decision and their presence or absence shall not be used in establishing a quorum. Documentation of key information provided by the ad hoc advisor shall be summarized in the REB minutes and, if available, the written report shall be placed in the REB files.

2.2.4 Observers at REB Meetings

The REB may allow observers to attend its meetings. Where the REB finds that an observer qualifies as an expert in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to the discussion. Observers shall not participate when the REB discusses its decision, reaches consensus or votes on the application. The minutes will reflect the presence of any observers as well as their expertise and contributions, when applicable.

2.2.5 Member, Advisor, and Observer Conflicts of Interest

The REB shall adhere to the conflict of interest guidelines as outlined in the most current Tri-Council Policy Statement and as described in NIC policies. Members, advisors, and observers of the REB will disclose any actual, perceived or potential personal interest in research presented to the REB and shall be absent during discussion or decision-making when these proposals are reviewed.

Members, advisors, and observers of the REB will not be present when their own research is reviewed. As well, they will not participate in decision making for researchers with whom they have been in direct academic conflict or collaboration (e.g., projects of faculty members who are under their direct supervision or faculty members who directly supervise them).

2.2.6 Resignations and Removals of REB Members and Chair

An REB member may resign before the conclusion of their term upon provision of notice to the REB Chair or designee. The REB Chair may resign before the conclusion of their term upon provision of notice to the Vice-President, Academic.

Where concern is related to REB duties, removal of members or the Chair will typically occur only after they have been alerted to deficiencies and provided guidance towards improved performance.

The REB Chair can recommend to the Vice-President, Academic the removal of a member at any time. Reasons for removal include but are not limited to failing to fulfill their designated REB duties or contravening NIC's codes of conduct. The Vice-President, Academic, may rescind the appointment of a member at any time. The Vice-President, Academic will convey in writing to the Chair why an appointment has been rescinded.

The REB Chair may – if they are not fulfilling their designated REB duties (see 2.2.2) in a timely, competent and ethical manner and/or have contravened NIC policies, including codes of conduct – be removed (a) by a motion and a majority vote by Board members and recommendation to the office of the Vice-President, Academic or (b) by the Vice-President, Academic. The Vice-President, Academic will convey in writing to the Board why the Chair has been removed.

An REB member shall resign immediately, or be removed by the Chair or Vice-President, Academic if they do not resign, if the REB determines they have contravened NIC policies or codes of conduct, including engaging in research misconduct, mismanaged a conflict of interest, or has engaged in any other relevant behavior that could be perceived as compromising their ethical judgment.

The REB Chair shall resign from their role immediately, or be removed as Chair by the Vice-President, Academic and have their appointment rescinded if they do not resign, if the REB members or Vice-President, Academic determines the Chair has contravened NIC policies or codes of conduct, including engaging in research misconduct, mismanaged a conflict of interest, or has engaged in any other relevant behavior that could be perceived as compromising their ethical judgment.

In the case where the Chair resigns or is removed, the REB will hold an election as soon as possible. If

the election is during the departing Chair's two-year appointment, the appointment of the new Chair will not be for the full two-year term in order to maintain the existing election and appointment pattern.

Every effort will be made to recruit a similarly qualified replacement prior to the departure of a member to preserve the level of experience and expertise and to ensure the continuity of the functions of the REB.

2.3 Delegated Ethics Review Panels

Delegated Ethics Review Panels (DERPs) may be established under the supervision and authority of the institutional REB. The purpose of a DERP is to complete the ethics review for minimal-risk student research projects that are completed as part of an NIC course. A department, faculty or school may wish to establish a DERP if a significant number of their courses or programs include primary research involving humans. In such cases, the department, faculty or school will consult with the REB in developing a review process. This collaborative process will result in a formal statement on the operation and membership of the new DERP; this statement of procedures will be reviewed and approved by the REB on a bi-annual basis.

DERP membership will consist of at least three (3) members of a department, faculty, or school.

The REB has the authority to delegate review of minimal-risk course-based student projects to DERPs, as appropriate (this does not include projects that are part of a faculty member's own research). If the Chair elects not to delegate a minimal risk application, he/she will communicate the reasons to the relevant DERP. Conversely, DERPs are free to decline delegation of an application and must communicate their reasons to the REB Chair or designee within three business days of receiving notification from the REB Chair or designee.

