Application for Ethics Approval for Human Participant Research

FOR OFFICE USE ONLY

REB NUMBER	DATE RECEIVED
CHAIR'S SIGNATURE:	

Instructions:

1. Download this application and complete it on your computer. Hand written applications will not be accepted.
2. Refer to the appropriate College policies before completing this application: Ethics Approval - Camosun Innovates - Camosun College.
3. Please note that several questions have dropdown menus. Click on the "Select" dropbox to see the list of options.
4. Submit a copy of the completed, signed application with all attachments to REBChair@camosun.bc.ca.
5. If you need assistance, contact the REB office at 250 370 4940 or at REBChair@camosun.bc.ca.
6. Incomplete applications, including those without signatures, as well as unclear applications, will be returned to the applicant.

The information collected on this form will be used to assess your request for ethical review in compliance with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS 2) and will be shared with the Camosun College Research Ethics Board and its staff.

1 PRINCIPAL INVESTIGATOR

Surname	Given Name(s)
School (or Institution if not Camosun)	Department

2 STUDENT'S DIRECT SUPERVISOR (IF APPLICABLE)

Surname	Given Name(s)
School (or Institution if not Camosun)	Department

3 PRIMARY INFORMATION

3.1 Title of project (Title, PI name and institution, and funding will be listed in public report to Camosun's Board of Governors)	
3.2 If your research is funded, specify the source and administrator of the funds (Attach budget in Appendix A)	
3.3 Project Period (enter "approval date" if no delay between approval and start of research) **NOTE: Ethics approval is valid for one year. Projects extending beyond this date must submit an application for renewal form.**	
Start Collection	End Collection
3.4 Has this or a similar application been submitted to any other research ethics board? If yes, attach a copy of the proposal and approval if available. No	
Name of institution	Date of approval:

3.5	Identify any other institutions, agencies or community groups involved in your research. For each one, include a contact person and that person's contact information.

3.6 Consultation with Eyē? Sqā'lewen*:*

If you want to do research with Indigenous people, please read the Guide to Research With Indigenous Communities before going any further.

Please note that Indigenous knowledge can be held collectively by all members of a community, although some members may have particular responsibility for its transmission. (See Chapter 9 of the TCPS 2 for further information on research involving Indigenous people.) If your research is purposely or primarily directed at or with Indigenous people or it involves indigenous knowledge, land or artifacts, please contact Eyē? Sqâ'lewen at Indigenousresearch@Camosun.ca. Eyē? Sqâ'lewen will guide you in connecting with community members who can explore with you whether or not and how the community will collaborate in a research project.

Once you have an arrangement in place with the community, you may submit your application to the REB. Ensure that the community contacts have checked any research questions you wish to ask participants to ensure that the participants have the authority to answer them. You should be familiar with or becoming familiar with Indigenous research protocols. Consider looking at UNDRIP, TRC Calls to Action, AFN and OCAP research protocols.

I have consulted with Eyē? Sqâ'lewen:

- ☐ Yes
- ☐ No
- ☐ Not Applicable

4 CAMOSUN COLLEGE CONTACT (IF THE INVESTIGATOR IS EXTERNAL)

Surname	Given Name(s)
School, Institution or Organization	Department

5 CO-INVESTIGATORS, RESEARCH ASSISTANTS AND TRANSCRIBERS

Ensure that you provide each person's full name and department, institution, or organization.

5.1 Surname	Given Name(s)
School, Institution, or Organization	Department

5.2 Surname	Given Name(s)
School, Institution, or Organization	Department

5.3 Surname	Given Name(s)
School, Institution, or Organization	Department

6 SIGNATURES

Principal investigator	SIGNATURE	DATE
Student's Direct Supervisor (if applicable)	SIGNATURE	DATE
Administrative/Departmental Head or Faculty Dean	SIGNATURE	DATE

Signatures of applicants certify (a) that the information contained in this application is accurate; (b) that the conduct of the proposed research will not commence until Camosun College REB approval has been granted, and (c) that each signing party agrees to abide by the Tri-Council Policy for Ethical Conduct of Research Involving Human Subjects.

Signatures of Direct Supervisors certify that the supervisors have reviewed and approved the project for submission for REB review.

Signatures of the Administrative Head or Faculty Dean (as appropriate) confirm that the Principal Investigator has the qualifications, experience and facilities to carry out this research project.

7 SUMMARY OF PURPOSE AND OBJECTIVES OF PROJECT

8 SUMMARY OF METHODOLOGY AND PROCEDURES

If your study involves deception, you must also complete the page in this application titled 'Deception Form'.
ALL SUBMISSIONS MUST INCLUDE a copy of the research plan or protocol for the research to be conducted in Appendix B

9 DESCRIPTION OF POPULATION

9.1 How many participants will be invited in total?	9.2 How many in the control group (if applicable)?	9.3 Minimum number of participants required for the study?

