Appendix A

College of the Rockies Research Ethics Board Application for Ethics Approval

For Research Involving Humans

Instructions:

1. Download this application and complete it on your computer. Hand written applications will not be accepted.
2. Please refer to the appropriate college policies before completing this application.
3. Submit the original and one (1) copy of this completed, signed application with all attachments to: Chair, College of the Rockies Research Ethics Board, c/o Office of the Vice President, Room 245B.
4. If you require assistance, contact the COTR-REB Chair.
5. Incomplete applications cannot be processed and will be returned to the applicant.

A. Principal Investigator

There can be only one local Principal Investigator. For co-investigator and other research team members, provide their name(s) and contact information below in Section B, Other Investigator(s) & Research Team.

Last Name: First Name:

Department/Faculty: Email:

Phone: Fax:

Mailing Address:

Title/Position:

B. Project Information

Project Title:

Anticipated Start Date: Anticipated End Date:

Geographic location(s) of study:

Keywords: 1. 2. 3. 4.

For Research Ethics Board use	Application No.	
Research Ethics Board Chair Approval:	Date:	
Start Date:	Expiry date:	File closed:

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Other Investigator(s) and Research Team:

(*Include co-investigators, students, employees, volunteers, community organizations).*

Contact Name	Role in Research Project	Institutional Affiliation	Email or Phone

C. Agreement and Signatures

Principal Investigator affirms that:

- *I have read this application and it is complete and/ accurate.*
- *The research will be conducted in accordance with College of the Rockies regulations, policies and procedures governing the ethical conduct of research involving humans.*
- *The conduct of the research will not commence until ethics approval has been granted.*
- *The researcher(s) will seek further COTR-REB review for any changes to the approved research.*
- *Adequate supervision will be provided for students and/or staff.*

Principal Investigator

_____

Signature

_____

Print Name

_____

Date

Dean

Dean affirms that:

- *adequate research infrastructure is available for the conduct and completion of this research and that the researchers are qualified to conduct the research.*

_____

Signature

_____

Print Name

_____

Date

D. Project Funding

Have you applied for funding for this project? ☐ Yes ☐ No

Has notice of award been received? ☐ Yes ☐ No

If yes to either, please complete the following:

Source(s) of Project Funding	Project Title used in Funding Application(s)

Will this project receive funding from US Funders (*e.g. NIH*)? ☐ Yes ☐ No

If yes, provide further information:

E. Level of Risk

For the purposes of this Policy, "minimal risk" research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research (TCPS2, p. 23).

Based on this definition, do you believe your research qualifies as "minimal risk" research?

☐ Yes ☐ No

Explain your answer by referring to the level of risk stated in the TCPS2 definition above:

F. Scholarly Review

What type of scholarly review has this research project undergone?

☐ External Peer Review *(please attach a copy of external peer review)*

☐ Supervisory Committee or Supervisor

☐ None

☐ Other, please explain:

G. Other Approvals

Do you need to seek approval from other agencies, community groups, local governments, Aboriginal communities etc.?

☐ Yes ☐ No

(Please attach proof of having made a request for permission and any approval letter already received. Please forward further approvals upon receiving them.)

H. Description of Research Project

1. Purpose and Rationale of Research

Briefly describe in lay language suitable for review by non-scientific COTR-REB members:

(Please use 150 words or less.)

1a. The research purpose and objective(s) *(please attach a copy protocol)*

1b. The importance and anticipated contributions of the research

I. Recruitment

1. Recruitment and Selection of Subjects

1a. Inclusion Criteria: Briefly describe the target population(s) for recruitment. Ensure that all subject groups are identified (*e.g. group 1 - teachers, group 2 - administrators, group 3 – parents*).

1b. Why is this population of interest?

1c. What is the expected number of subjects? (For multi-site studies, include total number of subjects and the number of subjects that are expected to be recruited locally.)

1d: Exclusion criteria: Describe which subjects will be excluded from participation, and explain the criteria for their exclusion.

1e. Provide a detailed description of your exact recruitment process. Explain:

i) Who will recruit/contact subjects (*e.g. researcher, assistant, third party*)

ii) Describe any relationship between the investigator(s) and subjects(s) (*e.g. instructor-student, manager-employee*). Complete item 3 if there is a power over relationship.

iii) Describe how recruitment will be conducted (*e.g. in person, by telephone, letter, snowball sampling, word of mouth, advertisement*) and from what source(s) will the subjects be recruited. If applicable, include how contact information for subjects will be obtained.(Note that "cold-calling" is not normally permitted).

iv) Describe the steps in the recruitment process, including how subjects will be consenting.

v)

Recruitment Materials Checklist:

As applicable, attach all documents referenced in this section *(check those that are appended):*

☐ Script(s) – in-person, telephone, 3rd party, e-mail, etc.

