

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 one (1) hard copy of this completed, signed application with all attachments to:
Chair, College of the Rockies Research Ethics Board (room S113)
4. Submit one (1) electric copy via email to the COTR-REB Chair at dwiens@cotr.bc.ca
5. If you require assistance, contact the COTR-REB Chair at dwiens@cotr.bc.ca
6. 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:

Title/Position:

Phone:

Fax:

Mailing Address:

Email:

B

PROJECT INFORMATION

Project Title:

Anticipated Start Date:

Anticipated End Date:

Geographic location(s) of study:

Keywords:

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

*Adapted for use with permission from
the University of Victoria & the University of British Columbia and Langara College*

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
& SIGNATURESPRINCIPAL
INVESTIGATOR

I affirm 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.*

Signature

Print Name

Date

DEAN

I affirm 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 FUNDE (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
APPROVALSDO 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 & RATIONALE OF RESEARCH

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

A. THE RESEARCH PURPOSE AND OBJECTIVE(S)

please attach a copy protocol

Please use 150 words or less

B. THE IMPORTANCE AND ANTICIPATED CONTRIBUTIONS OF THE RESEARCH

Please use 150 words or less

I

RECRUITMENT

1. RECRUITMENT & SELECTION OF SUBJECTS**A. 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

B. WHY IS THIS POPULATION OF INTEREST?**C. 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

D. EXCLUSION CRITERIA

Describe which subjects will be excluded from participation and explain the criteria for their exclusion

E. PROVIDE A DETAILED DESCRIPTION OF YOUR EXACT RECRUITMENT PROCESS.**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 THE NEXT QUESTION (iii) **IF THERE IS A POWER OVER RELATIONSHIP**

iii) DESCRIBE HOW RECRUITMENT WILL BE CONDUCTED AND FROM WHAT SOURCE(S) WILL THE SUBJECTS BE RECRUITED

e.g. in person, by telephone, letter, snowball sampling, word of mouth, advertisement

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

A. 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.

DATA COLLECTION METHODS

3. DATA COLLECTION

A. WHICH OF THE FOLLOWING METHODS WILL BE USED TO COLLECT DATA?

Check all that apply

<input type="checkbox"/> Interviewing participants <input type="checkbox"/> in-person <input type="checkbox"/> by telephone <input type="checkbox"/> using web-based technology <i>explain</i> <div style="float: right; text-align: right;"> <input type="checkbox"/> Conducting group interviews or discussions including focus groups <input type="checkbox"/> Other, describe </div>	
NOTE: Attach draft review questions	
<input type="checkbox"/> Administering a questionnaire or survey <input type="checkbox"/> In person <input type="checkbox"/> email <input type="checkbox"/> telephone <input type="checkbox"/> web-based <input type="checkbox"/> Other, describe:	<input type="checkbox"/> Attach questionnaire or survey <input type="checkbox"/> standardized <i>one with established reliability & validity</i> <input type="checkbox"/> non-standardized <i>one that is un-tested, adapted or open-ended</i>
<input type="checkbox"/> Administering a computerized task <i>describe in 1b</i>	
<input type="checkbox"/> Observing participants <i>In 1b, describe who and what will be observed. Include where observations will take place.</i>	
<input type="checkbox"/> Recording of participants using <input type="checkbox"/> audio <input type="checkbox"/> video <input type="checkbox"/> photos or slides	Will images be used in disseminating results? <input type="checkbox"/> Yes <i>If yes, please include release to use participant images in consent materials</i> <input type="checkbox"/> No
Analyzing secondary data or secondary use of data <p>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. <i>e.g. patient or school records, personal writings, lesson plans</i></p> <input type="checkbox"/> SECONDARY DATA INVOLVING ANONYMIZED INFORMATION <i>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.</i>	
<input type="checkbox"/> SECONDARY DATA WITH IDENTIFYING INFORMATION <i>Data contains names and other information that can be linked to individuals, e.g., student report cards, employment records, meeting minutes, personal writings.</i>	
<i>In item 3B describe the source of the data and explain whether and how consent was obtained from the individuals for use of their data.</i>	
<input type="checkbox"/> Using human samples <i>e.g., saliva, urine, blood, hair</i> <i>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.</i>	
<input type="checkbox"/> Other specify:	

B. PROVIDE A SEQUENTIAL DESCRIPTION OF THE PROCEDURES/METHODS TO BE USED IN YOUR RESEARCH

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.

C. WHERE WILL PARTICIPATION TAKE PLACE?

Provide specific location e.g., classroom, private residence, participant's workplace.

D. 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*

- | | |
|---|--|
| <input type="checkbox"/> Standardized Instrument(s) | <input type="checkbox"/> Survey(s), Questionnaire(s) |
| <input type="checkbox"/> Interview and/or Focus Group Questions | <input type="checkbox"/> Observation Tools |

K

POSSIBLE INCONVENIENCES, DISCOMFORTS, RISKS, HARMS & BENEFITS 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

2. 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

A. WHAT ARE THE RISKS?

B. WHAT WILL YOU DO TO TRY TO MINIMIZE OR PREVENT THE RISKS?

C. HOW WILL YOU RESPOND IF THE RISK OF HARM OCCURS? *e.g. what is your plan?*

L COMPENSATION & REMUNERATION

1. COMPENSATION

A. IS THERE ANY COMPENSATION FOR PARTICIPATING IN THE RESEARCH?

e.g. reimbursement for transportation, parking, childcare, etc.