9.4 Inclusion criteria. Who is being recruited, and what are the criteria for their selection? Please enter as an itemized list. (Note: TCPS2 encourages as broad an inclusion of participants as possible, including age, gender, and other characteristics.)

9.5 Exclusion criteria. Who will be excluded from the study and what are the criteria for their exclusion? (Note: TCPS2 discourages exclusion of participants by age, gender, or other arbitrary criteria. Please include justification for your exclusion of certain groups, including mature minors.)

9.6	How are the participants being recruited? If the initial contact is by letter, email, or posted recruitment notice, attach a copy in Appendix A. If your study involves telephone contact, you must also complete the 'Telephone Contact' form.
9.7	If a control group is involved, and their selection and/or recruitment differs from the above, provide details

10 PROJECT DETAILS

10.1	What are the project-related qualifications of all those conducting the study?
10.2	Where will the project be conducted (be as specific as possible)?
10.3	Will the research be carried out over multiple occasions? If so, you must describe your plan to get informed consent and evidence thereof on each occasion. No

10.4 How much time do you anticipate that each participant will dedicate to the project?

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

☐ YES / VARIES

☒ NO

If YES or VARIES, please describe below:

Ii) The nature of the relationship.
ii) Why it is necessary to conduct research with participants over whom you have power.
iii) What safeguards (steps) will be taken to minimize inducement, coercion or potential harm.
iv) How the dual-role relationship and the safeguards will be explained to potential participants.

10.6 Describe the risks and benefits of the proposed research, including any discomfort or incapacity the participants are likely to experience? What is your response plan if the risk or harm occurs?

Sensitive Participant Matter Reminder: Respondents should be forewarned of questions they may find private, stressful or sacred. It is not always practical to do so as part of the interview's front end. Warnings can be placed later in the interview and can take a naturalistic form as long as their content specifically refers to the sensitive matter. Indicate how you propose to deal with sensitive items, if any, in your interview.

If the project is an Indigenous research project, then an extra effort should be made to forewarn the community contacts and participants about questions they may find private, stressful or sacred. Ideally, this will have happened at the initial consultation with the community and Eyē? Sqâ'lewen, before this application form is filled out.

10.7 For research involving a double-blind code, what provisions are made to break the code when needed? Who has the code?

10.8 If monetary compensation is to be offered to the participants, provide details of amounts and payment schedules. Say whether or not the money will be given if the participant withdraws from the study. If a gift is to be offered, say what it is, what its approximate monetary value is, when it will be given and whether or not the gift will be given if the participant withdraws from the study.
Note: gifts should not be of a value sufficient to appear coercive.

If the gift is part of a cultural protocol, please note that protocols differ across communities. For instance, the researcher might give a gift to a graduate student from one Indigenous community at their first meeting. In a different Indigenous community, protocol might dictate that the gift be given at the end of the work.

11 DATA

Note that Indigenous leaders affirm that knowledge conveyed in research results does not belong to the researcher or a sponsoring institution. (See UNDRIP, TRC Calls to Action, AFN and OCAP.) Ensure that this point is not overlooked in the documentation of consent or of a research collaboration with an Indigenous community.

11.1 Who will have access to the data (please provide names)? If you are using an online survey, where will the data collected by the survey be stored? (See section 30.1 of the BC Freedom of Information and Protection of Privacy Act for guidance.)

11.2 How will the confidentiality of the data be maintained? If you need to link individual participants with their responses / data, if feasible, assign each participant a study ID prior to collecting data. Type each participant's name along with their unique study ID. Store this document separately from data documents. Dispose of the linking document as soon as it is no longer needed. State when it will be destroyed.

11.3 What are the plans for future use of the raw data beyond that described in this protocol? The TCPS 2, says that,

> [i]n general, research that relies exclusively on secondary use of anonymous information is exempt from REB review (Article 2.4). Research that relies exclusively on secondary use of non-identifiable information generally requires REB review. However, consent is not required for this type of research (Article 5.5B).

11.4 Will the data be destroyed? If not, where will it be stored? If it will be destroyed, say how, where, and when.

11.5 Will any data which identifies individuals be available to persons or agencies outside Camosun College? If yes, who and for what purpose will the data be released? Describe any steps you will take to ensure that data released will be maintained in the same level of confidentiality.

