



Research Ethics Board

REVIEWER COMMENTS AND RECOMMENDATIONS

Applicant and Study Summary Information

Faculty/Principal Investigator:	Click here to enter text.
Principal Applicant/Student Investigator:	Click here to enter text.
Other Team members:	Click here to enter text.
Study Title:	Click here to enter text.
REB Number:	Click here to enter text.

Describe your concerns or collegial comments below:

Major Concerns:	
Minor Concerns:	
Collegial Comments/Suggestions:	

Reviewer's Recommendation:

- ☐ Ethics Approval (without hesitation)
- ☐ Conditional Ethics Approval subject to clarification and revisions of minor concerns
- ☐ Defer Ethics Clearance subject to clarification of major concerns
- ☐ Recommend Not Cleared

Reviewer:

Date of Review:

Reviewer Checklist

Please complete this checklist as you review the protocol. Please indicate whether the researcher has given adequate consideration and safeguards to the following areas of concern.

*NOTE: CR = Clarification Required; N/A = Not Applicable

APPLICANT AND PROJECT DETAILS				
	Yes	No	CR	NA
TCPs2 was Completed by all team members and certificates provided				
Do the individuals have the experience and qualifications to conduct this type of research?				
Partners described and their role clear				
Other REB approvals?				
Scholarly Merit Review				
Comments: Click here to enter text.				
RESEARCH PROJECT DESCRIPTION				
Purpose and Background:	Yes	No	CR	NA
Is the research question clearly stated?				
Main objectives/goals of study are clear				
Comments: Click here to enter text.				
Social and Scientific Value:	Yes	No	CR	NA
Will the research generate knowledge that could reasonably benefit society or well-being?				
Comments: Click here to enter text.				
Methodology/Procedures:	Yes	No	CR	NA
Is the methodology/design adequate to answer the research question?				
Is the sample size sufficient to answer the research question?				
Study setting and timeframe are clear.				
Is the data analysis adequately described?				
Is the data analysis appropriate?				
Comments: Click here to enter text.				
RECRUITMENT OF PARTICIPANTS AND PARTICIPATION				
Inclusion / Exclusion Criteria	Yes	No	CR	NA
Target population, sample and recruitment methods are clearly described				
Is the plan for recruitment described				
Are criteria for inclusion/exclusion clearly stated and equitable (i.e. no exclusions on basis of race, age, gender, etc)?				
If exclusion of any population group is their appropriate justification				

Does the nature of the research create vulnerability for any of the groups listed below? Check all that apply: <input type="checkbox"/> People with relevant health issues <input type="checkbox"/> Children <input type="checkbox"/> People in medical emergencies <input type="checkbox"/> Elderly people <input type="checkbox"/> Indigenous people <input type="checkbox"/> People in poverty <input type="checkbox"/> People in long-term care <input type="checkbox"/> People in prison <input type="checkbox"/> People with mental-health issues <input type="checkbox"/> People who are unable to consent <input type="checkbox"/> Other: Click or tap here to enter text.				
Have the TCPS2 guidelines been followed in the recruitment of these individuals?				
Comments: Click here to enter text.				
Participant Recruitment:				
	Yes	No	CR	NA
Do you have any concerns about inappropriate inducement?				
Does the recruitment process violate the participant's privacy in any way?				
Has someone within the participant's circle of care or within the organization made the initial contact on behalf of the investigator?				
Are recruitment procedures in any way coercive or unduly influential?				
Comments: Click here to enter text.				
YUKON FIRST NATIONS				
	Yes	No	CR	NA
Is there evidence of consultation with First Nations (FN)?				
Have they provided written evidence of consultation and assent from First Nations?				
Does this project include First Nations members in any way?				
Do they have a research agreement with First Nations participants?				
Any considerations given for FN intellectual property or data ownership?				
Comments: Click here to enter text.				
RISK/BENEFIT ASSESSMENT				
	Yes	No	CR	NA
Is this considered a minimal risk study?				
Are there any of the following possible risks (check any that apply): <input type="checkbox"/> Physical <input type="checkbox"/> Psychological/Emotional <input type="checkbox"/> Legal <input type="checkbox"/> Social <input type="checkbox"/> Economic <input type="checkbox"/> Academic <input type="checkbox"/> Other _____				
Are risks to participants minimized by a sound research design?				

Are risks to participants reasonable concerning the anticipated benefits to participants?				
Are any possible risks to participating greater than those the participants might encounter in their everyday life?				
Is the information about risks in the research summary consistent with the Information Sheet?				
Are there risks to the researchers?				
Are the benefits clearly stated?				
Is the information about risks in the application consistent with the Consent information for participants?				

