**Application for Ethics Approval for Research Involving Humans**

*Be sure to answer all questions (enter “n/a” where not applicable — do not leave a blank).*

*Completed form and appendices to be sent by email to the Chair, Research Ethics Board* (reb@nic.bc.ca).

**Note:** All research at NIC that employs deception, involves Indigenous communities, focuses on Indigenous issues, and/or focuses on vulnerable populations must undergo a full REB review (i.e., not eligible for expedited review).

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# 1. Principal Investigator & Study Team

### 1.1 Principal Investigator: Click or tap here to enter text.

Primary Appointment: Click or tap here to enter text.

Department: Click or tap here to enter text.

Institution: Click or tap here to enter text.

Email: Click or tap here to enter text.

Secondary appointments

or affiliations, if applicable: Click or tap here to enter text.

### Supervisor / Instructor (only complete 1.2 if you are a student):

Name: Click or tap here to enter text.

Department: Click or tap here to enter text.

Institution: Click or tap here to enter text.

Email: Click or tap here to enter text.

Has your supervisor reviewed

your application and signed

the *Supervisor Approval Form?* [ ]  Yes [ ]  No

(attach as appendix)

### Co-Investigator: Click or tap here to enter text.

Primary Appointment: Click or tap here to enter text.

Department: Click or tap here to enter text.

Institution: Click or tap here to enter text.

Email: Click or tap here to enter text.

Secondary appointments

or affiliations, if applicable: Click or tap here to enter text.

### Additional Study Team Members *– attach appendix and include all information as required above*

**1.5 Tri Council Policy Statement (TCPS2) Tutorial**

Have all research team members completed the required [TCPS2 tutorial](http://tcps2core.ca/welcome)?

 [ ]  Yes [ ]  No

### If “No”, will all researchers involved in the study complete the TCPS2 tutorial before research begins?

 [ ]  Yes [ ]  No

### If not all research personnel will complete the TCPS2 tutorial before research begins, explain why.

###  Click or tap here to enter text.

# 2. Study Dates & Funding Information

**2.1 Project Period**

Please choose **ONE** of the following:

[ ]  You (or the team) plan to start collecting data immediately after obtaining ethics and any other required approvals (the start date of the Certificate of Ethics Approval will reflect the approval date)

**OR**

[ ]  You (or the team) plan to start data collection later (i.e., two or more months after approval date)

Proposed start date: Click or tap to enter a date.

Proposed end date: Click or tap to enter a date.

**2.2 Source of Funds**

**2.2.1 Types of Funds**

Please select the applicable box(es) below to indicate the type(s) of funding you are receiving to conduct this research.

[ ]  Grant-in-aid

[ ]  Grant

[ ]  For-Profit Sponsor (Industry or Pharmaceutical)

[ ]  Internal Funds (e.g., professional development allocation)

[ ]  No Funding

[ ]  Other (enter details below)

Please provide additional details on your funding source(s).

 Click or tap here to enter text.

**2.2.2** For industry-sponsored studies, provide organization name(s) and sponsor contact(s):

 Click or tap here to enter text.

# 3. Summary of Study and Recruitment

### 3.1 Project Title

Enter the title of this research study as it will appear on NIC REB documentation. Project title **must match** the title on all application documents.

 Click or tap here to enter text.

### 3.2 Project Summary

Provide a brief statement about the project written in simple language, including study purpose, research question(s), hypothesis (if one exists), study population, study location, and research method. Do not exceed 300 words.

 Click or tap here to enter text.

### 3.3 Research Level

### Identify the level of study related to the research (e.g., undergraduate, post-degree diploma, Master’s, doctoral, post-doctoral, trade), if applicable. Mark n/a if you are not a student.

###  Click or tap here to enter text.

**3.4 Potential Benefits**

Identify any potential or known benefits to participants, to the College, to society, and/or to the body of knowledge.

 Click or tap here to enter text.

### 3.5 Number of Participants

How many participants will take part in the study? (a range is acceptable)

 Click or tap here to enter text.