3.0 TYPES OF RESEARCH SUBJECT TO REVIEW

3.1 Research subject to ethical review by the REB

Unless specifically excluded (see below), ethics review and approval prior to the commencement of research is required for any study that involves human participants, human remains, ancestral remains, cadavers, tissues, biological fluids, embryos or fetuses to be conducted at North Island College by a student or employee of the College or by an external individual, educational institution, or community agency. Approval is also typically required where researchers are asking participants about cultural heritage, especially where it involves Indigenous peoples and communities. Cultural heritage is an inherently dynamic concept, but is generally linked to artefacts, archaeological research involving burial sites, and ancestral remains, but also includes intangibles such as traditional knowledge, a relationship with particular lands, sacred narratives, and customs. See 5.4 for additional information.

3.2 Research not subject to ethical review by the REB

The following types of research are exempt from the requirement for ethical review by the REB.

- Research or other study of the published writing or other public utterances of human subjects.
- Questionnaires concerning teaching performance or course content distributed to a class by instructors, deans, or others.
- Research conducted by Institutional Research & Planning, or by others authorized by the Vice-President, Academic, where such research is conducted to meet external reporting

requirements or to facilitate the management of the institution.
- Naturalistic observation of participants in public settings (e.g., political rallies, demonstrations or public meetings) where it can be expected that participants anticipate public visibility.
- Creative practice activities, unless the creative practice is used to obtain responses from participants that will be analyzed to answer a research question.
- Research that relies exclusively on the re-use of identified human somatic cell lines in the public domain.

Activities outside the scope of research requiring REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than the REB.

4.0 ETHICS REVIEW APPLICATIONS

Applications are categorized by level of risk. Minimal risk research is defined as research where the chance of and magnitude of harms for participants is similar to or less than they would experience in their everyday life. Researchers submitting minimal risk applications may request an expedited review.

Researchers must complete an ethics application and submit the application, along with any appendices, to the Chair of the REB (REB@nic.bc.ca). All applications and REB material relating to applications will be stored as per NIC Policy #1-05 Records Management.

There are three application streams that require different application forms.

An instructor will complete the form *PPM 1-12 B Application for Course-Based Ethics Approval – Instructor* where research assignments to be undertaken by students are similar and minimal risk.

A student will complete the form *PPM 1-12 B Application for Course-Based Ethics Approval – Student* where each course-based project may have differing approaches and is minimal risk.

For all research outside of course-based projects, and for course-based projects that are above minimal risk, researcher(s) or instructor must complete the form *PPM 1-12 C Application for Ethics Approval*.

Students, whether enrolled at NIC or another institution, applying to NIC's REB must have their instructor/supervisor complete the *REB Supervisor Approval* form.

5.0 REVIEW BY THE REB

The REB tailors the level of scrutiny to the level of risk presented by the research and assesses the ethical acceptability of the research through consideration of the foreseeable risks, the potential benefits, and the ethical implications of the research, both at the stage of the initial review and throughout the life of the project.

5.1 Consent

5.1.1 Informed Consent

REB members will review a proposed consent process to ensure that prospective and existing participants shall be able to make a free and informed decision (e.g., free of excessive inducement, coercion, and/or undue influence) on whether to participate in the research. The REB shall further

ensure that consent is ongoing and maintained throughout, from initial contact through to the end of the participant's involvement in a study. Researchers will be required to affirm consent with participants where risks or potential benefits have changed. Researchers will also be required to make consent-related plans for changes in the decision-making capacity of participants.

The researcher will propose the method for consent, including written or verbal or implied (e.g. returning a questionnaire) and documentation with a rationale if written informed consent (i.e., informed consent form signed by participant and/or authorized third party) is not to be used.

The REB may approve a process that allows the informed consent document to be delivered by regular mail, fax or email to the potential participant, and to conduct a consent interview by telephone or video-conference when the participant can review the consent document as it is discussed.

In some types of research, the REB may approve the process of verbal consent, a verbal agreement or other means (e.g., a handshake) where written consent is impossible to obtain or where a group or individual may perceive a written signed consent as mistrust on the part of the researcher.

The REB will review the proposed consent documents to ensure that they contain adequate information to safeguard the privacy and confidentiality of research participants.

REB approval is required for the use and/or creation of a repository to store data and/or human biological material. The repository and any future use of data and/or human biological material must be carefully described for participants.

5.1.2 Consent Must Precede Collection of or Access to Data

Consent must be obtained from the participant or their authorized third party, before research may commence, unless a departure from the general consent requirements is approved by the REB. This includes interaction, intervention or access to the participant's information.

5.1.3 Departures from General Consent

The Researcher may propose an alteration to the consent process for consideration by the REB. This may include

- partial disclosure or deception, or
- an exception to the requirement for prior consent.