Comments: [Click here to enter text.](#)

PRIVACY AND CONFIDENTIALITY OF DATA				
Data Management: Collection, Storage, Protection & Transmission:	Yes	No	CR	NA
Will data be collected at the lowest level of identifiability possible (e.g., initials instead of a name, age instead of DOB)?				
Are adequate provisions made to protect participants' privacy and maintain the data's confidentiality?				
Plan to ensure the confidentiality of data is adequate?				
Plan to ensure the security and encryption of data is adequate?				
Plan to ensure transmission/movement of data is adequate?				
Plan for the deletion of the data is adequate.				

Comments: [Click here to enter text.](#)

USE OF DATA				
	Yes	No	CR	NA
Clear details on how data use will support research objectives				
Any future data use planned?				
Methods of dissemination indicated, and details included in consent form.				

INFORMATION SHEET AND CONSENT FORM				
	Yes	No	CR	NA
Has the Yukon University consent form template been used?				
Are information/consent documents appropriately headed and printed in large enough type ?				
Are information/consent documents free of <u>unexplained</u> technical terms, acronyms & jargon?				
Are information/consent documents free of language that waives the participant's legal rights or that releases the investigator, institution, or sponsor from liability?				
Is the Information sheet written consistently in the second person ("You"/"your")?				

Comments: [Click here to enter text.](#)

PURPOSE OF THE STUDY:				
	Yes	No	CR	NA
Is there an introduction in the Information sheet explaining:				
<ul style="list-style-type: none"> That this is research? That this is an INVITATION to participate? That participation is voluntary? 				
Is the purpose of the study clearly described?				
Is the expected duration of participation in the trial described?				
Is the number of participants to be involved in the study described?				
Comments: Click here to enter text.				
STUDY PROCEDURES:				
	Yes	No	CR	NA
Are any screening procedures included in the information sheet?				
Are participant responsibilities described (e.g. order of procedures, amount of time required)?				
Comments: Click here to enter text.				
RISKS & BENEFITS				
	Yes	No	CR	NA
Are the foreseeable risks clearly described and the probability of their occurrence given? (e.g., psychological – risk of embarrassment, stress, etc.)				
Are the potential benefits described? If there is no intended benefit to the participant, is this clearly stated?				
Comments: Click here to enter text.				
COMPENSATION OR REIMBURSEMENT				
	Yes	No	CR	NA
If participants are to be compensated or reimbursed for their participation, are the conditions and the amount of the compensation described including what happens should the participant withdraw from the study?				
Comments: Click here to enter text.				
CONFLICT OF INTEREST AND COMMERCIALIZATION				
	Yes	No	CR	NA
Conflict of interest issues are clearly described?				
Commercialization potential is clearly outlined and complete?				
Comments: Click here to enter text.				
PRIVACY & CONFIDENTIALITY				
	Yes	No	CR	NA
Does the Information sheet describe:				
<ul style="list-style-type: none"> Procedures to ensure confidentiality of data and anonymity of participants' data? How the data will be used? 				

<ul style="list-style-type: none"> • Length of data retention? • Measures to ensure physical security of data? 				
If information will be released to any other party for any reason, does the Information sheet: <ul style="list-style-type: none"> • State the persons/agencies with whom the information will be shared? • What may be disclosed? • The purpose of the disclosure? 				
Comments: Click here to enter text.				
WITHDRAWAL				
	Yes	No	CR	NA
Does the Information sheet explain: <ul style="list-style-type: none"> • Whether the participant has the choice not to answer any of the questions, and if not, why? • That the participant can withdraw from the study at any time? • Whether data can be removed from the study after it has been submitted, and if not, why the data cannot be removed? 				
Comments: Click here to enter text.				
CONTACTS	Yes	No	CR	NA
Is the participant told whom to contact regarding the study?				
Is the participant told whom to contact about their rights as a research participant (YukonU REB Co-Chairs) ethics@yukonu.ca				
Comments:				
CONSENT/SIGNATURE PAGE	Yes	No	CR	NA
Is the Consent form written in the first person singular ("I", "me", "my")?				
Does the Consent form indicate that the participant understands and agrees to participate in the research?				
Are the appropriate signatures provided (i.e. printed name and signature of the participant or their legally authorized representative, the person obtaining consent and the date of each signature)?				
Will minors give assent to the research, in addition to the guardian's consent? Is an Assent form included?				
Does the consent include a statement that "I will receive a SIGNED copy of this form"?				
Is the consent form on institutional letterhead?				
Comments:				
APPENDICES (ATTACHMENTS)	Yes	No	CR	NA
Are all required documents attached?				
TCPS2 Certificates				
Ethics approval from partner institutions				
Research agreements, proof of consultation and approval from Yukon FN				
Research licence				

Recruitment materials				
Debriefing materials/forms				
Project overview				
Missing items:				