**3.6 Time to Participate**

Identify a realistic number of minutes or hours required of participants (a range is acceptable). If there will be multiple participation events, please indicate how many and how long each will last.

 Click or tap here to enter text.

### 3.7 Inclusion Criteria

Describe the participants being selected for this study and detail the criteria for their inclusion.

 Click or tap here to enter text.

### 3.8 Exclusion Criteria

Out of your pool of eligible participants, will any be excluded due to other characteristics? If no exclusion criteria are applicable, indicate n/a.

 Click or tap here to enter text.

### 3.9 Recruitment

**3.9.1** Who will contact prospective participants?

 Click or tap here to enter text.

**3.9.2** Describe the recruitment process (e.g., public posting, verbal invitation as part of an informal conversation or culturally specific event, third party recruitment, email, student/staff institutional homepage, etc.)?

 Click or tap here to enter text.

Attach all recruitment materials (e.g., letters of initial contact, posters, scripts, advertisements, etc.) as appendices. If recruitment will be conducted verbally (e.g., a verbal invitation as part of an informal conversation or culturally specific event), please describe above and, if necessary, explain more thoroughly in an appendix.

**3.9.3** How will prospective participants identify themselves to researchers OR be identified by researchers?

 Click or tap here to enter text.

**3.10 Reimbursement and Incentives**

Are there any expressions of gratitude or inducement for participating in the research? (E.g. gifts, money, social advantage, bonus points, etc.)

 [ ]  Yes [ ]  No

If “Yes”, please describe and explain why you consider it necessary.

 Click or tap here to enter text.

### 3.11 Use of Existing Records

If existing records (e.g., health records, course grade sheets or other records/databases) will be used to access information about potential participants, please describe how institutional and/or individual permission will be obtained to access this information, and to collect and use this information. Note that individual consent to participate is dealt with below in the section on consent.

 Click or tap here to enter text.

**3.12 Permission for Study**

Are there any organizations, groups, and/or other entity who may expect to provide permission before you undertake your study?

 [ ]  Yes [ ]  No

If “Yes”, please list the organization(s), group(s), and/or other entity or entities.

 Click or tap here to enter text.

If “Yes”, attach as an appendix a formal letter of permission for the study. If there are multiple responsible parties, attach letters as separate appendices. If a formal letter is not available or appropriate, explain how support has been or will be sought OR why you will not be seeking permission.

 Click or tap here to enter text.

### 3.13 Research Methods

Describe the research methods and methods for recording data that will be utilized.

 Click or tap here to enter text.

### 3.14 Summary of Procedures

Describe briefly in a step-by-step manner what the researcher will be doing with participants after they have been recruited and consented.

 Click or tap here to enter text.

# 4. Conflict of Interest

In the context of this application, conflict of interest (COI) does not generally include membership in and/or political or cultural alignment with individuals or groups that are part of one’s study. Conflicts of interest (COIs) in research are situations where someone’s personal interests (typically financial and/or career related) could compromise or could be perceived to compromise the collection and/or integrity of the data.

Conflicts of interest can arise naturally from an investigator’s engagement inside and outside the College, and the mere existence of a COI or the perception of a COI does not necessarily imply wrongdoing on anyone’s part. Nonetheless, real and perceived COI must be recognized, disclosed, and assessed. This question asks investigators to disclose COIs that may relate to the research study that is the subject of the REB application.

While not exhaustive, below are examples that may give rise to a COI. The principal investigator, co-investigator, and/or their partners/immediate family members:

* + - has/have a financial interest in or expects to receive a financial interest (e.g. ownership of stock, stock options, salary, consulting fees, retainers, honoraria, bonuses, gifts, speaker’s fees, advisory board remuneration) in or from any entity (a company, partnership, or non-profit corporation) whose interests could be affected by the outcome of this research;
		- provide/s services (e.g., free or fee-paying consulting, advisory, board membership, etc.) to any entity (a company partnership, or non-profit corporation) whose financial interests could be affected by the outcome of this research; and/or
		- has/have intellectual property rights or interests linked in any way to this study (e.g., patents, copyrights, royalties or other payments, etc.).