In considering these alterations, the REB shall ensure that

- the research involves no more than minimal risk to participants,
- the alteration is unlikely to adversely affect the welfare of participants,
- the research would be impossible or impracticable to carry out if prior consent of participants is required,
- the precise nature and extent of any proposed alteration is defined, and
- there is a described plan to debrief, with the plan offering participants the chance to refuse consent and/or withdraw data and/or withdraw biological materials unless it is deemed impossible, impracticable or inappropriate to do so.

See 5.1.10 for information on the use of broad consent for the storage and secondary use of participants' data and human biological materials.

5.1.4 Consent for Research in Health Emergencies

The REB establishes the criteria for the conduct of research involving medical emergencies prior to approval of the research. The researcher must justify to the REB the reasons why an exception to obtaining informed consent from participants is required.

The REB allows research that involves health emergencies to be carried out without the free and informed consent of the participant or of their authorized third party if ALL of the following apply:

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

When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent is sought for continuation in the project and for subsequent research-related procedures.

5.1.5 Decision-Making Capacity

For research involving individuals who lack capacity to provide consent, either temporarily or permanently, the REB shall ensure that

- participants will be involved as much as possible in the decision-making process;
- consent will be sought and maintained from an authorized third party, who is not the researcher, nor a member of the research team; and
- 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 benefit is only for others in the same category, the participant's welfare must be protected throughout.

If the participant lacking legal decision-making capacity has some ability to understand the significance of research, they shall be given the opportunity to provide assent or dissent to participation. Dissent shall preclude participation.

Prospective participants who may lack legal capacity to make decisions but may still be capable of verbally or physically assenting to, or dissenting from, participation in research include

- those whose capacity is in the process of development, such as children, whose capacity for judgment and self-direction is maturing;
- those who were once capable for making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating; and
- those whose capacity remains only partially developed, such as those living with permanent cognitive impairment.

If assent for research is required, the researcher must submit to the REB the proposed procedures for obtaining consent from the authorized third party and assent from the research participant. The Researcher must submit an assent form or summary of the assent process to the REB for approval.

When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, the researcher will seek the participant's consent as a condition of continuing participation.

If an individual signed a research directive indicating their preference for ongoing and/or future participation in research, in the event that the individual loses capacity or upon their death, an authorized third party may be guided by these directives during the consent process.

5.1.6 Research on Dependent Populations or Where Undue Influence Exists

The informed consent of each participant involved in the research must be obtained. In addition to consent of the participant themselves, informed consent of the entity or individual seen to exercise authority over the population must be obtained. Extra care must be taken by researchers to ensure that those in charge of captive or dependent situations do not employ undue influence and/or manipulation on the population over which they have authority.

Where consent of the participant themselves cannot be obtained, it must be sought from the entity or individual seen to exercise authority over the population, together with the written consent from a person who acts as an independent advocate for the participants. Captive and dependent participants must always have the right and power to veto any consent provided by others.

5.1.7 Research Involving Children

Informed consent of the parent(s) or guardian(s) of the child must be obtained prior to research commencing. In school, camps or other group settings, consent of the principal, director or other appropriate authority must also be obtained.

Where a child is a ward of the state or of an agency, informed consent of both the agency director and the person having custody must be obtained.

Children, of their own accord, must be given the opportunity to refuse to participate or to withdraw once research has started.

5.1.8 Consent by Head of Family or Community

In cultures where consent to participate in research must be obtained from the participant's family head or community head, the researcher should propose a consent process to the REB that will include free and informed consent of the family or community head as well as of the prospective participant.

The researcher must ensure that the prospective participant is able to provide free and informed consent to participate without coercion or undue influence by the family or community head. Consent by the family or community head alone is insufficient for the research to proceed.

5.1.9 Consent Monitoring

In considering the adequacy of informed consent procedures, the REB may require monitoring of the consent process by an impartial observer.

Such monitoring may be particularly warranted when the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided.

Monitoring may also be appropriate as a corrective action when the REB has identified problems associated with a particular researcher or a research project.

5.1.10 Consent and Secondary Use of Identifiable Information and/or Human Biological Materials for Research Purposes

Researchers seeking broad consent for future use of data and/or biological material will carefully identify and describe for participants all collection and storage strategies, a consent-withdrawal process, and the nature and types of future research that may be conducted, including where that research may be conducted. The researcher, the relevant authority of the REB-approved repository, and future researchers share the responsibility of ensuring that the terms of participant consent are respected, and that privacy and confidentiality are protected.