☐ Invitation to participate

☐ Advertisement, Poster, Flyer

2. Power-Over

Are you or any of your co-researchers in any way in a position of authority or power over subjects? Examples of a "power-over" situation include teachers-students, therapists-clients, supervisors-employees and possibly researcher-relative or researcher-close friend.

☐ Yes ☐ No ☐ Varies

If *yes* or *varies*, describe below:

The nature of the relationship.

i) Why it is necessary to conduct research with participants over whom you have power.

ii) What safeguards (steps) will be taken to minimize undue influence, coercion or potential harm.

iii) How the dual-role relationship and the safeguards will be explained to potential participants.

J. Data Collection Methods

1. Data Collection

1a. Which of the following methods will be used to collect data? *(Check all that apply.)*

<table>
<tr><td colspan="2">☐ Interviewing participants:
☐ in-person
☐ by telephone
☐ using web-based technology (explain)
☐ Conducting group interviews or discussions (including focus groups)
☐ Other, describe

Attach draft review questions.</td></tr>
<tr><td>☐ Administering a questionnaire or survey:
☐ In person
☐ by telephone
☐ mail back
☐ email
☐ web-based
☐ Other, describe:</td><td>☐ Attach questionnaire or survey:
☐ standardized (one with established reliability and validity)
☐ non-standardized (one that is un-tested, adapted or open-ended)</td></tr>
<tr><td colspan="2">☐ Administering a computerized task (describe in 1b)</td></tr>
</table>

☐ **Observing participants**

{In 1b, describe who and what will be observed. Include where observations will take place.}

☐ **Recording of participants using**: ☐ audio ☐ video ☐ photos or slides	Will images be used in disseminating results? ☐ Yes *(If yes, please include release to use participant images in consent materials.)* ☐ No

Analyzing secondary data or secondary use of data (Refers to information/data that was originally gathered for a purpose other than the proposed research and is now being considered for use in research., *e.g. patient or school records, personal writings, lesson plans).*

☐ Secondary data involving anonymized information (Information/data is stripped of identifiers by another researcher or institution **before** being shared with the applicant; information/data is only anonymous if it cannot be re-linked to subjects*).*

☐ Secondary data with identifying information (Data contains names and other information that can be linked to individuals*, e.g., student report cards, employment records, meeting minutes, personal writings).*

In item 1b describe the source of the data, and explain whether and how consent was obtained from the individuals for use of their data.

☐ **Using human samples** (*e.g., saliva, urine, blood, hair*)

Ensure that you comply with Biosafety regulations regarding the storage and use of biological materials. Please consult the Conflict of Interest Policy B3005, Section 2.6.
☐ **Other**, specify:

1b. Provide a sequential description of the procedures/methods to be used in your research study. List all of the research instruments and assessment tools, and in an appendix provide copies of all instruments. If not yet available, provide drafts or sample items/questions. For multi-method or other complex research, use the following sections in ways best suited to explain your project.

1c. Where will participation take place? (Provide specific location, *e.g., Langara classroom, private residence, participant's workplace.*)

1d. How much time will be required of participants?

Data Collection Methods Checklist:

As applicable, attach all documents referenced in this section *(check those that are appended):*

☐ Standardized Instrument(s)

☐ Survey(s), Questionnaire(s)

☐ Interview and/or Focus Group Questions

☐ Observation Tools

K. Possible Inconveniences, Discomforts, Benefits, Risks and Harms to Participants

1. Benefits

Identify any potential or known benefits associated with participation and explain below.
Keep in mind that the anticipated benefits should outweigh any potential risks.

☐ To the participant ☐ To society ☐ To state of knowledge

3. Inconveniences

Identify and describe any known or potential inconveniences to participants:
Consider all potential inconveniences, including time devoted to the research.

3. **Estimate of Risks, including Discomforts, Physical, Psychological, Economic or Social Risks. (These risks can include such things as embarrassment, fatigue, stigmatization, and loss of status or privacy)**

3a. What are the risks?

3b. What will you do to try to minimize or prevent the risks?

3c. How will you respond if the risk of harm occurs? (*e.g. what is your plan?*)

L. Compensation and Remuneration

1. Compensation

1a: Is there any compensation for participating in the research *(e.g. re-imbursement for transportation, parking, childcare, etc.)*?

