COLLEGE OF THE ROCKIES

PROCEDURES

Title of Policy	Ethical Conduct for Research Involving Human Subjects
Policy Number	7.1.2
Effective Date	January 2023

GUIDELINES/STEPS

A. Establishment of a College Research Ethics Board (REB)

A. 1 The chair is responsible for ensuring quorum of the REB.

A. 2 The chair will make a call for membership once per year. Membership is on a volunteer basis.

A. 3 Members are required to have or be working towards their TCPS2: CORE certificate.

A. 4 The chair will refer to Chapter 6 of the TCPS 2 regarding governance of the REB.

A. 5 Meetings for the REB will be based on need as determined by the REB chair.

B. Proportionate Ethics Review Process

B. 1 No research involving human subjects is to commence, nor may funds for such purposes be released, until an ethics review, based on a proportionate ethics review process, has been completed. In extenuating circumstances, funds may be released in the development stage of research by the Manager, Applied Research and Innovation provided the study is in the process of ethics review.

B. 2 REB chair or designate determines when REB review is required. The REB chair will use the appendix, attached at the end of this procedures document, when considering the need for REB review. However, the decision is ultimately up to the REB chair whether a project requires review or not.

B. 3 Upon receipt of a complete REB application, the REB chair will determine if the project requires: 1) full board review or 2) delegated review. The REB chair will consider the review process based on the following aspects of the proposal:

- Rationale
- Protection of participant confidentiality
- Inclusion of vulnerable populations
- Whether research meets the criteria of minimal risk
- Research involves deception or alterations to elements of the full informed consent process (in which case, the project must be reviewed by the full board).

B. 4 Full board Review

B. 4. 1 In the case of a full board review the following will occur:

- The REB chair will call a meeting of the REB.
- The REB, with full quorum (see TCPS 2 article 6.4), will review the project for ethical acceptability according to policy 7.1.2 and guiding authorities on the ethical conduct of research (TCPS 2 and BC Freedom of Information and Protection of Privacy Act).
- The REB will determine the acceptability of the research project, including any provisos, by way of consensus. If consensus cannot be achieved the chair will determine a process for moving forward with the decision (TCPS 2 article 6.13).
- Once a decision is reached, the researcher will be notified by email via a formal letter of the decision including any provisos or concerns.
- Any outstanding provisos will need to be met and approved by the chair before the researcher can begin the project.
- If the project is rejected, the researcher can pursue an appeal process as outlined in Procedure E below.

B. 5 Delegated review

B. 5. 1 In the case of a delegated review the following will occur:

- The REB chair will designate a member of the REB (this can include the chair) to review the project and decide about the ethical acceptability of the project.
- The reviewer is responsible for communicating the decision to the researcher by email via a formal letter including any provisos or concerns.
- Delegated reviewers retain the prerogative to refer any research proposal or matter related to their review to the full board for review or consideration.
- The reviewer and researcher are responsible for ensuring the provisos are met before the researcher begins their project.
- All documentation of the review process will be provided to the REB chair for filing purposes.
- If the project is rejected, the researcher can pursue an appeal process as outlined in Procedure E below.

C. Multiple Jurisdictions Review Process

C. 1 In the case of a research project covering multiple jurisdictions, the researcher will need to do the following, *either*:

- Provide a complete and approved harmonized review through the Provincial Research Ethics Platform (PREP), or

- Provide a complete and approved REB application from the researcher's home institution, an REB application from the College of the Rockies, and any other relevant project documents (protocol, surveys, consents, recruitment materials, etc.). This will then go through the REB approval process outlined in Procedure B.

D. Types of REB Decisions

D. 1 **Approval**: A letter of approval is issued and research may begin (the REB may include minor requests for information or suggestions with this approval), or

D. 2 **Provisos**: Some concerns need to be addressed before approval can be given. The REB may authorize its chair to issue a letter of approval once the concerns have been satisfactorily addressed, or

D. 3 **Preliminary Approval**: Projects that require ethical review to obtain research funds with which to develop infrastructure for a research project involving humans or to develop a questionnaire or survey (etc.) may receive *preliminary approval* with the understanding that any part of the research dealing with humans cannot commence until the REB has formally approved a final research proposal.

D. 4 **Deferral**: The REB is unable to make a final decision (this may involve concerns about fundamental ethical issues regarding the research, including basic concerns about methodology). The decision is deferred for a later full board review at such time as the investigators submit the supplementary information or documentation as specified by the REB.

D. 5 **Rejection:** The study is not approved, and the investigators cannot proceed with the project as submitted. (See procedure E below for appeal process).

D. 6 Notwithstanding, the College has the right to refuse certain research to be conducted under the College's name, even though the REB has found it ethically acceptable.

E. Appeals Process

E. 1 In the case that an applicant requests a reconsideration of a decision made by the REB, the TCPS 2 will be followed, in that:

E. 1. 1 The REB will reconsider any decision negatively impacting a research project upon the researcher's request (TCPS Sec. 1, D5, Art. 1.10)

E. 1. 2 The REB will provide an explanation of the reasons for opinions or decisions and written grounds for the decision.