In addition, the researcher must satisfy the following conditions:

- Identifiable information/materials is essential to the research,
- The use of identifiable information/materials without the participant's renewed consent is unlikely to adversely affect the welfare of individuals to whom the information relates,
- Appropriate measures to protect the privacy of individuals and to safeguard the identifiable information/materials are in place,
- The researcher will comply with any known preferences previously expressed by individuals about any use of their information/materials, and
- The researcher provides prospective participants an option to consent to each – the initial collection of data and/or human biological materials and the later secondary analysis – separately.

In cases where the secondary use of identifiable information/materials without the requirement to seek additional consent has been approved by the REB, if the researcher proposes to contact individuals for additional information and/or materials, REB approval must be obtained prior to contact.

5.2 Scholarly Support for Research Design

As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research.

5.3 Negative Effects and/or Unpopular Research

Research that may legitimately have a negative effect on public figures in politics, business, labour, the arts, or other walks of life, or on organizations should not be blocked solely by the use of harms-benefits analysis or because of the potentially negative nature of the findings.

5.4 Interests of Researchers

Researchers often have a variety of concerns, interests, and membership(s) that relate to the issues, individuals, and/or groups they are studying. Researchers are expected to declare their interests as part of explaining why they are conducting the research, but these linkages, including political or cultural alignment with individuals or groups that are part of the study, do not in themselves constitute a conflict of interest (COI). Instances of COI in research are situations where someone's personal interests (typically financial and/or career related) could compromise or could be perceived to compromise study design, recruitment, data collection, data security, and/or mobilization. Conflicts of interest can arise naturally from an investigator's engagement inside and outside the College, and the mere existence of a COI or the perception of a COI does not necessarily imply wrongdoing on anyone's part. Nonetheless, real and perceived COI must be recognized, explained, and assessed.

While not exhaustive, below are examples that may give rise to a COI. The principal investigator, co-

investigator, and/or their partners/immediate family members:

- has/have a financial interest in or expects to receive a financial interest (e.g., ownership of stock, stock options, salary, consulting fees, retainers, honoraria, bonuses, gifts, speaker's fees, advisory board remuneration) in or from any entity (a company, partnership, or non-profit corporation) whose interests could be affected by the outcome of this research;
- provide/s services (e.g., free or fee-paying consulting, advisory, board membership, etc.) to any entity (e.g., a company partnership or non-profit corporation) whose financial interests could be affected by the outcome of this research; and/or
- has/have intellectual property rights or interests linked in any way to their study (e.g., patents, copyrights, or royalties or other payments, etc.).

5.5 Research Involving First Nations, Inuit and Métis Peoples of Canada

Any research involving Indigenous people – including First Nations, Inuit, and/or Metis Peoples, and including human/ancestral remains – must be guided and reviewed with careful consideration of the material in the current Tri-Council Policy Statement (TCPS) and the *Declaration on the Rights of Indigenous Peoples Act* (DRIPA); such research is subject to NIC ethics review, even where community ethics review or some other form of local approval has been sought.

The TCPS is a framework and subject to revisions and reflection as procedures and understandings change. Researchers are expected to carefully consult the TCPS, review relevant contemporary literature, and to respectfully engage with, build, and maintain a relationship – if a relationship does not already exist – with all First Nations, Inuit and/or Métis communities and leaders who are involved with and/or affected by the study.

Researchers are expected to seek out and respect ethical guidance from the Indigenous individuals, communities, leaders, and/or groups involved with and/or affected by the study. Whether formally documented or community customs, orientation to and implementation of ethical guidance demands respectful collaboration and ongoing dialogue.

Consistent with the *United Nations Declaration on the Rights of Indigenous Peoples* (UNDRIP), DRIPA, and other relevant guiding frameworks such as free, prior, and informed consent (FPIC), NIC's REB recognizes that the knowledge systems of Indigenous peoples must be sought out, acknowledged, and represented during all stages of research, including preparatory reviews of oral and written resources, development of the project purpose and research question(s), study design, data collection, analysis, mobilization, and authorship. Researchers are encouraged to include Indigenous individuals as part of their research team designing and carrying out the project.

The principles of ownership, control, access, and possession (OCAP) have been developed by First Nations in Canada to guide decision-making on the collection, uses, storage, and sharing of information. These principles align with the collective benefit, authority to control, responsibility, and ethics (CARE) approach developed by the Global Indigenous Data Alliance. During a project – including study design, data collection, data storage, publication, and mobilization – researchers are expected to work with Indigenous individuals, communities and leaders to ensure concerns and principles identified by frameworks such as OCAP and/or CARE are discussed, agreed upon, and implemented.