☐ Yes ☐ No

1b: Is there any remuneration (i.e. payment for time and effort) for participating in the research (e.g. gifts, honoraria, bonus points)

☐ Yes ☐ No

If yes, explain the nature of the remuneration and why you consider it to be necessary:

1c: Explain what will happen to compensation and/or remuneration if participants withdraw during or any time after data collection *(e.g. compensation and/or remuneration must be pro-rated, full compensation/remuneration will be given, etc.).*

M. Free and Informed Consent

The following questions address the competence of participants to give consent, the process used in your research to obtain consent, ongoing consent, and the participants' right to withdraw.

1. Participant's Capacity (Competence) to Provide Free and Informed Consent

Identify your prospective participants: *(Check all that apply.)*

Competent	**Non-Competent**
☐ Competent adults ☐ A vulnerable population (*e.g. Inmates, children)*	☐ Non-competent adults: ☐ Consent of legally authorized representative will be obtained ☐ Assent of the participant will be obtained
☐ Competent youth ☐ Youth 13 to 18 (incl.): consent of youth will be obtained, and parental agreement will be sought ☐ Youth 13 to 15 (incl.): consent of youth will be obtained, and parental agreement will be sought ☐ Youth 13 to 15 (incl.): consent of youth will be obtained, and parental agreement will *NOT* be sought ☐ Youth 16 to 18 (incl.): consent of youth will be obtained, and parental agreement will *NOT* be sought	☐ Non-competent youth 13-18 (incl.): ☐ Consent of parent/guardian will be obtained ☐ Assent of the youth will be obtained

☐ Competent children ☐ Children under 13: consent of child will be obtained, and parent/guardian agreement will be obtained ☐ Other, explain:	☐ Non-competent children under 13: ☐ Consent of parent/guardian ☐ Assent of the child will be obtained

2. Informed Consent

2a If you are you requesting a waiver or alteration (e.g. deception) to Informed Consent, describe how your research complies with TCPS2 Article 3.7 and 3.8.

2b Describe the exact steps you will follow in the process of explaining and obtaining informed consent.

4. Means of Obtaining Consent:
(*Check all that apply, attach copies of all consent materials.)*

☐ **Signed** consent. (*Attach consent script(s) and consent form(s).)*

☐ **Verbal** consent. (*Attach information letter(s). Explain below why written consent is not appropriate and how verbal consent will be documented*.)

☐ **Implied** consent (*e.g. anonymous, mail back or web-based survey. Attach information letter.)*

☐ **Other** means. Specify.

☐ Consent **will not be obtained**.

5. Ongoing Consent

Ongoing consent is required for research that occurs over multiple occasions and/or multiple research activities and or extended periods of time (i.e., more than one point of contact, including second interviews, review of transcripts, etc.)

5a. Will your research occur over multiple occasions or an extended period of time?

☐ Yes ☐ No

5b. If yes, describe how you will obtain ongoing consent:

6. Subject's Right to Withdraw

Free and informed consent requires that participants have the right to withdraw at any time without consequence or explanation.

Describe what participants will be told about their right to withdraw from the research at any time.

7. What will happen to the person's data if s/he withdraws part way through the study?

Free and Informed Consent Checklist:

As applicable, attach all documents referenced in this section *(check those that are appended):*

☐ Consent Form(s) – Include forms for all participant groups and data gathering methods

☐ Letter(s) of Information for Implied Consent

☐ Verbal Consent Script

N. Anonymity and Confidentiality

1. Anonymity

Anonymity means that no one, including the principal investigator, is able to associate responses or other data with individual participants.

1a. Will the participants be anonymous in the data gathering phase of research?

☐ Yes ☐ No

1b. Will the participants be anonymous in the dissemination of results *(e.g. use of video, photos)*?

☐ Yes ☐ No

2. Confidentiality

Confidentiality means the protection of the person's identity and the protection, access, control and security of his or her data and personal information during the recruitment, data collection, reporting of findings, dissemination of data (if relevant) and after the study is completed (e.g., storage, destruction).

2a. Will the confidentiality of the participants and their data be protected?

☐ Yes, completely (no exceptions, legal or otherwise)

☐ Yes, with limits (*Check relevant boxes below.)*

☐ Limits due to the nature of group activities *(e.g. focus groups)* the researcher can not guarantee confidentiality

☐ Limits due to context: The nature or size of the sample from which participants are drawn makes it possible to identify individual participants *(e.g. school principals in a small town)*

☐ Limits due to selection: The procedures for recruiting or selecting participants may compromise the confidentiality of participants *(e.g. participants are identified or referred to the study by a person outside the research team)*

☐ Limits due to legal requirements for reporting

☐ Other:

☐ No - If confidentiality will not be protected, explain why. If you are asking the participants to waive their right to confidentiality (you plan to identify them with their data), explain what steps will be taken to respect their privacy, if any.

2b. If confidentiality will be protected, describe the procedures to be used to protect the identity of participants and for preserving the confidentiality of their data *(e.g. assignment of unique study numbers to subjects, use of pseudonyms, changing identifying information and features, coding sheet, use of master lists linking subjects to coded research data forms, etc)*.

2c. If there are limits to confidentiality due to the methods *(e.g. group interview)*, sample size or legal requirements *(e.g. reporting child abuse)* so that you cannot

guarantee confidentiality, explain what the limits are and how you will disclose them to the participants:

O. Use and Disposal of Data

1. Use(s) of Data

1a. How will all the data be used to support the research objectives?

1b. Will your research data be analyzed, now or in future, by yourself for purposes other than this research project?

☐ Yes ☐ No ☐ Possibly

1c. If yes or possibly, how will you obtain consent for future data analysis from the participants *(e.g. request future use in current consent form)*?

1d. Will your research data be analyzed, now or in future, by other persons for purposes other than explained in this application?

☐ Yes ☐ No ☐ Possibly

1e. If yes or possibly, by whom and how will you obtain consent from the participants for future data analysis by other researchers *(e.g. request future use in current consent form)*?

2. Commercial Purposes

2a. Do you anticipate that this research will be used for a commercial purpose?

☐ Yes ☐ No

2b. If yes, explain how the data will be used for a commercial purpose:

3. Maintenance and Disposal of Data

Describe your plans for preserving, protecting and destroying all the types of data associated with the research (*e.g. paper records, audio or visual recordings, electronic recordings, coded data, master lists*) after the research is completed:

3a. means of storing data (*e.g., a locked filing cabinet, password protected computer files*):

3b. location of storing data:

3c. duration of data storage (if data will be kept indefinitely, explain):

3d. methods of destroying or archiving data:

4. Dissemination

How do you anticipate disseminating the research results? (*Check all that apply)*

☐ Directly to participants ☐ Thesis/Dissertation/Class presentation

☐ Presentations at scholarly meetings ☐ Published article, chapter or book

☐ Internet ☐ Media (*e.g. newspaper, radio, TV*)

☐ Other, explain:

P. Researchers

1. Conflict of Interest

1a. Are you or any of the research team members in a perceived, actual or potential conflict of interest in regard to this research project (*e.g. in relation to participants, partners in research, private interests in companies or other entities*)? (See Policy B3005: Conflict of Interest Related to Research.)

☐ Yes ☐ No

1b. If yes, please provide details of the conflict and how you will manage it:

2. Researcher(s) Qualifications

In light of your research methods, the nature of the research and the characteristics of the participants, what training or qualifications do you and/or your research team have?

3. Risk to Researcher(s)

3a. Does this research study pose any risks to the researchers, assistants and data collectors?

3b. If there are any risks, explain the nature of the risks, how they will be minimized, and how they will be responded to if they occur.

Q. Further or Special Questions

1. Multiple Site Research

1a. Does this project involve collection of data at multiple sites within Canada requiring the approval of other sites, bodies or organizations (*e.g., other ethics board(s)*)?

☐ Yes ☐ No

1b. If you responded Yes to 1a. above, list the sites, bodies or organizations:

2. International Research

2a. Will this study be conducted in a country other than Canada?

☐ Yes ☐ No

2b. If yes, describe how the laws, customs and regulations of the host country will be addressed:

3. Other Information

If there is anything else you would like to inform the LC-REB about this study, provide the details below:

Attachments*

*Ensure that all applicable attachments are included with all copies of your application.

Incomplete applications will not be processed and will be returned to the applicant.

As applicable, label and attach the following documents (check those that are appended):

Section I - Recruitment Materials:

☐ Script(s) – in-person, telephone, 3rd party, e-mail, etc.

☐ Invitation to participate

☐ Advertisement, Poster, Flyer

Section J - Data Collection Methods:

☐ Standardized Instrument(s)

☐ Survey(s), Questionnaire(s)

☐ Interview and/or Focus Group Questions

☐ Observation Tools

Section M - Free and Informed Consent:

☐ Consent Form(s) – Include forms for all participant groups and data gathering methods

☐ Letter(s) of Information (including for Implied Consent)

☐ Verbal Consent Script

Other documents

☐ Approval from external organizations (or proof of having made a request for permission)

☐ Permission to gain access to confidential documents or materials

☐ Copies of external peer reviews

☐ Copies of protocol

☐ Human Tissues form

☐ Other, please describe: