
TITLE: RESEARCH INVOLVING HUMANS

POLICY STATEMENT:

Red Deer College (RDC) is committed to maintaining the highest ethical standards in Research involving human Participants and to seeing that their welfare, rights, and dignity are protected. To this end, RDC endorses the current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and maintains a Research Ethics Board (REB) to ensure that all Research involving human Participants is carried out in compliance with the *Tri-Council Policy Statement (TCPS)*, applicable legislation, and RDC policy. Research that has an impact on Indigenous Peoples and communities is carried out in compliance with OCAP® (Ownership, Control, Access, Possession) Principles.

PURPOSE:

This policy is intended to ensure that Research involving human Participants complies with the highest ethical standards and practices as outlined in the TCPS, legislation, OCAP® Principles, and RDC policy. It outlines core ethical principles for the conduct of Research involving humans, establishes the mandate of RDC's REB, and delineates the responsibilities of researchers, the REB, and the broader College community.

SCOPE:

This policy applies to all Research involving human Participants that: a) is conducted by members of the RDC community; b) is undertaken under the auspices of, or in affiliation with, RDC; or c) uses College equipment, facilities, space, resources, employees, or students. Course-Based Student Research also falls within the scope of this policy.

PRINCIPLES:

1. Policies at RDC:
 - 1.1. Treat all persons fairly and respectfully.
 - 1.2. Are non-discriminatory and non-intrusive.
 - 1.3. Incorporate open, honest, and timely communication.
 - 1.4. Are made in a timely manner.
 - 1.5. Provide appropriate confidentiality and privacy.
 - 1.6. Provide appropriate access to the College and education.
 - 1.7. Ensure that all persons have access to informed support regarding policies, procedures, rights, and responsibilities.
 - 1.8. Operate with clear written expectations for conduct and handling of complaints.
 - 1.9. Meet all regulatory standards.
 - 1.10. Maintain and clearly state a high standard of instruction and administration in all areas of educational programs and services.
 - 1.11. Are communicated in alternate forms to those who require such accommodation.

2. The following principles apply specifically to this policy:
 - 2.1. RDC recognizes the significant potential benefits of Research for society and the need to respect academic freedom in order to maximize those benefits.
 - 2.2. With academic freedom comes the responsibility to ensure that Research involving humans meets high scientific and ethical standards that respect and protect Participants and their communities.
 - 2.3. As an institution with a particular focus on applied and community-based research, RDC is committed to the co-creation of knowledge and conducting research in genuine partnership with Participants and their communities.
 - 2.4. RDC adopts the core ethical principles of the TCPS as foundational elements of this policy (TCPS2, 2014, Chapter 1):
 - 2.4.1. Respect for Persons:
 - 2.4.1.1. Appreciating the intrinsic value of human beings.
 - 2.4.1.2. Respecting the autonomy of individuals to decide whether they will participate in Research, while protecting those with developing, impaired, or diminished autonomy.
 - 2.4.1.3. Securing the free, informed, and ongoing consent of Research Participants.
 - 2.4.1.4. Balancing individual and collective interests by being attentive to the specific context of the project and the communities to which the Participants belong.
 - 2.4.2. Concern for Welfare:
 - 2.4.2.1. Considering how Research impacts Participants' physical, mental, and spiritual health, as well as their physical, economic, social and cultural circumstances and the communities to which they belong.
 - 2.4.2.2. Safeguarding the privacy and confidentiality of Participants and ensuring that their information is secure.
 - 2.4.2.3. Carefully protecting the welfare of Participants and promoting that welfare in view of any foreseeable risks associated with the Research.
 - 2.4.2.4. Minimizing the risks associated with any given Research project.
 - 2.4.3. Justice:
 - 2.4.3.1. Treating people fairly and equitably, with equal respect and concern.
 - 2.4.3.2. Affording special attention to people or groups in vulnerable or marginalized circumstances.
 - 2.4.3.3. Establishing inclusive participation criteria, justified by the Research question.
 - 2.4.3.4. Ensuring that no particular segment of the population is burdened by the harms of Research or denied the benefits of the knowledge generated from it.

DEFINITIONS:

Course-based Student Research: assignments or projects involving research with human participants carried out by individual students, small groups, or as a single class project. Course-based research assignments vary in scope, but may include: students conducting interviews, administering standard tests, or distributing questionnaires outside the class to hone their interviewing or questionnaire-design skills; students conducting research projects where they pose research questions, gather data from human participants, and analyze the data for class presentations or reports; or other activities considered research within the discipline in which the course is taught.

OCAP® Principles: standing for ownership, control, access, and possession, OCAP® asserts that Indigenous Peoples have control over data collection processes in their communities, and that they own and control how this information can be used (First Nations Information Governance Centre, 2017).

Participant: an individual whose data, responses to interventions, stimuli, or questions by a researcher are relevant to answering a Research question (TCPS2 2014).