Research that asks participants about cultural heritage, artifacts, traditional knowledge or unique characteristics typically requires REB approval. Primary research on cultural heritage that does not include living participants – including archaeological research involving burial sites, ancestral remains,

sacred landscapes, traditional knowledge, sacred narratives, and the handling of artifacts – may also require REB review. In addition, such research may involve ethical obligations and issues that are not dealt with in academic research applications yet are important to an Indigenous community or communities. In all cases, researchers must ensure they work with communities to address expectations and concerns.

5.6 Coordinated Reviews, Reciprocal Agreements, and Delegated Review to an External, Specialized, or Multi-Institutional Research Ethics Board

North Island College REB is responsible for the ethical acceptability of research undertaken within its jurisdiction by external researchers. For research that spans multiple institutions, NIC's REB may communicate any ethical concerns and coordinate with other institutional REBs also considering the project.

NIC may also establish formal agreements between its REB and another institution's REB whereby the REBs will accept, with an agreed level of oversight, the review by the REB at the other institution.

NIC may also permit its REB to join an external, specialized or multi-institutional REB. NIC's REB may allow this external, specialized or multi-institutional board to conduct reviews on its behalf for minimal risk project without a formal agreement or on its behalf for above-minimal risk projects with a formal agreement between or among the REBs and their institutions. NIC's REB, in any arrangement, must actively ensure that a board conducting a review on its behalf has adequate knowledge of participant populations in the NIC region.

Studies involving human pluripotent or human totipotent stem cells that have been derived from an embryonic source and/or that will be grafted or transferred in any other form into humans or non-human animals involve a two-stage approval. First, researchers must receive approval from the national Stem Cell Oversight Committee (SCOC). Then, researchers submit to NIC's REB with evidence of SCOC approval.

5.7 Review of Research in Other Jurisdictions or Countries

Research to be performed by NIC students or employees outside the jurisdiction of NIC shall undergo prospective ethics review by both NIC's REB and by the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

5.8 REB Review During Publicly Declared Emergencies

Publicly declared emergencies arise suddenly or unexpectedly and require urgent or quick responses. Examples include natural disasters, large communicable disease outbreaks, environmental disasters and humanitarian emergencies. Such emergencies may represent significant risks for research participants in ongoing research or in new research initiated as a result of the emergency. Potential research participants who may not normally be considered vulnerable may become so by the very nature of the public emergencies, while those already vulnerable may become acutely so.

Research ethics review during publicly declared emergencies may necessitate the use of innovative practices. Depending upon the nature of the emergency, for example, the REB might not be able to meet in person, and delegated review procedures may have to be designed to respond to either urgent opportunities for new research or to current ongoing research.

The existence of an emergency does not override established procedures to protect the welfare of research participants. Any relaxation of the usual procedural requirements for review should be proportionate to the complexity and urgency of the emergency, as well as to the risks posed by the research under review. Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency must be documented and appropriately justified.

6.0 REB DECISIONS & APPEALS

6.1 Full Board or Ad Hoc Decisions

A review of proposed research by the REB results in a decision expressed as

- approved,
- approved with minor revisions,
- approved with major revisions, or
- rejected.

The REB Chair or designee will convey this decision as soon as possible by email to the researcher. Where minor or major revisions are required, they are to be clearly specified to facilitate compliancy.

The REB has the responsibility to review ongoing research, proportionate to the level of risk posed by the research. The REB has the discretion to temporarily or permanently withdraw approval for research if there is an increase in the level of risk to participants or other ethical implications arise that may affect participant(s) welfare (see below).

Researchers are to notify the REB at the conclusion of their research approval period, using NIC's *REB Project Completion Form*. Should an extension to the approved period be required, researchers must complete an *Application for Continuing Review*.

6.2 Delegated Ethics Review Panel Decisions

A Delegated Ethics Review Panels (DERP) will normally conduct an expedited review of each application, in keeping with the Tri-Council Policy Statement and the policy stated in this document, and its decision will be stated as

- approved,
- approved with minor revisions,
- approved with major revisions, or
- rejected.

The DERP will convey its decision to the REB Chair and to the applicant(s); should the application be rejected, the DERP must communicate the decision to the REB Chair. If the recommendation under delegated review is to disapprove the research, a final decision must be made by the REB at a Full Board meeting.

The DERP will report all decisions and convey all documentation to the REB upon accepting an application for review and upon arriving at a decision, permitting the REB to maintain surveillance over all research undertaken at the North Island College. All documents relating to the application are to be tracked and stored by both the DERP and the REB. Each DERP will confer with the REB Chair annually to confirm accurate tracking of research projects and decisions.

The REB remains responsible for the ethical acceptability of all research done within the jurisdiction of North Island College and retains ultimate authority over approving research.

6.3 Suspension or Termination of REB Approval

6.3.1 Reasons for and Process of Suspension or Termination of REB Approval

If any concerns are raised during the REB's oversight of the research related to new information or to the conduct of the research, the REB may suspend or terminate its approval of the research as appropriate. These concerns may include but are not limited to

- the research not being conducted in accordance with the REB-approved protocol or REB requirements,
- the research is associated with unexpected serious harm to participants (i.e., as may be determined following REB review of reportable events),
- failure to comply with prior conditions imposed by the REB (i.e., under a suspension or approval with modifications),
- repeated or deliberate failure to properly obtain or document consent from research participants,
- repeated or deliberate failure to obtain prior REB review and approval of amendments or modifications to the research, or
- repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB.

The REB Chair or designee is authorized to suspend REB approval of research. If the Chair or designee suspends approval of the research, he/she must notify REB members as soon as possible. The REB is authorized to terminate its approval of the research following a review at a Full Board meeting.

Prior to suspending or terminating REB approval, the REB must consider

- risks to current participants,
- actions to protect the safety, rights and well-being of currently enrolled participants,
- whether participants should be informed of the termination or suspension,
- whether adverse events or outcomes should be reported to the REB, and
- identification of a time frame in which the corrective measures are to be implemented.

The REB Chair or designee will notify the researcher of any suspensions or terminations of REB approval, and the reasons for the decision.

Unless otherwise stated by the REB, when the REB Chair or designee suspends or terminates ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events.

If the research approval is suspended or terminated by the REB, the REB Chair or designee will issue a formal letter to the Researcher with the reason(s) for the REB action and the corrective measures proposed by the REB (if any). Suspensions may be lifted after corrective actions are completed to the REB's satisfaction.

6.3.2 Reporting Suspensions or Terminations of Research Approval

The REB Chair or designee will report any suspension or termination of REB approval to the Vice-President, Academic of North Island College within three business days after the Board has made its decision and before notifying the researcher(s).

6.4 Right of Reconsideration and Appeal

Investigators whose research proposals are not approved have the right to request a reconsideration of the decision by the full membership of the REB and have the right to be heard at the next meeting. Researchers may request reconsideration by submitting a letter to the Chair of the REB, providing the foundation of their request. In the event that the reconsideration process is exhausted without satisfaction to the researcher, an appeal process is available that would involve either an ad hoc review by NIC faculty and staff or review by an REB at a different institution.

The organization at which the appeal will take place will be determined on a case-by-case basis by the REB in consultation with the researcher (and their affiliated organization). The appeal committee shall have the authority to review the basis of the decisions made by the REB and in so doing it may approve, disapprove or request modifications to the research proposal. Its decision shall be final and shall be communicated to the researcher and NIC's REB in writing.

7.0 LINKS TO RELATED POLICIES, DOCUMENTS AND ORGANIZATIONS

The Panel on Research Ethics, Government of Canada
https://ethics.gc.ca/eng/home.html

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)
https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

Natural Sciences and Engineering Research Council of Canada
https://www.nserc-crsng.gc.ca/index_eng.asp

Social Sciences and Humanities Research Council of Canada
https://www.sshrc-crsh.gc.ca/home-accueil-eng.aspx

Canadian Institutes of Health Research
https://cihr-irsc.gc.ca/e/193.html

Implementing the United Nations Declaration on the Rights of Indigenous Peoples Act, Government of Canada
https://www.justice.gc.ca/eng/declaration/index.html

Declaration on the Rights of Indigenous Peoples Act, Government of British Columbia
https://www2.gov.bc.ca/gov/content/governments/indigenous-people/new-relationship/united-nations-declaration-on-the-rights-of-indigenous-peoples

Truth and Reconciliation Commission of Canada, Government of Canada
https://www.rcaanc-cirnac.gc.ca/eng/1450124405592/1529106060525

8.0 CROSS REFERENCE

NIC Policy #3-06 – Community Code of Academic, Personal and Professional Conduct
NIC Policy #3-27 – Integrity in Research and Scholarship