11.6 What are your plans for disseminating the results of your research to the participants?

11.7 Will your project use (please attach in Appendix C):

- ☐ Questionnaires (submit a copy)
- ☐ Interviews (submit a copy of questions)
- ☐ Observations (submit a brief description)
- ☐ Tests (submit a brief description)
- ☐ Other (please submit a brief description)

12 FUNDING INFORMATION

12.1 Agency / Source of Funds:	12.2 Funds Administered By:
☐ Internal ☐ External ☐ Self-funded	☒ Camosun College ☐ Other:

13 CONFLICT OF INTEREST DECLARATION

13.1 Are there any aspects of this proposal, such as financial gain or commercialization, which raise concern about a conflict of interest?

☐ Yes
☒ No

If yes, please explain:

14 INFORMED CONSENT

14.1 Who will consent and/or assent?

☐ Agency officials

☐ Authorized community members, knowledge keepers and/or cultural authorities

Only check this box if signed consent forms will not be used. Where there are good reasons for not documenting consent using a signed consent form, the alternative procedures used to seek and confirm consent must be described in detail in Appendix D. In some cases, oral consent, a handshake or the giving and receiving of gifts is comparable to a signed consent form. (See TCPS 2, Ch. 3, Article 3.12.)

☐ Other (See below)

Capacity refers to the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate. See TCPS 2, Ch. 3, Section C, for further information.

Article 3.10 of the TCPS2 states: "Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants' dissent will preclude their participation"

Identify your potential participants: (Check all that apply.)

Competent	**Non-Competent**
Competent adults	Non-competent adults:
☐ Competent adults, without qualification ☐ A protected or vulnerable population (*e.g., inmates, patients*)	☐ Consent of family/authorized representative will be obtained ☐ Assent of the participant will be obtained (note that assent of the participant is always required)
Competent youth aged 13 to 18: ☐ Consent of youth will be obtained and parental/guardian consent is required, due to institutional requirements (such as school districts) or due to the nature of the research (e.g., risks, etc.) ☐ Consent of youth will be obtained, parents/guardians will be informed (participant is always required) ☐ Consent of youth will be obtained, parents/guardians will NOT be informed ☐ Other, explain:	Non-competent youth: ☐ Consent of parent/guardian ☐ Assent of the youth will be obtained (note that assent of the participant is always required)
Competent children under 13 (*who are able to provide fully informed consent):* ☐ Consent of child will be obtained and consent of parent/ guardian will be obtained ☐ Other, explain:	Non-competent children *(young children and/or children with limited* ☐ Consent of parent/guardian ☐ Assent of the child will be obtained (note that assent of the participant is always required)

14.2 Will participants have any other problems giving informed consent on their own behalf? Consider physical or mental condition, age, language, and other barriers.

15 QUESTIONNAIRES TO BE COMPLETED BY PARTICIPANTS

Questionnaires should contain an introductory letter which includes an abbreviated version of the same information contained in a consent form with the addition of: (Please check each item in the following list before submission of this form to insure that your questionnaire contains all the required elements.)

☐ The statement that if the questionnaire is completed it will be assumed that consent has been given.
- (This is sufficient if the research is limited to questionnaires; any other procedures or interviews require a consent form signed by the participant.)

☐ An explanation of how to return the questionnaire (if printed).

☐ A copy of the explanatory letter as well as a copy of the questionnaire (for surveys circulated by mail).

OR

☐ Not applicable.

16 CONSENT FORM

Please check each item in the following list before submission of the consent form in Appendix D to ensure that the written consent form that you attach t**o** your application contains all necessary items.

☐ Title of the project.

☐ Identification of investigators, including a telephone number. Research for an applied project for program requirements or graduate thesis should be identified as such and the name and telephone number of the faculty advisor included.

☐ Brief but complete description of the purpose of the project and of all procedures to be carried out in which the participants are involved. The description should be written at a level of language and detail that someone with a Grade 8 education and no prior knowledge of your project could understand.

☐ A description of the risks and benefits of participation in the project.

☐ A description of the extent to which the participants will be anonymous and to which their confidentiality will be protected.

Distinguishing between Anonymity, Confidentiality and Non-identifiability
- Anonymous information: information that never had identifiers attached to it and the risk of identification of the participants is low (Section A, Chapter 5). In some cases, researchers cannot offer anonymity to participants, even if they plan to anonymize the data, because the researchers will still know who participated. Usually, secondary use of anonymous information is exempt from REB review (Article 2.4).
- Anonymized information: information that is stripped of identifiers, and no code is kept to allow future re-linkage. You cannot claim to offer anonymity to participants, even if you intend to anonymize the data by removing identifiers, if you will still know who the participants are.
- Non-identifiable information: information that does not identify an individual by itself or in combination with other available information. (Section A, Chapter 5). “Research that relies exclusively on secondary use of non-identifiable information generally requires REB review. However, consent is not required for this type of research” (Article 5.5B).
- Confidentiality – An ethical and/or legal responsibility of individuals or organizations to safeguard information entrusted to them, from unauthorized access, use, disclosure, modification, loss or theft (TCPS 2 Glossary).