For further information, consult [*TCPS2 2022 – Researcher Conflict of Interest*](https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf#page=132)

**4.1** Are the researcher(s), members of the research team, and/or their partners or immediate family members in a situation in which they have or could be perceived to have a personal interest in connection with this study that conflicts with or could conflict with their obligations to the participants, their institution or, where applicable, to the sponsor? Or do the researcher(s)/team members/family members have any personal interest(s) that could compromise or reasonably be perceived to compromise the conduct of the research or the integrity of the data generated by the study?

[ ]  Yes [ ]  No

If “Yes”, please provide details.

 Click or tap here to enter text.

**4.2** Do any of the researchers conducting this study occupy more than one role with respect to potential participants (e.g., acting as both a researcher and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, manager, student, or employer, etc.) that may create a real, potential, or perceived conflict of interest that could affect the integrity of the research?

 [ ]  Yes [ ]  No

If “Yes”, please provide details.

 Click or tap here to enter text.

**4.3** Please advise how you propose to manage any actual, perceived, or potential COI outlined above in 4.1 or 4.2.

 Click or tap here to enter text.

# 5. Research Involving Indigenous Issues, Individuals, and/or Communities

The *TCPS2 2022* suggests that Indigenous community agreement may be required when research involves Indigenous people(s), the cultural knowledge and/or resources of Indigenous people(s), or where individuals speak on behalf of Indigenous people(s). Please read [*Chapter 9 of TCPS2*](https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf#page=154) and address any issues.

* + 1. Does this research focus on Indigenous people, communities, or organizations?

 [ ]  Yes [ ]  No

If yes, are you a member of the people, community, and/or organization you are studying?

 [ ]  Yes [ ]  No [ ]  Unsure [ ]  Prefer not to answer

If yes, please provide details.

 Click or tap here to enter text.

1. Will the research be conducted on Indigenous reserve(s), Métis settlement(s), or lands governed under a self-government agreement or an Inuit or First Nations land claims agreement?

 [ ]  Yes [ ]  No

If yes, please provide details

 Click or tap here to enter text.

**5.3** Do any of the criteria for participation include membership in an Indigenous community, group of communities, or organization, including urban Indigenous populations?

 [ ]  Yes [ ]  No

If yes, please provide details

 Click or tap here to enter text.

**5.4** Does the research seek input from participants regarding an Indigenous community’s cultural heritage, artifacts, traditional knowledge, or unique characteristics?

 [ ]  Yes [ ]  No

**5.5** Will Indigenous identity or membership in an Indigenous community be used as a variable for the purposes of analysis?

 [ ]  Yes [ ]  No

**5.6** Will the results of the research refer to Indigenous communities, peoples, language, history or culture?

 [ ]  Yes [ ]  No

If you answered “Yes” to any of 5.4, 5.5, or 5.6, please provide details:

 Click or tap here to enter text.

###  5.7 Community Engagement

 If you answered “Yes” to any of 5.1 - 5.6 above, have you initiated or do you intend to initiate an engagement process with the Indigenous group, community or communities for this study?

 [ ]  Yes [ ]  No

**5.7.1** If you answered "Yes" to question 5.7, describe the process that you have followed or will follow with respect to community engagement. Include the role or position of those consulted, including their names, if appropriate.

 Click or tap here to enter text.

Attach any documentation of consultations (i.e. formal research agreement, letter of approval, email communications, etc.) as an appendix.

### 5.7.2 If you answered "No" to question 5.7, briefly describe why community engagement will not be sought and how you can conduct a study that respects Indigenous communities and participants in the absence of community engagement.

 Click or tap here to enter text.

**5.8 Research Agreement**

Is a research agreement confirming mutual expectations and commitments between researchers and Indigenous communities in place?

