

RESEARCH INVOLVING HUMAN SUBJECTS			
<b>Effective Date</b>	14 May 2020	<b>Policy Type</b>	Academic
<b>Responsibility</b>	President	<b>Cross-Reference</b>	<ol style="list-style-type: none"> <li>1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (current version)</li> <li>2. Agreement on the Administration of Agency Grants and Awards (current version)</li> <li>3. Integrity in Research and Innovation Policy</li> <li>4. Ethics and Accountability Policy</li> <li>5. Enterprise Risk Management Policy</li> </ol>
<b>Approver</b>	Academic Council	<b>Appendices</b>	Appendix 1: Terms of Reference for the Research Ethics Board Appendix 2: Procedures for Research Ethics Review
<b>Review Schedule</b>	Five years, or as warranted by Tri-Council Policy Statement Revisions		

**1. Policy Statement**

- 1.1. This policy describes the requirements for research ethics review, informs the review process, and provides operating procedures for the GPRC Research Ethics Board (REB).

**2. Background**

- 2.1. The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) is a joint policy of Canada’s three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or “the Agencies.” To be eligible to receive and administer research funds from the Agencies, GPRC, as a signatory to the Agreement on the Administration of Agency Grants and Awards by Research Institutions, has agreed to ensure that research conducted under its auspices adheres to Agency Policy described in Section 4.3 of the 2018 Agreement. Individually, GPRC-affiliated researchers are expected to adhere to the TCPS and College policy related to responsible conduct of research, *irrespective of receipt of Tri-Council funding*. The language of this policy directly and substantively reflects the language of the TCPS.

**3. Policy Objective**

- 3.1. All research activities involving human subjects, where faculty, staff, students, and others having a recognised relationship with the College are acting as researchers or participants, will be designed, reviewed, and conducted ethically.

## 4. Scope

- 4.1. This policy concerns any GPRC instructor, staff member, student, associate, or visitor involved with research on human subjects. It is intended to protect internal and external research subjects from undo or uninformed harm and to instill community confidence in the College's intent to ensure all research activities are conducted ethically.

## 5. Definitions

- 5.1. Chapter 9 Research: Research involving individuals or communities self-identifying as Indigenous Peoples of Canada.
- 5.2. Course review: Review of human subject research presented to the REB on a 'per-course' or 'per-section' basis.
- 5.3. Intervention: Planned imposition of a set of conditions (task, activity, treatment, environment, etc.) on participants for the purposes of research.
- 5.4. Observational Research: Research involving humans that does not involve an intervention.
- 5.5. Principal Investigator: The leader of a research team who is responsible for the ethical conduct of the research, and for the actions of any member of the research team.
- 5.6. REB: Research Ethics Board
- 5.7. Research: any undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.
- 5.8. Research Involving Humans: Research requiring ethics review and approval by a REB before the research commences:
  - 5.8.1. Any research involving living human participants
  - 5.8.2. Any research involving human biological materials, derived from living or deceased individuals.
  - 5.8.3. Pilot studies involving (5.8.1) and/or (5.8.2) conducted for the purpose of assessing the feasibility and/or informing the design of a larger study.
- 5.9. TCPS: The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* is the standing guiding document to which GPRC requires compliance in the conduct of human subject research.
- 5.10. Vulnerable Persons: Individuals or groups whose circumstances make them vulnerable in the context of the research, and, those who live with relatively high levels of risk on a daily basis.

## 6. Guiding Principles

- 6.1. All GPRC-involved research involving human subjects, and all related College policy and practices will adhere to the principles, guidelines, and requirements of the current *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), or any subsequent documents that Tri-Council or the Panel on Research Ethics may issue concerning the conduct of research. In any instance of dispute between College policy, practices, and protocols and the TCPS, the TCPS will prevail, except in instances where College policy exceeds TCPS minimum requirements.
- 6.2. Any individual conducting research is responsible to ensure their conduct complies with the *Canadian Charter of Rights and Freedoms*, and the Law.
- 6.3. **Respect for Human Dignity**: This is an underlying value of both the TCPS and GPRC. The TCPS requires that research involving human subjects be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due, expressed through three core principles: Respect for Persons, Concern for Welfare, and Justice.
  - 6.3.1. At all times when designing or conducting research involving humans, researchers must be respectful of the participant's perspective and the varied social, economic, and cultural contexts that inform that perspective.

- 6.4. Knowledge of Ethical Conduct of Research: The Principal Investigator and members of the research team are required to provide documented evidence that they possess knowledge in the ethical conduct of research equal to, or exceeding the *TCPS 2 Tutorial Course on Research Ethics (CORE)*.
- 6.5. Consent:
  - 6.5.1. Anyone participating in research should do so voluntarily, understanding the purpose of the research, its risks, and the potential benefits. No research may proceed with anyone who has refused to participate. In cases where a participant is unable to provide informed voluntary consent, consent may be given by an authorized third party, as defined in the TCPS.
  - 6.5.2. Consent shall be given voluntarily.
    - 6.5.2.1. Consent can include no element of coercion, including inappropriate incentives or penalties (for example, the deducting of marks from students who withdraw from participating as research participants). GPRC neither encourages nor discourages the use of research participation incentives.
  - 6.5.3. Consent can be withdrawn at any time.
    - 6.5.3.1. A participant withdrawing consent may also request the withdrawal or destruction of their data or human biological materials where practicable and possible.
  - 6.5.4. Consent shall be informed.
    - 6.5.4.1. Researchers shall provide full disclosure of all information necessary for making an informed decision to participate.
  - 6.5.5. Research participants are entitled to know how their data were used, and should be informed of how to access the results of the research following its conclusion.
  - 6.5.6. The principal investigator is responsible for ensuring that the consent process follows TCPS requirements and guidelines, and is responsible for the actions of any member of the research team involved in the consent process.
- 6.6. Fairness and Equity in Research Participation:
  - 6.6.1. Appropriate Inclusion: Unless there is valid reason, researchers shall not exclude individuals from the opportunity to participate in research on the basis of culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender, or age.
  - 6.6.2. Inappropriate Inclusion: Researchers have the ethical responsibility to ensure that individuals or groups whose circumstances make them vulnerable in the context of the research and those who live with relatively high levels of risk on a daily basis (vulnerable persons) will not have their vulnerability exacerbated through their inclusion as participants.
    - 6.6.2.1. Researchers should take measures to ensure that individuals or groups are not overburdened through repeated inclusion as research participants in different or repeated studies. Researchers should be aware that other institutions might be accessing the same individuals or groups as research subjects.
- 6.7. Benefit and Risk: All research involving human subjects must only be conducted following an analysis concluding that the benefits of conducting the research to participants and society outweighs the potential risk of harm to participants, society, and the College.
  - 6.7.1. The research must have a reasonable likelihood of promoting social good.
  - 6.7.2. All proposed research should be subject to scholarly merit review appropriate for the normal practices of the relevant disciplines.
    - 6.7.2.1. REB Scholarly Review: At the discretion of the REB, scholarly review can be conducted by the REB itself for low risk research.
    - 6.7.2.2. Peer Review: In cases where the proposed research is deemed to pose higher risk, or, where scholarly merit is not clear, the REB may request a review of merit to be conducted by an independent panel of disciplinary experts.

- 6.7.3. Certain activities may pose a risk of stigma or other harm to communities, even if only a portion of the community is participating in the research. The researcher is expected to engage the community and to minimize the risks of research to participants, the community as a whole, and to non-participant individual members of the community.
  - 6.7.3.1. Research involving communities should be designed to benefit the community as well as the individuals within the community. In cases of research involving vulnerable persons or communities, the principle of 'nothing about us without us' should be upheld, meaning participants and/or their representatives should be full partners in the research design, conduct, analysis, and dissemination.
  - 6.7.3.2. The TCPS 'Chapter 9' guidelines may be helpful in discussion of respectful relationships, collaboration, and engagement between researchers and participants from distinct communities, whether Indigenous or not.
- 6.7.4. In considering benefit and risk, the researcher should consider alternative strategies to reduce risk of harm, for example, the use of published data, or non-interactive/ intervening methodologies.
- 6.8. All research involving human subjects, other than the exceptions noted, will be subject to a Research Ethics Review conducted by the College's Research Ethics Board (REB). All REB reviews will be guided by both the TCPS and College Policy and Procedures.
  - 6.8.1. Researchers will submit proposals for REB review and approval prior to the start of recruitment of participants, data collection, access to data, or collection of human biological materials.
  - 6.8.2. Student Research: Any research conducted by students registered in credit or non-credit courses, where the research is part of the curriculum, will be subject to research ethics review.
    - 6.8.2.1. Student paid or volunteer work undertaken for an external institution, employer, or agency, and for which there is no connection to GPRC credit, non-credit, or research programs, and does not involve other GPRC student or staff participants, is exempt from GPRC research ethics review.
    - 6.8.2.2. Student work undertaken for a credit or non-credit course or research program at another institution, for which there is no involvement of GPRC student or staff participants, will be subject to the research ethics review process of that institution.
  - 6.8.3. Course-based Activities and Research Exempt from REB Review: Four types of investigations are exempt from review, provided they are 'minimal risk' to participants as defined in the TCPS.
    - 6.8.3.1. Investigations that rely exclusively on publicly-available information that is legally accessible to the public and appropriately protected by law; or, that is publicly accessible and there is no reasonable expectation of privacy, are exempt from REB review.
      - 6.8.3.1.1. The use of data from publicly accessible digital sites where there is a reasonable expectation of privacy, such as online groups with restricted membership, is subject to REB review.
    - 6.8.3.2. Investigations involving the observation of people in public places that do not involve any intervention staged by the researcher, or direct interaction with individuals or groups, and, the persons observed have no reasonable expectation of privacy, and, any dissemination of research results does not allow identification of specific individuals, is exempt from REB review.
    - 6.8.3.3. Investigations that rely exclusively on secondary use of anonymous information or anonymous human biological materials from a recognised ethical source, where the process of data linkage or recording or dissemination of results does not generate identifiable information, are exempt from REB review.

- 6.8.3.4. Non-Research Activities. Two sub-classes of investigation are considered 'non-research' within the TCPS definitions and are exempt from REB review.
  - 6.8.3.4.1. Quality assurance and improvement studies, program evaluation activities, and performance reviews; testing within normal educational requirements when used exclusively for assessment, management, or improvement purposes, are considered non-research.
  - 6.8.3.4.2. Creative activities, unless employed as research practice to obtain responses from participants, are considered non-research.
- 6.8.4. Course-Based Research Activities Conducted for Pedagogical Purposes: In-class research activities intended solely for pedagogical purposes require delegated REB review by either the Department Chair or the REB, provided they are of 'minimal risk' to the participants as defined in the TCPS.
  - 6.8.4.1 If these activities are used for the purposes of research for the researcher's own research program or are for theses or equivalent research projects, regular REB review may be required.
- 6.8.5. In addition to meeting GPRC Research Ethics Review policy, researchers must ensure that ethics review requirements prescribed by any jurisdiction within which the research may take place, within or outside of Canada, satisfy the standards and requirements of the relevant ethical review bodies.
- 6.8.6. In any case where doubt exists as to qualification for exemption, REB confirmation should be sought by the researcher or the Department Chair, as the case may be.
- 6.9. Research Involving the First Nations, Inuit, and Métis Peoples of Canada ('Chapter 9' Research): GPRC rigorously adheres to the aims of TCPS Chapter 9 specifying that research with Indigenous Peoples only be conducted from a foundation of respect, trust, and reciprocity.
  - 6.9.1. Any researcher seeking to undertake research with First Nations, Inuit, and Métis peoples must have read and understood TCPS Chapter 9.
  - 6.9.2. No researcher shall undertake research with any First Nations, Inuit, or Métis individuals, groups, or communities without having first established a respectful, mutual, and lasting relationship with the participant(s). Building these relationships may take considerable time and the relationships should be expected to extend past the completion of the research.
  - 6.9.3. Researchers must be aware that targeted participant cohorts in many urban, rural, and northern locations and settings may include First Nations, Inuit, or Métis individuals. The same principles of respect and reciprocity will apply in the conduct of research.
  - 6.9.4. In the conduct of any research involving First Nations, Inuit, or Métis individuals, groups, or communities, researchers are advised to seek guidance from recognized Indigenous elders, knowledge keepers, leaders, and other experts on the design, conduct, and output of their research.
  - 6.9.5. Aboriginal custom may restrict the observation, recording, or reporting of ceremonies or other cultural activities. Approval of appropriate community-recognized individuals must be sought.
- 6.10. Dissemination: Researchers shall disseminate, through publication or otherwise, the analysis of data and interpretation of research results including those that do not support the research hypotheses.
  - 6.10.1. The dissemination shall take place in a timely manner without undue restriction. Any undue prohibition, embargo, or limitation on the publication or dissemination of research findings is considered unethical.
  - 6.10.2. Equitable Distribution of Research Benefits: Provision of research findings to participants is as important as dissemination to the research community.
- 6.11. Reporting: Researchers undertaking continuing research extending beyond one year must submit an annual status report to the REB.
  - 6.11.1. Researchers must notify the REB of any substantive deviations to the research plan.

- 6.11.2. If the research fails to submit the report within deadlines established by the REB, the REB may decide to terminate approval for the research.
- 6.12. Education: GPRC will make educational resources relating to research ethics available to staff and student researchers, and to members of the REB.
- 6.13. Public considerations of ethical conduct are complex and continually evolving. GPRC recognizes the need for agility to respond to changing public requirements and will re-consider decision-making guidelines and will update policy and procedures as necessary.

## 7. Roles and Responsibilities

Stakeholder	Responsibilities
Academic Council	<ul style="list-style-type: none"> <li>• Approve and formally support the policy</li> </ul>
President	<ul style="list-style-type: none"> <li>• Responsible for ensuring the College's Research Ethics policies, processes, and protocols adhere to the <i>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans</i> and the <i>Agreement on the Administration of Agency Grants and Awards</i></li> <li>• Review and formally support the policy</li> </ul>
Vice-President, Academics and Research	<ul style="list-style-type: none"> <li>• Review and formally support the policy</li> </ul>
GPRC R&I	<ul style="list-style-type: none"> <li>• Draft, review, and formally support the policy</li> </ul>
Chair, REB	<ul style="list-style-type: none"> <li>• Ensure the conduct of the Research Ethics Board adheres to the policy</li> <li>• Periodically review and advise on the need for policy revision</li> </ul>
Researcher	<ul style="list-style-type: none"> <li>• At all times, conduct research involving humans in an ethical manner and adhere to the principles and requirements of this policy, the TCPS, and any other pertinent policies, contracts, or agreements</li> </ul>

## **8. Exceptions to the Policy**

- 8.1. This policy shall be in force as written, except in cases where it contravenes current or revised Tri-Council Policy, which shall take precedence.

## **9. Inquiries**

- 9.1. Director, Research & Innovation.

## **10. Amendments (Revision History)**

- 10.1. This policy succeeds “Research and Ethics Policy: Research Involving Humans” (2010).
- 10.2. Approved by Academic Council 14 May 2020.

## Appendix 1 – Terms of Reference and Operating Guidelines for the GPRC Research Ethics Board (“Terms of Reference”)

1. The GPRC Research Ethics Board (“REB”) Terms of Reference shall adhere to the requirements and guidelines of the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans 2014, as amended.
2. Reporting:
  - 2.1 The REB reports to the President or President’s delegate.
3. Appointment of Members:
  - 3.1 The President or President’s delegate appoints all members of the REB. The REB Chair will appoint non-voting ad hoc subject expert advisors, as needed.
  - 3.2 The Chair will be selected by consensus of all REB members. If consensus is not reached, the majority of a vote cast by all REB members will decide the Chair. In the event of a draw vote, the President or President’s delegate will appoint the Chair.
4. Term of Engagement:
  - 4.1 Each REB member will serve a term not exceeding three (3) years.
  - 4.2 Terms may be renewed successively one time.
5. Composition:
  - 5.1 The REB shall consist of a minimum of five (5) members of whom:
    - 5.1.1 at least two members possessing expertise in relevant research disciplines, fields, and methodologies covered by the REB;
    - 5.1.2 at least one member knowledgeable in ethics;
    - 5.1.3 at least one member knowledgeable in the relevant law;
    - 5.1.4 at least one community member who has no other affiliation with the institution.
6. Meetings:
  - 6.1 The REB shall meet at least three times per year.
  - 6.2 Meetings of the REB will be face-to-face where possible, or via videoconference, teleconference, or other such technologies if necessary.
  - 6.3 Quorum: A quorum for the transaction of any business at a meeting of the REB shall be not less than five (5) of the members.
  - 6.4 Decisions: Decisions are to be arrived at by consensus or, if consensus cannot be reached, by majority vote. In the event of a tie-vote, the Chair may either elect to cast a deciding vote, or alternatively, choose to table the decision pending further advice from ad hoc advisors.
  - 6.5 Conflict of Interest: A member shall exclude themselves from any deliberation or vote on a proposal for research for which they have a direct or indirect interest.
  - 6.6 Non-members shall be excluded from REB meetings at the time decisions are to be made by the members. Notwithstanding the foregoing, any person present solely to keep record of the meeting may remain in an REB meeting for this purpose.

7. Records and Reporting:
  - 7.1 Meeting Records: The Chair will provide minutes of all REB meetings and records of decisions to GPRC Research & Innovation.
  - 7.2 REB Membership Records: The College will maintain general records related to REB membership and qualifications of the members, including copies of curricula vitae, and evidence of research ethics training.
  - 7.3 Reporting: By the first day of December of each year, the REB will submit a report to Academic Council, copied to GPRC Research & Innovation. The report will describe the number of proposals reviewed in each category (delegated review, full review, continuing review), a generic description of ethical issues or concerns addressed in the past year, and, as necessary, any recommendations for changes to policy, procedures, or protocols.
  
8. Public Disclosure:
  - 8.1 The REB membership, dates of appointment, and the Terms of Reference shall be available to the public on the GPRC Research & Innovation website.
  
9. Review:
  - 9.1 The Terms of Reference shall be reviewed on an annual basis.

## Appendix 2 – Procedures for the Research Ethics Review (“Procedures”)

1. The GPRC Research Ethics Board (“REB”) Procedures shall adhere to the requirements and guidelines of the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans 2014, as amended.
2. Submission:
  - 2.1 Researchers shall submit proposals for REB review and approval of ethical acceptability prior to the start of participant recruitment, data access, or collection of human biological materials.
  - 2.2 Required application materials to be submitted to the REB shall be posted on the GPRC Research & Innovation website.
  - 2.3 Further materials to be submitted by the researcher may be requested by the REB, as necessary.
3. Determining the Level of Research Ethics Review:
  - 3.1 The level of REB review shall be determined by the level of foreseeable risks to participants and will be classified by the REB Chair as requiring one of the following:
    - 3.1.1 Full Board Review: Full Board Review shall be considered the default requirement for research involving humans.
    - 3.1.2 Delegated Review for minimal risk research: The REB delegates the ethics review to individual(s) selected from among the REB membership.
    - 3.1.3 Delegated Review for minimal risk course-based research activities for pedagogical purposes: The REB delegates the ethics review to non-REB member(s) or to individual(s) selected from among the REB membership.
4. REB Delegated Reviewers:
  - 4.1 For Delegated Review for minimal risk research, **two (2)** members of the REB shall be selected as delegated reviewers.
  - 4.2 For Delegated Review for minimal risk course-based research activities for pedagogical purposes, the applicable Department Chair shall be selected as delegated reviewer. In the event that the Department Chair is unable to fulfill the task, at their request, **one (1)** member of the REB shall be selected as delegated reviewer instead.
  - 4.3 Where delegated reviewers consider a decision to refuse ethics approval, the decision shall be referred to the full REB for review.
5. Decisions:
  - 5.1 Discussion: The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals and may invite researchers to attend a REB meeting to provide further information about their proposal. Researchers shall not be present when the REB is making its decision.
  - 5.2 Negative Decisions: When the full REB is considering a decision to refuse ethics approval, it shall provide the researcher with its reasons and give the researcher an opportunity to reply before a final decision is made.
  - 5.3 Communication: Decisions of the REB shall be communicated to the researcher in writing.
  - 5.4 The REB may set the term of approval and level of continuing research ethics review in any decision.

6. Continuing Research Ethics Review:
  - 6.1 At minimum, continuing research ethics review shall consist of an annual status report and an end-of-study report to be provided by the researcher.
  - 6.2 For projects lasting longer than one year, upon receipt of the annual status report, the REB will determine whether there has been a change in risk or research methodology which warrants re-assessment by the REB. If re-assessment is required, the level of review will be determined pursuant to paragraph 3 of this Appendix.
  - 6.3 The REB may impose additional continuing review requirements at any time.
7. Reports of Unanticipated Issues:
  - 7.1 Researchers have the responsibility to report to the REB any unanticipated issue or event that may increase the level of risk to participants or has other ethical implications that may affect participants' welfare that was not previously disclosed.
8. Requests for Changes to Approved Research:
  - 8.1 Researchers shall submit a request to the REB for review of any substantive changes to approved research.
9. Record Keeping:
  - 9.1 The REB shall prepare and maintain comprehensive records, including all documentation related to the projects submitted for review, attendance at REB meetings, and minutes reflecting REB decisions.
  - 9.2 Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for the decision.
10. Reconsideration of REB Decisions:
  - 10.1 Researchers have the right to request, and REBs have an obligation to provide, reconsideration of decisions affecting a research project.
11. Appeal of REB Decisions:
  - 11.1 If a disagreement between the researcher and the REB cannot be resolved through reconsideration, the researcher shall have the option of appealing the REB decision.
  - 11.2 The College shall establish or appoint an appeal committee, which committee shall not include any members of the REB.
  - 11.3 A Representative of the REB shall be given the opportunity to address the appeal committee, prior to any decisions being made on appeal.
12. Public Disclosure:
  - 12.1 The Procedures shall be available to the public on the GPRC Research & Innovation website.
13. Review:
  - 13.1 The Procedures shall be reviewed on an annual basis.