Research: an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation (TCPS2 2014).

GUIDELINES:

1. Research Ethics Board (TCPS2, 2014, Chapter 6)

- 1.1. The RDC Research Ethics Board (REB) is established by authority of the President of the College.
- 1.2. The REB operates at arm's length from the College in order to ensure independence in its decision making.
- 1.3. The membership, governance, and protocols governing the REB shall comply with the current TCPS and the Terms of Reference for RDC's REB.

2. REB Authority and Mandate

- 2.1. The REB has the authority to approve, reject, require modifications to, or terminate any proposed or ongoing Research involving human Participants. This includes the authority to continue to review all approved Research projects until they are fully concluded.
- 2.2. Research involving human Participants that shall undergo RDC REB review includes all Research that:
 - 2.2.1. is conducted within RDC,
 - 2.2.2. is conducted by College employees or students within the capacity of their employment or enrollment at RDC, or
 - 2.2.3. receives funding administered by the College.

3. Tri-Council Policy Statement Pre-eminence

- 3.1. All Research, ethics applications, reviews, and communications shall be conducted and evaluated in accordance with the articles of the current TCPS.

- 3.2. In the event of any conflict between the current TCPS and any provision of this policy and its supporting documents, the TCPS shall apply and take precedence.

4. Right to Appeal (TCPS2, 2014, Chapter 6)

- 4.1. Researchers have the right to request, and the REB has the obligation to provide, reconsideration of a decision.
- 4.2. In cases where the REB and the researcher cannot reach an agreement through discussion, the researcher has the right to appeal the decision of the REB.
- 4.3. RDC will at all times have an agreement with a REB at an accredited Canadian public post-secondary institution to act as its Appeal Board. As requested, the RDC REB will also serve as the Appeal Board for REBs at other accredited Canadian post-secondary institutions.

5. Conflicts of Interest

- 5.1. Actual, potential, or perceived conflicts of interest of researchers and individuals in the review process are made known and dealt with in accordance with RDC's Conflict of Interest and Conflict of Commitment Policy.

6. Indigenous Research Ethics (TCPS2, 2014, Chapter 9)

- 6.1. Where the Research is likely to affect the welfare of an Indigenous community, or communities, to which prospective Participants belong, researchers shall seek engagement with and approval from the relevant community. Situations where engagement and approval is required include, but are not limited to, the following:
 - 6.1.1. Research will be conducted on the lands of First Nations, Inuit, or Métis.
 - 6.1.2. Indigenous Participants will be recruited specifically because their Indigenous identity is an important consideration for the entire research study or a subgroup of the study.
 - 6.1.3. Participants will be asked to discuss an Indigenous community's cultural heritage, artifacts, traditional knowledge, or unique characteristics.
 - 6.1.4. The Research study plans to analyze how Participants' Indigenous identity, or membership in an Indigenous community, relates to the information or data collected.
 - 6.1.5. The Research study will refer to Indigenous communities, peoples, language, history, or culture in the final report where results are interpreted.
- 6.2. Prior to the commencement of the Research, researchers must address and resolve, to the satisfaction of all parties, any divergences between the application of the TCPS and this policy and the application of OCAP® or other community-based ethics codes.

PROCEDURE:

1. Responsibilities of the REB

- 1.1. The REB functions impartially, provides reasoned and appropriately documented opinions and decisions based on the application of the current TCPS and this policy, and communicates all approvals and refusals in writing.

- 1.2. The REB adheres to the principle of proportionate review: the degree of scrutiny of an application for ethics approval is apportioned according to the risk to the study participants.
- 1.3. The REB maintains a comprehensive [website](#) containing detailed information on application and appeal processes, all necessary forms, and answers to frequently asked questions.

2. Responsibilities of Researchers

- 2.1. Researchers familiarize themselves and comply with the requirements of this policy and, in particular, the current TCPS.
- 2.2. It is the researcher's responsibility to know, obtain, and respect any additional approvals needed.
- 2.3. It is the researcher's responsibility to develop appropriate protocols for gaining guardian consent, when applicable.
- 2.4. Researchers submit Research proposals for REB review and approval prior to the start of recruitment of Participants, access to data, or collection of human biological materials.
- 2.5. No Research activities are to begin until the applicant receives written approval from the REB.
- 2.6. Once a project has been approved, researchers:
 - 2.6.1. Monitor their Research to ensure that it is conducted in an ethical manner and according to the protocols approved by the REB.
 - 2.6.2. Report unanticipated issues or changes to the REB.
 - 2.6.3. Supervise all team members in the application of the Research procedures and ensure that they are properly qualified and versed in the conduct of ethical Research as outlined in the TCPS and related RDC policies.
 - 2.6.3.1. Student Research projects require particularly close, on-going supervision in order to ensure that proper protocols are respected.
 - 2.6.4. Submit an annual status report to the REB.

3. Responsibilities of the College

- 3.1. RDC provides sufficient financial and administrative resources to support the REB in the fulfillment of its duties.
- 3.2. The College accords the REB independence in its decision-making.
- 3.3. RDC ensures that researchers working with human Participants understand their responsibilities for the ethical conduct of their Research and receive appropriate training in the skills necessary for such conduct.

4. Research Requiring REB Approval (TCPS2, 2014, Chapter 2)

- 4.1. Research involving living human Participants.
- 4.2. Procedures that have a low degree of invasiveness (e.g. surveys, interviews, exercise or psychometric testing, examination of patient records), as well as more invasive procedures (e.g. blood sampling, administration of a substance).

- 4.3. Course-based Student Research also requires REB approval, but each student's project does not need to be reviewed by the REB. The assignment is reviewed and the instructor then acts as chief researcher for each student's project and ensures that they follow the approved research protocols.
- 4.4. Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials, and stem cells. This applies to materials derived from living and deceased individuals.
 - 4.4.1. RDC's REB does not currently have the capacity to review this type of Research, but it will ensure that projects of this type are referred to a REB at another accredited Canadian institution for the necessary review.

5. Examples of Research Excluded from REB Review

- 5.1. Research that relies exclusively on publicly available, legally accessible, and appropriately protected information.
- 5.2. Research involving the unobtrusive observation of unidentifiable people in public places.
- 5.3. Research that relies exclusively on secondary use of anonymous information or anonymous human biological materials.
- 5.4. Quality assurance and quality improvement studies, program evaluation activities, and performance reviews or testing within normal educational requirements when used exclusively for assessment, management, or improvement purposes.

6. Uncertainty About the Need for REB Review

- 6.1. The opinion of the REB shall be sought whenever there is doubt about the applicability of this policy to a particular Research project.

7. Modifications to Approved Research Projects (TCPS2, 2014, Chapter 6)

- 7.1. The principal investigator is responsible for notifying the REB immediately if any significant changes in the Research methodology and procedures are anticipated.
- 7.2. Modifications that substantively alter the Research require REB approval prior to implementation. The Research may not continue until approval is again granted.

8. Processes for Seeking Indigenous Research Partnerships

- 8.1. When proposing to conduct Research that involves First Nations, Inuit, or Métis Participants or communities, researchers are expected to demonstrate a prior, direct, personal, and continuing relationship with the people, the language, the knowledge, and the community.
- 8.2. Researchers are required to demonstrate an understanding of the OCAP® principles and reflect those principles in the Research design.
- 8.3. Researchers are required to create a Proposal for a Research Partnership (for presentation to the recognized leadership or representatives of the community) and a Research Agreement to be signed by all research partners. (See template for Research Proposal on REB [website](#)).
 - 8.3.1. It is the researcher's responsibility to demonstrate how the Research will directly benefit the community and meet its current needs, as identified by

the community itself. The Researcher must also show how the accrual of any future benefits will comply with OCAP® principles.

- 8.4. Throughout the entire process, researchers shall demonstrate how they have considered the views of all relevant sectors of a community, including individuals and subgroups that may not have a voice in the formal leadership.

9. Non-compliance

- 9.1. Non-compliance includes failure to obtain REB approval for Research involving humans, failure to comply with any conditions of an approval issued by the REB, or failure to obtain REB approval for substantive changes to an approved Research project.
- 9.2. RDC considers the improper treatment of human Participants in Research to be a serious offence, subject to severe penalties, including, but not limited to, the withdrawal of privileges to conduct Research involving humans or other disciplinary action.

Acknowledgements: *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2 2014), December 2014 and Blue Quills First Nations College Research Ethics Policy, 2009.

OFFICER RESPONSIBLE: President

POLICY CATEGORY: Non-Academic

RECOMMENDING AUTHORITY: Research Ethics Board

CONSULTATION FOR REVIEW: A representative group of Senior Administration and faculty members, staff and students.

POLICY REVIEW DATE: January 2023

EFFECTIVE DATE: January 1, 2018

REVISION HISTORY:

- July 1, 2006 (Ethical Conduct for Research Involving Human Participants)
- June 1, 2012
- January 1, 2018 (revised and renamed Research Involving Humans)

RELATED POLICIES:

- [Academic Freedom](#)
- [Conflicts of Interest and Mandatory Disclosure](#)
- [Harassment and Discrimination](#)
- [Information Access and Protection of Privacy](#)
- [Information and Technology Management](#)
- [Information and Technology Security](#)
- [Integrity in Research and Scholarship](#)
- [Intellectual Property](#)
- [Scholarly Activity](#)
- [Sexual Violence](#)

- [Student Misconduct: Academic and Non-Academic](#)
- [Student Rights and Responsibilities](#)

CONNECTION TO BOARD POLICIES:

All RDC policies support relevant Board of Governors policies.