☐ Include a description of how this will be accomplished, e.g., describe how records in the principal investigator’s possession will be coded, kept in a locked filing cabinet or on a password-protected computer hard drive. In the case of printed questionnaires, include a statement discouraging participants from including their names or other identifying information

☐ Statement of the total amount of time that will be required of a participant.

☐ Details of monetary compensation or gift, if any, to be offered to participants. Say whether or not participants will receive the money or gift if they withdraw part way through the research.

☐ An explanation of what will happen to a participants’ data if they withdraw part way through the research.

☐ An offer to answer any inquiries concerning the procedures to ensure that they are fully understood by the participant and to provide debriefing, if appropriate.

☐ A statement that if they have any concerns about their rights or treatment as research participants, they may contact the REB Chair, at 250-370-4940 or REBChair@Camosun.ca

☐ A statement of the participant's right to refuse to participate or withdraw at any time (e.g., "It is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign this consent form. After signing the consent form and after starting participation you are still free to leave the study at any time without any consequences and without giving any reason.").

☐ A statement that withdrawal or refusal to participate will not jeopardize further treatment, or influence class standing, as applicable.
Note: This statement must also appear on letters of initial contact. For research done in the schools, indicate what happens to children whose parents/guardians do not consent.

☐ A statement acknowledging that the participant has received a copy of the consent for the participant's own records.

☐ A statement that the participant is consenting to participate (by signing).

☐ A place for signature of participant consenting to participate in the research project, investigation, or study and a place for the date of the signature.

☐ Parental/guardian consent forms must contain a statement of choice providing an option for refusal to participate, e.g. "I consent / I do not consent to my child's participation in this study." Also, verbal assent must be obtained from the child, once the parent has consented.

17 ATTACHMENTS

17.1 Check items attached to this submission, if applicable. Incomplete submissions will not be reviewed.

☐ Letter of initial contact (Appendix A)
☐ Advertisement for volunteer participants (Appendix A)
☐ Recruiting letters from third parties (Appendix A)
☐ Research plan (Appendix B)
☐ Documentation of Indigenous community research or knowledge keeper collaboration (Appendix B)
☐ Questionnaires, tests, interviews, etc. (Appendix C)
☐ Participant consent form (For research taking place over multiple occasions, multiple consent forms are required) (Appendix D)
☐ Control group consent form if different from participant consent form (Appendix D)
☐ Parent / guardian consent form (Appendix D)
☐ Agency consent (Appendix D)
☐ Confidentiality agreement for research assistants, including transcribers (Appendix D)
☐ Deception form, including a copy of transcript of written or verbal debriefing (see below, attach as Appendix E)
☐ Telephone contact form (see below, attach as Appendix F)
☐ Other – Specify:

18 ADDITIONAL INFORMATION

Use this space to provide information which you think will be helpful to the REB

19 DECEPTION FORM: IF YOUR STUDY INVOLVES DECEPTION, COMPLETE ITEMS 1 TO 3. IF NOT, SKIP TO THE NEXT PAGE.

19.1 Deception undermines informed consent. Indicate (a) why you believe deception is necessary to achieve your research objectives; (b) whether you think the research can be done any other way; and (c) why you believe that the benefits of the research outweigh the cost to the participants.

19.2 Outline the anticipated impacts of your deception on the participants once they have learned of it.

19.3 Describe how you will debrief participants at the end of the study.

20 TELEPHONE CONTACT FORM: IF YOUR STUDY INVOLVES TELEPHONE CONTACT ONLY, COMPLETE ITEMS 1 AND 2.

20.1 Telephone contact makes it impossible for a signed record of consent to be kept. Indicate why you believe that such contact is necessary to achieve your research objectives:

20.2 Include a copy of the proposed 'front end' script of your telephone interview in Appendix F. Please check each item on the following list before submission of request for review to ensure that the front end covers as much as possible of the normal consent procedures:

- ☐ Identification of researcher. Basic purpose of project.
- ☐ Nature of questions to be asked, especially if sensitive questions are to be asked.
- ☐ Description of extent of anonymity and confidentiality.
- ☐ Indication of right of refusal to answer any question.
- ☐ An offer to answer any questions before proceeding. (see below, item 3)
- ☐ A specific inquiry about willingness to proceed.
- ☐ The means by which respondent was selected.
- ☐ An indication of the estimated time required for the interview.
- ☐ The means by which guarantees of anonymity and confidentiality will be achieved