 Yes

 No

B. IS THERE ANY REMUNERATION FOR PARTICIPATING IN THE RESEARCH?

e.g. payment for time and effort, gifts, honoraria, bonus points

 Yes

 No

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

1B 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.

FREE & 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
<input type="checkbox"/> Competent adults <input type="checkbox"/> A vulnerable population <i>e.g. Inmates, children</i>	<input type="checkbox"/> Non-competent adults: <input type="checkbox"/> Consent of legally authorized representative will be obtained <input type="checkbox"/> Assent of the participant will be obtained
<input type="checkbox"/> Competent youth <input type="checkbox"/> Youth 13 to 18 (incl.): consent of youth will be obtained, and parental agreement will be sought <input type="checkbox"/> Youth 13 to 15 (incl.): consent of youth will be obtained, and parental agreement will be sought <input type="checkbox"/> Youth 13 to 15 (incl.): consent of youth will be obtained, and parental agreement will NOT be sought <input type="checkbox"/> Youth 16 to 18 (incl.): consent of youth will be obtained, and parental agreement will NOT be sought	<input type="checkbox"/> Non-competent youth 13-18 (incl.): <input type="checkbox"/> Consent of parent/guardian will be obtained <input type="checkbox"/> Assent of the youth will be obtained
<input type="checkbox"/> Competent children <input type="checkbox"/> Children under 13: consent of child will be obtained, and parent/guardian agreement will be obtained <input type="checkbox"/> Other, explain:	<input type="checkbox"/> Non-competent children under 13: <input type="checkbox"/> Consent of parent/guardian <input type="checkbox"/> Assent of the child will be obtained

2. INFORMED CONSENT

- A. 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.
- B. DESCRIBE THE EXACT STEPS YOU WILL FOLLOW IN THE PROCESS OF EXPLAINING AND OBTAINING INFORMED CONSENT.

3. MEANS OF OBTAINING CONSENT

Check all that apply, attach copies of all consent materials.

Signed consent - *Attach consent script(s) & 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

4. 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.*

A. WILL YOUR RESEARCH OCCUR OVER MULTIPLE OCCASIONS OR AN EXTENDED PERIOD OF TIME?

Yes

No

B. IF YES, DESCRIBE HOW YOU WILL OBTAIN ONGOING CONSENT:

5. 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.

6. 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 & CONFIDENTIALITY

1. ANONYMITY

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

A. WILL THE PARTICIPANTS BE ANONYMOUS IN THE DATA GATHERING PHASE OF RESEARCH?

Yes

No

B. 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

A. 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

the researcher can not guarantee confidentiality e.g. focus groups

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.

B. IF CONFIDENTIALITY WILL BE PROTECTED, DESCRIBE THE PROCEDURES TO BE USED TO PROTECT THE IDENTITY OF PARTICIPANTS & 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

- C. 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



USE & DISPOSAL OF DATA

1. USE(S) OF DATA

- A. HOW WILL ALL THE DATA BE USED TO SUPPORT THE RESEARCH OBJECTIVES?

- B. WILL YOUR RESEARCH DATA BE ANALYZED, NOW OR IN FUTURE, BY YOURSELF FOR PURPOSES OTHER THAN THIS RESEARCH PROJECT?

Yes

No

Possibly

- C. 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

- D. WILL YOUR RESEARCH DATA BE ANALYZED, NOW OR IN FUTURE, BY OTHER PERSONS FOR PURPOSES OTHER THAN EXPLAINED IN THIS APPLICATION?

Yes

No

Possibly

- E. 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

- A. DO YOU ANTICIPATE THAT THIS RESEARCH WILL BE USED FOR A COMMERCIAL PURPOSE?

Yes

No

- B. 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:

A. MEANS OF STORING DATA e.g., a locked filing cabinet, password protected computer files

B. LOCATION OF STORING DATA

C. DURATION OF DATA STORAGE if data will be kept indefinitely, explain

D. METHODS OF DESTROYING OR ARCHIVING DATA

4. Dissemination

HOW DO YOU ANTICIPATE DISSEMINATING THE RESEARCH RESULTS? *Check all that apply*

- | | |
|--|---|
| <input type="checkbox"/> Directly to participants | <input type="checkbox"/> Thesis/Dissertation/Class presentation |
| <input type="checkbox"/> Presentations at scholarly meetings | <input type="checkbox"/> Published article, chapter or book |
| <input type="checkbox"/> Internet | <input type="checkbox"/> Media e.g. newspaper, radio, TV |
| <input type="checkbox"/> Other, explain: | |

P

RESEARCHERS

1. CONFLICT OF INTEREST

A. 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

B. 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)

A. DOES THIS RESEARCH STUDY POSE ANY RISKS TO THE RESEARCHERS, ASSISTANTS & DATA COLLECTORS?

B. 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

A. 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

B. IF YOU RESPONDED YES TO 1A (ABOVE), LIST THE SITES, BODIES OR ORGANIZATIONS

2. INTERNATIONAL RESEARCH

A. WILL THIS STUDY BE CONDUCTED IN A COUNTRY OTHER THAN CANADA?

Yes

No

B. 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 COTR-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: