



University Policy/Procedures/Guidelines

Indigenous Research Involving Human Participants

Topic:	Research: Compliance with external legislative frameworks
Approval Authority:	APPRC and Senate
Approval Date:	TBC
Effective Date:	1 July 2023
Last Revised:	

1. Purpose

1.1. It is the policy of York University to ensure the ethical conduct of research involving human participants and to comply in full with the *Tri-Council Policy Statement on Research Involving Human Participants (DATE)* as it may be amended from time to time. The University has two separate and distinct policies that govern its research involving Human Participants:

- The Senate Policy on Research Involving Human Participants
- The Senate Policy on Indigenous Research Involving Human Participants

1.2 In recognition of distinct Indigenous knowledges and approaches to research that may involve Indigenous Peoples (First Nations, Inuit, and Métis) and to ensure that appropriate sensitivity to cultural and community rights, roles and responsibilities is applied to all research projects conducted under the auspices of York University, the Policy on Indigenous Research Involving Human Participants and an autonomous research ethics review board have been established to govern the review of all research involving Indigenous Peoples. Since the establishment of research ethics boards (REBs) across Canada, the research ethics process has become a required but transactional relationship in which researchers merely submit a protocol for review, revisions, and approval; most REBs have limited engagement in the actual research process. Given the need to foreground the voice and needs of Indigenous

communities¹ within Indigenous research, the Indigenous Research Ethics Board (IREB) at York is available to engage with researchers throughout the entire research process, including meeting with and providing advice with regards to emerging issues at the intersection of indigenous research and ethics compliance. (The IREB is supported by the Office of Research Ethics)

Review by the University's Indigenous Research Ethics Board applies to all Indigenous research conducted under the auspices of York University; for all other research conducted at the University, the [Senate Policy on Research Involving Human Participants](#) and its associated [Human Participants Review Committee](#) (the HPRC) apply.

1.3 The IREB serves the York research community in at least the following ways:

- a. by contributing to the education of its members and the broader York community about research ethics;
- b. by acknowledging and promoting the inclusion of expertise from traditional knowledge keepers;
- c. by acknowledging and promoting the aim that research should have positive impacts, and repair and reconnect community relationships;
- d. by creating relational accountability of research by establishing relationships between the communities in which they serve and York University;
- e. by acknowledging the interdependence of humans and the natural world and spirit world, and the responsibility that all people have to those relationships;
- f. by engaging with researchers and applying an indigenous lens to questions of research ethics as they may arise throughout the entire research process
- g. by conducting independent, multi-disciplinary review of research proposals that meet all national requirements; and
- h. by overseeing the ethics review processes delegated to and conducted by Faculty, Department, School, and Graduate Program review bodies.

¹ Indigenous Communities – describes a group of people with a shared identity or interest that has the capacity to act or express itself as a collective. In this Policy, a community may include members from multiple cultural groups. A community may be territorial, organizational, or a community of interest. “Territorial communities” have governing bodies exercising local or regional jurisdiction (e.g., members of First Nations who reside on reserve lands). “Organizational communities” have explicit mandates and formal leadership (e.g., a regional Inuit association or a friendship centre serving an urban Indigenous community). In both territorial and organizational communities, membership is defined and the community has designated leaders. “Communities of interest” may be formed by individuals or organizations who come together for a common purpose or undertaking, such as a commitment to conserving a First Nations language. Communities of interest are informal communities whose boundaries and leadership may be fluid and less well- defined. They may exist temporarily or over the long term, within or outside of territorial or organizational communities.

An individual may belong to multiple communities, both Indigenous and non-Indigenous (e.g., as a member of a local Métis community, a graduate students' society and a coalition in support of Indigenous rights). An individual may acknowledge being of First Nations, Inuit or Métis descent but not identify with any particular community. How individuals define which of their community relationships are most relevant will likely depend on the nature of the research project being proposed.

2. Scope and Application

2.1. Research Involving Indigenous Peoples

- a. The policy shall apply to all Indigenous research involving human participants including their lands, materials, human remains, cadavers, tissues, biological fluids, embryos, and fetuses and researchers in all Faculties and the University Libraries conducting such research. The policy is intended to protect Indigenous Peoples and communities, the researcher and/or principal investigator, individual participants, and the University jointly and collectively; it seeks to protect all parties to the research endeavour.
- b. The following Policies, Procedures and resources support the Senate Policy on IREB: Research Involving Indigenous People for access to ethics review processes, Researcher Toolkit, IREB protocol forms, IREB ICF and guidelines as they relate to research involving Indigenous Peoples. These resources are accessible on the Office of Research Ethics website.

2.2. Confidentiality

All information provided by Principal Investigators and other researchers is confidential and shall be retained in the Office of Research Ethics on that basis to the fullest extent possible by law.

2.3. Research Not Covered by This Policy and Procedures

Any research activity for which this policy is silent (such as clinical trials, research involving human biological materials and/or human genetic research), the relevant sections of the current [Tri Council Policy Statement](#) (2022; TCPS) shall be relied upon for guidance. Alternatively, researchers may consult with the Office of Research Ethics for advice and direction

3. Definitions

3.1. For the purpose of this policy and its associated procedures, and in accordance with the [Tri-Council Policy Statement](#) (2022):

- a. ‘research’ is defined as any undertaking intended to extend knowledge through a disciplined or systematic investigation and it includes pilot or preliminary research that involves human participants;
- b. Indigenous Peoples includes First Nations, Inuit, and Métis Peoples located within Canada. In this context, the term “Indigenous Peoples” typically refers to persons of Indian, Inuit or Métis descent, regardless of where they reside and whether their names appear on an official register. Self-identification is a fundamental criterion for defining Indigenous Peoples. The term “Indigenous”

does not reflect the distinctions among First Nations, Inuit and Métis peoples, who have their own histories, cultures and languages, so an attempt has been made to limit use of the term in this Policy to instances where a global term is appropriate. Indian peoples commonly identify themselves by distinct nation names such as Mi'kmaq, Dene or Haida, and as First Nations;

- c. 'human participants' are persons who provide data or information to the researcher, who are not acting in their professional capacity, but as subjects in the public domain;
- d. 'researcher' and/or 'Principal Investigator' includes:
 - i. any research affiliated with York University who conducts or advances the creation or dissemination of new knowledge with, for, or about Indigenous persons in a capacity that accesses University students staff, faculty or any other human participants;
 - ii. any other person who conducts or advances research and is connected with the University; this includes people affiliated with universities receiving research funds from York;
 - iii. any person who conducts research using University resources (whether research space, materials, equipment, or human resources).
- e. The term "member" when used in this Policy and its accompanying procedures includes Indigenous Elders, Indigenous community members, faculty, emeritus faculty, contract faculty, staff, administrators, students, visiting or adjunct scholars, fellows and chairs, and any research associates or assistants, whether paid or unpaid.

4. Policy and Guidelines

4.1. Policy Statement

It is the policy of York University to ensure the ethical conduct of Indigenous research involving human participants and to comply in full with the [Tri-Council Policy Statement on Research Involving Human Participants](#) (2022) as the Tri-Council policy may be amended from time to time.

4.2. Principles and University Commitments

Researchers are obligated to strive for ethical conduct at all times in relation to their research. This IREB policy underscores the importance of a distinctly Indigenous ethics process that reviews all research with, by, for and about Indigenous Peoples at York. The Senate of York University affirms that all researchers must respect the safety, welfare, and dignity of human participants in their research and treat them fairly, and not as a

means to an end. The University values and protects the academic freedom of its researchers. The ethics review process shall not unfairly censor researchers in the conduct of their research. However, academic freedom is conditional on all researchers respecting the rights and well-being of human participants. The IREB allows for Indigenous approaches, knowledges, and histories to bear on these ethical review processes.

This policy acknowledges the need for ongoing change and refinement of applicable policies to be accountable to Indigenous knowledges, languages, and Peoples, as well as changes in research ethics, methods, and contexts. Ethical guidelines shall be respected and revised as necessary. Continued awareness and debate of the topic in the research community is essential.

The University's principal reference for ethics review is the [Tri-Council Policy Statement \(TCPS\)](#), with which the University has agreed to comply pursuant to the Memorandum of Understanding (September 2002) between the University and the three funding agencies that make up the Tri-Council.

5. Roles and Responsibilities

5.1. Review by the University's Indigenous Research Ethics Board applies to all Indigenous research as defined above; for all other research, York's research ethics board, known as the Human Participants Review Committee (the HPRC) applies.

Similar to the HPRC, the IREB is a sub-committee of the Academic Policy, Planning and Research Committee (APPRC) of Senate. The IREB is charged with reviewing the ethical acceptability of all Indigenous research involving human participants conducted by members of the University, and with carrying out the procedures within its jurisdiction or under its auspices. All research involving human participants conducted by faculty, staff or students, regardless of where the research is conducted, is subject to review and approval by the relevant research ethics board (REB) in accordance with the most recent Tri-Council Policy Statement prior to the commencement of any research activities. The IREB composition, mandate, and operations shall conform to the specifications set out in the procedures that accompany this policy.

5.2. IREB shall report at least annually to the Academic Policy, Planning and Research Committee of Senate. APPRC shall, in turn, transmit reports to Senate and make them accessible.

5.3. The primary responsibility of the IREB is to ensure, through the review and approval of research ethics protocols, that researchers respect the safety, welfare, dignity, rights and diversity of human experience and participants in their research and treat them equally and fairly and not as a means to an end.

5.4. The IREB shall discharge the following specific duties:

- a. engage with researchers by providing advice and guidance as it speaks to the submission of a research ethics protocol by applying an indigenous lens to questions of research ethics as they may arise throughout the entire research process;
- b. conduct ethics reviews within the context of the University's responsibility to ensure that the research meets high scientific and scholarly standards. All research involving Indigenous Peoples - student, staff, faculty or external researchers - shall fall under the purview of the IREB for the purposes of review and approval. Only the IREB has the authority to review Indigenous research involving human participants;
- c. terminate any research that it considers to be threatening or causing distress to the participants, deviates from the approved Protocol, or has not been approved by the appropriate body;
- d. provide Faculties and Libraries with the resources necessary to enable them to become familiar with and adhere to this Senate Policy;
- e. act as an advisory body for the University, educating the community on ethics in research and providing guidance on the ethics review policy, processes and procedures;
- f. provide resources (outreach and education) to the Faculties and Libraries so as to enable them to provide the necessary education and advice to research assistants and students about the relevant aspects of ethics in Indigenous research and the need to treat participants ethically and respectfully.

6. Review

This policy will be reviewed by the Office of Research Ethics one year after implementation, and then every five years going forward. During the review, the policy will remain in full force and effect.

7. Procedures - See Appendix (attached)

8. Funding for IREB Operations

7.1. Through both financial and in-kind support from the Office of Research Ethics and the Associate Vice-President Research, the IREB shall have the requisite financial and administrative support (including the funding of at least three traditional knowledge keepers) to ensure that it has both the autonomy and resources to fulfill its responsibilities.

Legislative history:	Approval by APPRC (pending); Approval by Senate (pending)
Date of next review:	2023-2024
Policies superseded by this policy:	N/A
Related policies, procedures and guidelines:	Senate Policy on Research Involving Human Participants

APPENDIX: Procedures Governing the Indigenous Research Ethics Board (attached)

Procedures Governing the Indigenous Research Ethics Board

1.1 Research Ethics Board and Governance Framework

An appropriate and compliant governance structure is a fundamental element of any effective ethics review policy and process. The governance structure ensures that the relevant Research Ethics Board (REB) operates with a clear mandate, authority and accountability, within clearly defined responsibilities and with the institutional independence necessary to undertake their decision-making processes appropriately and effectively. York University has two university wide REBs – the IREB and the HPRC. The Indigenous Research Ethics Board – the IREB – reviews ALL research involving Indigenous Peoples; this includes all student and faculty-led research. The York University Research Ethics board – the HPRC – reviews ALL non-Indigenous research. York University’s Research Ethics Boards – IREB and the REB are sub-committees of the Academic Policy, Planning and Research Committee of Senate.

1.2 Overall Mandate of the IREB

The IREB, on behalf of the institution, is mandated to review all Indigenous human participant research including approving, rejecting, proposing modifications to or terminating of any proposed or ongoing research involving humans. Additionally, upon request of individual researchers, it will engage with researchers throughout the entire research process, including meeting with and providing advice from conceptualization of research through to its completion and dissemination. This mandate extends to all research conducted under the auspices of or within the jurisdiction of the institution.

In keeping with the requirement of the Tri-Council Policy Statement that the highest body of the institution shall establish the REB(s), Senate has created the Indigenous Research Ethics Board (IREB) and, for non-Indigenous Research the York University Research Ethics Board (HPRC). Appointments to the IREB shall be made by the Associate Vice-Presidents, Research who oversee research with human participants as delegated by the Vice-President, Research and Innovation upon the sole recommendation of the Indigenous Council at York University.

1.3 Membership

- a. The composition of the IREB shall reflect the University’s commitment to diverse Indigenous nations and Indigenous Peoples (First Nations, Inuit, and Métis) as well as principles of diversity, equity, decolonization inclusion. In recognition of the limited number of Indigenous scholars on campus the term of service for members shall be 3 years.

- b. At a minimum, the TCPS requires that a REB must be comprised of 5 members. Accordingly, the IREB shall be comprised of at least 5 faculty members including a diversity of First Nations, Inuit, and Métis Peoples and gender identities. The Indigenous Council shall nominate candidates to the Associate Vice-Presidents Research. The faculty member appointments shall be consistent with the principles of Guidelines and Procedures for Senate Nominations.
- c. The IREB shall also consist of at least three external Elders/Knowledge Keepers and the Chair of the Research Responsibility Group of the Indigenous Council. This composition must be maintained at all times in order to ensure compliance with this policy.
- d. In addition, IREB shall have:
 - i. three Indigenous community representatives (at least one of whom will be a youth 16-19 years) who have no affiliation with the University and who will be provided an annual honourarium. The Indigenous Council shall nominate candidates to the Associate Vice-President Research.
 - ii. at least one Indigenous undergraduate and one graduate student each of whom will be provided an annual stipend. The Indigenous Council shall nominate candidates to the Associate Vice-President Research.
- e. The following shall provide the IREB with administrative support and advice where relevant as non-voting members:
 - i. the Director, Office of Research Ethics
 - ii. the Manager, Office of Research Ethics
 - iii. the Director, Information, Privacy and Copyright
 - iv. the Biological Safety Officer
- f. Additional members may be appointed as required to ensure that all relevant subject areas are adequately represented. Further, where full membership is not warranted or applicable, Ad Hoc Advisors may be consulted. The advice of Ad Hoc Advisors will be sought in the event that the IREB does not have the discipline specific expertise or requisite knowledge to provide appropriate review of a particular ethics protocol. It should be noted that Ad Hoc Advisors are not members of the IREB and therefore do not count towards quorum nor do they vote on IREB decisions.

1.4 Chair and Vice-Chair

The Chair of IREB shall be appointed by the Associate Vice-Presidents Research, as delegated by the Vice-President Research and Innovation, on the sole recommendation of the Indigenous Council. The Vice-Chair will be chosen on the recommendation of IREB Committee members. The Chair should, generally, serve for a term of three years with a possibility of renewal if or as needed.

1.5 Substitute Membership

A roster of substitute members to the IREB may be appointed by the Associate Vice-Presidents, Research to ensure continuity and compliance of the ethics review process in the event of illness and/or other unforeseen circumstances which prevent a quorum of membership of the committee and/or a lack of appropriate representative disciplines for the purposes of review.

1.6 Training

IREB members shall receive relevant training as it relates to research ethics policy and research ethics review procedures and processes.

Training shall be provided by the Office of Research Ethics in conjunction with the Indigenous Council. New members will be provided with the resources necessary to undertake their responsibilities as IREB members. In addition to the training provided by Office of Research Ethics (ORE) & Indigenous Council (IC), IREB members are expected to complete the TCPS online tutorial. On-going training will be provided to members of the IREB through education and outreach activities where relevant and necessary.