 [ ]  Yes [ ]  No

If “No”, justify your decision not to seek a research agreement ***or***, if you are currently developing an agreement, describe where you are in this process.

 Click or tap here to enter text.

# 6. Risk & Vulnerability

**6.1** Does the study involve any of the following risks?

**6.1.1** A participant may feel demeaned or embarrassed during their participation in the research.

 [ ]  Very Unlikely [ ]  Possibly [ ]  Likely

**6.1.2** A participant may experience fatigue or stress due to the research.

 [ ]  Very Unlikely [ ]  Possibly [ ]  Likely

**6.1.3** A participant may experience other emotional or psychological discomfort as a consequence of participation.

 [ ]  Very Unlikely [ ]  Possibly [ ]  Likely

**6.1.4** A participant may experience social risk, possible stigmatization, loss of status, privacy, membership, or reputation.

 [ ]  Very Unlikely [ ]  Possibly [ ]  Likely

**6.1.5** A participant may experience physical risk?

 [ ]  Very Unlikely [ ]  Possibly [ ]  Likely

**6.1.6** A participant may experience a legal or economic risk (e.g. job security, job loss)?

 [ ]  Very Unlikely [ ]  Possibly [ ]  Likely

**6.1.7** Will some of the participants lack knowledge about the research methods used in the study (e.g., not understand what is being asked of them, not understand their rights as participants)?

 [ ]  Very Unlikely [ ]  Possibly [ ]  Likely

**6.1.8** If you indicated in any of 1 - 7 above that risks are possible or likely, please explain what the risks are.

 Click or tap here to enter text.

**6.1.9** Describe what steps will be taken to minimize risks (e.g., participants can opt out of answering questions, support services will be distributed to participants).

 Click or tap here to enter text.

**6.1.10** Describe how you will respond if a harm related to these risks occurs.

 Click or tap here to enter text.

**6.2** According to the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* (*see* [*TCPS2 2022 - Participants' Vulnerability and Research*](https://mynic.nic.bc.ca/research_ethics_board/Documents/TCPS2%20-%202018%20Subsections/TCPS2%20-%20Particpants%27%20Vulnerability%20and%20Research.pdf)):

*The core principles of Respect for Persons, Concern for Welfare, and Justice entail special ethical obligations toward individuals or groups whose circumstances may lead to their vulnerability in the context of a specific research project and limit their ability to fully safeguard their own interests. (p. 73)*

Vulnerability is frequently linked with limited capacity for decision-making; vulnerability can also emerge when an individual or group has been or is marginalized in the context of rights and opportunities.

Note that the TCPS2 2022 does not suggest that individuals or groups deemed vulnerable or potentially vulnerable be excluded from research. Further, individuals within a vulnerable community should not be assumed to be vulnerable. The Policy emphasizes that

*[p]articipation should be based on inclusion or exclusion criteria that are justified by the research question. Researchers and REBs should recognize and address changes in a participant’s circumstances that may create, heighten, or attenuate their vulnerability, and provide special protections or consideration. (p. 73)*

**6.2.1** Is the group or are any of the individuals in your study vulnerable or potentially vulnerable within the context of your research?

 [ ]  Yes [ ]  No

If “No”, skip to 6.3.

If “Yes”, please provide details of the vulnerability or vulnerabilities.

 Click or tap here to enter text.

How will you address the vulnerability or vulnerabilities?

 Click or tap here to enter text.

**Note: 6.2.2 through 6.2.5 deal with consultation and may have been answered in Section 5 (Research Involving Indigenous Issues, Individuals, and/or Communities) or in questions 3.11, 3.12, or 6.2.1. If this is the case, indicate “Answered above” in the text box underneath the respective question(s).**

**6.2.2** Is there an organization or are there multiple organizations that represent(s) or advocate(s) for the interests of the participant(s) in your study?

 [ ]  Yes [ ]  No

If “Yes”, please provide details. If “No”, why not?

 Click or tap here to enter text.