E. 1. 3 Researchers are provided the right to request reconsideration, "to be heard" by the REB and to rebut the stated grounds and opinions for decisions.

E. 1. 4 In the case that consensus cannot be reached the researcher will be notified of the appeals process. This process includes re-review and submission to a partner institution in which a memorandum of understanding will be created for this purpose.

E. 1. 5 The decision of the third-party institution will stand.

F. Ongoing Review

F. 1 The REB chair is responsible for ensuring that continuing review of ongoing research takes place to the chair's satisfaction.

F. 2 Annual Approval

- Each year on or before the anniversary of the project approval, the researcher will submit a yearly update using the Study Progress Report Form accessible through the REB website. The form is submitted to the REB chair for review. If there are concerns with the study at this point, the researcher will be notified that research activities cease until approval to continue is granted. The REB chair will request a review of the study using procedure B.4 above.

F. 3 Study Completion

- At the completion of the study, the researcher will submit the Study Completion Form accessible through the REB website. The form is submitted to the REB chair.

G. Storage of Research Data

G. 1 The REB and researcher are to follow institutional rules around research data management whenever possible.

G. 2 Data is to be stored on encrypted files and stored on a password protected device whenever possible.

G. 3 Files are to be kept by the researcher for a minimum five years following the completion of the research or termination of the research by the REB, or as required by law (whichever is greater). For student research, data collected through course-based research is to be destroyed by the student once the project and course are completed unless otherwise specified in the REB application as to how and why data will be stored after project completion (see 7.1.7 Ethical Review of Course-Based Research Involving Human Participants – Procedures, specifically section C.12).

G. 4 Files for the research project's REB application and ongoing REB documents will be stored by the REB chair on the REB SharePoint website. The data will be appropriately destroyed a minimum of five years after the completion of the study.

G. 5 The REB chair will track ongoing research projects at the College on the REB SharePoint website. This will include project title, principal researcher and contact information, and project status.

H. Approval Process when working with Indigenous communities

H. 1 The researcher(s) will require additional approval from Indigenous Research Ethics Boards or relevant agency before receiving permission to engage in the proposed research.

H. 2 Where a community has formally engaged with a researcher or research team through a designated representative, the terms and undertakings of both the researcher and community should be set out in a research agreement before participants are recruited.

H. 3 The research agreement should be put in writing and will be part of the REB application package for review.

H. 4 The REB membership will include an Indigenous expert when reviewing applications of research that involve working with Indigenous communities, as per the College's REB Terms of Reference and as per TCPS (2022) mandated REB composition that includes at least two experts on the research matter.

Appendix:

Is it Research or Quality Improvement (QI)?

	Research	Quality Improvement
What is the purpose of your project?	To generate new knowledge, generalizable to the wider population.	To improve internal processes, practices or systems.
What is my role?	As a researcher, you are objective and attempt to isolate and remove personal bias (or disclose it) to support scientific rigor.	As a Team Lead for QI, you are often a part of the system you are trying to improve. Your subjective experience may have assisted in defining the problem you are trying to solve.
What are you trying to accomplish?	To test a new practice, theory, intervention or device.	Bring about immediate positive change to a local practice setting.
How many participants will you include?	Typically, the research participants must reflect the total population that is being studied. (E.g. formal power analysis; interview saturation etc).	Will use a convenience sample of participants or data. Small sample, but large enough to observe change in specific measures.
How long do you anticipate your project will take?	It will take considerable time. Sometimes years to collect data, report results and publish findings.	It will be done quickly, through rapid cycles of iterative change.
What kind of tool/instrument will you use to collect data?	Valid & reliable instruments that measure concepts of interest.	Data collection tools that allow for easy recording of quick-cycle information.
How will you analyze data?	With inferential statistics, descriptive statistics or qualitative methodology that can compare & contrast qualitative data.	With descriptive statistics that demonstrate change/trends (e.g., control chart).
Will you be able to vary your protocol during the study?	Design is tightly controlled in order to limit the effect of confounding variables on the variables of interest – essential to determine causality.	Design is flexible and nimble. Design will often be adapted to respond to the data. Ability to adapt is central to the Plan Do Study Act (PDSA) cycle.
Who will most likely benefit from your project?	There may not be any benefit to the research participants in the study. The generated knowledge is meant to have future benefits to the research population.	If process changes are trialed and then adopted, those directly working in and/or receiving services from the system will benefit from the project.
Is Research ethics approval required?	Yes. Contact your facility Research Ethics Office if you are still uncertain if your project is research or QI.	No, but some institutions have QI ethics review processes.
What do you plan to do with your findings?	Findings will be applied as widely as possible to increase the body of scientific knowledge, both through publication and presentation.	Apply learning and change practice in my setting immediately. Share locally and consider trialing spread to other locations.

Adapted by Facility Engagement Oct 2018 from Fraser Health "*Differentiation of Research, Quality Improvement and Program Evaluation*", Department of Evaluation and Research Services, March, 4, 2014.