1.7 IREB Standard Operating Procedures and/or Guidelines

In order to ensure consistency of decision-making processes as well as to ensure accountability of said processes, wherever possible, Standard Operating Procedures (SOPs) or Operations Guidelines should be developed and implemented as they speak to IREB operations. SOPs shall be developed, reviewed and updated, where applicable, on a regular basis. All relevant SOPs will be developed by and housed in the Office of Research Ethics and subject to review and/or approval by the IREB where applicable.

1.8 IREB Meetings, Quorum and Attendance

The IREB shall meet periodically and a minimum of 1 - 2 times annually for the purposes of discharging its responsibilities. At least once yearly, a meeting of the IREB may be convened for the purposes of reviewing SOPs, and other operational

and reporting documents where appropriate and applicable. Additional and emergency meetings of the IREB can be convened at the request of the Chair or members of the Committee for the purposes of reviewing research that is problematic, contentious, or for which a consensus decision cannot be reached via regular review processes. Quorum must include the Chair, at least one Elder, one community member and 3 additional members.

1.9 Reconsideration and Appeals

If an ethics review body refuses to approve the research or if the body requires amendment to the research as a condition of approval and the lead researchers or Principal Investigator disagrees with the proposed amendments, the Principal Investigator may provide a rationale for reconsideration of the IREB decision. Upon receipt of such a request, the IREB is required to provide a prompt reconsideration and decision pertaining thereto. Should the IREB and the researcher fail to come to an agreement with regards to the committee's decision, the researcher may appeal the ethics review body's decision to the Indigenous Research Ethics Board Appeal Committee (IREBAC) which shall conduct an ethics review of the research Protocol and the procedures followed by the body that conducted the first review. The appeal body is an ad hoc committee. Membership of the IREBAC shall be drawn from past members of the predecessor Indigenous Research Ethics Advisory Committee (pre-2023) and/or the Indigenous Research Ethics Board. However, members of the IREB whose decision is under appeal shall not serve on the appeal committee. Decisions of the Indigenous Research Ethics Board Appeal Committee are final and binding.

1.10 REB(s) Reporting Requirements

The IREB is required to provide an annual report to the Indigenous Council and to Senate via the APPRC for the purposes of information and oversight. The report shall include a list of all IREB approved protocols, an overview of IREB operations, education and outreach activities, a report on activities of the Committee and the Office of Research Ethics, and any other relevant matters.

1.11 Conflict of Interest

- a. Any conflict of interest that exists or may appear to exist as it relates to any of the researchers must be described, even though this need not halt the research. A conflict of interest may exist if there is potential benefit to the researcher(s) beyond the professional benefit from academic publication or presentation of the results (and consequent honoraria, royalties, etc.). In addition to researcher conflict of interest, there may be institutional conflicts of interests, as well as IREB members' conflict of interest. Just as all researchers are required to state

clearly any and all real or perceived conflict of interest on ethics protocols, so too IREB members are bound to the same disclosure and are required to state any real or perceived conflicts of interest they may have with regards to a particular protocol before the committee for review. To better manage such conflicts, IREB members will be reminded that they are required to recuse themselves from deliberations of any such research protocols. To manage institutional conflicts of interests, any real, potential or perceived institutional conflicts of interest should be reported to the relevant REB in accordance with the approved Senate Conflict of Interest policy.

- b. While it is preferable that conflicts of interest be avoided, in those cases where a conflict of interest cannot be avoided, researchers must declare said conflicts to the IREB and research participants alike, in as much detail as possible. Researchers are required to minimize or manage identified conflicts and provide the IREB with a detailed description of how such conflicts will be managed. For those instances where there may be a financial conflict of interest, researchers shall disclose all kinds and amounts of payment to the researchers by sponsors, commercial interests and consultative or other relationships. Where concerns are raised with regards to potential financial conflicts of interest, the IREB may require researchers to provide a copy of their budget so that it may be examined for inappropriate payments or unexplained expenses.
- c. Researchers should be aware that the IREB can determine, upon review of the stated conflict of interest and proposed method for management of same, that the researcher withdraw from the research or that others on the research team who are not in a conflict of interest make research-related decisions. Further, the IREB has the discretion to prohibit certain kinds of payment and the discretion to refuse to approve a protocol for which it feels the implications of the conflict of interest are too significant and/or cannot be managed effectively.