**6.2.3** If an organization or organizations exist(s), have you consulted with representatives?

 [ ]  Yes [ ]  No [ ]  Not Applicable

Please provide details.

 Click or tap here to enter text.

**6.2.4** Have you sought formal approval from the group or community involved in the study?

 [ ]  Yes [ ]  No

Attach any documentation of consultations (i.e. formal research agreement, letter of approval, email communications, etc.) as an appendix. If “No”, justify your decision not to seek a research agreement OR, if you are currently developing an agreement and/or consulting with community members, describe where you are in this process.

 Click or tap here to enter text.

**6.2.5** If no organizations exist, are there community members who take a leadership role and are being consulted or could be consulted?

 [ ]  Yes [ ]  No

Please provide details.

 Click or tap here to enter text.

**6.3** How will you monitor vulnerability, and what will you do if the vulnerability of a participant or participants changes during the study?

 Click or tap here to enter text.

**6.4** 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 2022, p.25](https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf%22%20%5Cl%20%22page%3D33)).

Using the TCPS definition of “minimal risk” cited above, 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 TCPS definition:

 Click or tap here to enter text.

# 7. Consent Process

**7.1 Obtaining Consent**

**7.1.1** Describe the steps or procedures to be followed for obtaining the informed consent of the participants for each distinct component of your study (e.g., for interviews, questionnaires, focus groups, participant observation, etc.).

 Click or tap here to enter text.

**7.1.2** Describe what will be told to participants about their right to withdraw at any time?

 Click or tap here to enter text.

**7.1.3** If compensation or other inducements are involved, explain what participants will be told about compensation, including what compensation they will or won’t receive if they withdraw.

 Click or tap here to enter text.

**7.2 Capacity to Consent**

**7.2.1** Will every participant have the capacity to give fully informed consent on his/her own?

 [ ]  Yes [ ]  No

If “No”, provide details on the nature of the incapacity (for instance, young age, mental or physical condition).

 Click or tap here to enter text.

**7.2.2** If a participant does not have the capacity to give fully informed consent, who will consent on his/her behalf?

 Click or tap here to enter text.

Ensure the relevant consent form (parent/caregiver, substitute decision maker, legally authorized representative) is attached as an appendix.

**7.2.3** If a participant does not have the capacity to give fully informed consent, will he/she be able to give assent to participate?

 [ ]  Yes [ ]  No

If “Yes”, explain how assent will be sought (attach a copy of the assent form as an appendix).

 Click or tap here to enter text.

### 7.3 Ongoing Consent

### Describe how you will gain ongoing consent if your research will occur over multiple occasions or for an extended period of time. Please include “n/a” if not applicable.

 Click or tap here to enter text.

**7.4 Provisions for Consent** (e.g., special assistance, Braille, translations/translator)

 Click or tap here to enter text.

**7.5 Restrictions on Disclosure to Participants**

Describe any restrictions regarding the disclosure of information to research subjects (during or at the end of the study), including those related to the publication of results.

 Click or tap here to enter text.

# 8. Security of Data and Confidentiality of Personal Information

### 8.1 Security of Data Storage during the Course of the Study

### Provide details on how and where data in various formats will be stored. In general, the REB is looking for hardcopies to be stored in locked filing cabinets in locked offices and digital files to be password-protected and/or encrypted on password-protected computers. Include whether or not your employer or others at your organization have access to the data and, if so, what you will do to mitigate this situation (e.g., aliases).

 Click or tap here to enter text.

**8.2 Access to Data**

Provide details on who will have access to the data. If any of the researchers are in a position of power over some or all participants (e.g., instructor and student, manager and employee), describe how this will be dealt with in relation to access.

 Click or tap here to enter text.

**8.3 Protection of Personal Information**

Will any identifying information be collected?

 [ ]  Yes [ ]  No

If “Yes”, will identifying information be included in the study? If not, how will the data be anonymized before inclusion?

 Click or tap here to enter text.

**8.4 Electronic Transfer of Data or Other Information**

Will any data or other information that identifies a participant be transferred electronically via the Internet (including email) during or after the study?

 [ ]  Yes [ ]  No

If “Yes”, describe in detail what information will be transferred over the Internet, to whom, and how the data will be transferred and what safeguards will be used to protect the identity of participants and the privacy of their data. Attach the data transfer agreement (if applicable) as an appendix.

If you are an NIC student, faculty, or staff and need to share digital data or files over the Internet, please contact the REB to discuss secure, NIC-supported file-transferring services.

### 8.5 Retention and Destruction of Data

### Describe your plans for destroying data after the research is completed. Typically, data is stored for five years after a study is completed.

 Click or tap here to enter text.

**8.6 Future Use of Data**

Will your research data be analyzed, now or in the future, by yourself or others for purposes other than this research project? If yes or possibly, by whom and how will you obtain consent from the participants for future data analysis by other researchers?

 Click or tap here to enter text.

### 8.7 Creation of a Research Database or Registry

Does this study involve the creation of or contribution to a research database or registry with a local custodian for future unspecified research?

 [ ]  Yes [ ]  No

If “Yes”, please identify the name of the registry, the name of the custodian, and a contact person to be in control of the data. Attach a registry agreement as an appendix (if applicable).

 Click or tap here to enter text.

**8.8 Feedback to Participants**

How and when will you contact participants to provide information on study outcomes and dissemination (e.g., publications, presentations)?

 Click or tap here to enter text.

# Peer Review

If this research proposal has received any formal independent scientific/methodological peer-review, please include the names of committees or individuals involved in the review. State whether the peer-review process is ongoing or completed.

**9.1** External peer-review details:

 Click or tap here to enter text.

**9.2** Internal (e.g., institution or hospital) peer-review details:

 Click or tap here to enter text.

# 10. External Approvals & Relationship to Previous or Ongoing Ethics Applications

### If your research project is multijurisdictional, please see 10.1. If your project is distinct but related to or very similar to an application or applications submitted to other institutions – previously or currently – please see section 10.3.

### 10.1 If your research project is multijurisdictional, please enter the name(s) of the institution(s).

 Click or tap here to enter text.

### 10.2 Have you sought ethics approval from other institutions?

 [ ]  Yes [ ]  No

**10.2.1** If “Yes”, did you receive approval?

 [ ]  Yes [ ]  No

If “Yes”, please attach the approval letter(s), or attach once received.

**10.2.2** If a request for approval has **not been** submitted, provide the reasons.

 Click or tap here to enter text.

**10.3** If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the institution or health authority name and associated research ethics board study number of that proposal.

 Institution Name(s): Click or tap here to enter text.

 REB study number(s): Click or tap here to enter text.

**10.3.1** If applicable, please describe the relationship between this proposal and the previously/simultaneously submitted proposal(s) above.

 Click or tap here to enter text.

**10.4** Have you received any information or are you aware of any rejection of this study by any Research Ethics Board?

 [ ]  Yes [ ]  No

If “Yes”, please provide known details and attach any available relevant documentation.

 Click or tap here to enter text.

# 11. Documentation

**11.1** Please attach all supporting documents required for conducting the study. The Research Ethics Board cannot change document names or dates. Use clear file names that distinguish appendices from one another and use running headers or similar to clearly label the document itself.

### INSTRUCTIONS

Submit final versions only.

Typical appendices:

* Advertisement to recruit participants
* Script for recruiters
* Informed consent form(s)
* Instrument(s) (survey, interview questions, etc.)
* Agreement(s) with a community or communities, funding organization(s), government(s), and/or educational institution(s).

### 11.2 Submitting revised documents

If you are asked to revise and resubmit a document, ensure that you enable “Track Changes” (or similar) before you begin revisions so your edits are easily identified.

You must indicate if you have added a new document and explain its purpose.

# 12. Clarifications and Support

For clarification on minimal risk or other elements of this application, or for support with the application process, please contact reb@nic.bc.ca.