Top of Form

### General Info

FileNo: -1

Title:

Start Date:

End Date:

Keywords:

### Project Members

##### Principal Investigator

Prefix:

Last Name:

First Name:

Affiliation:

Rank:

Gender:

Email:

Phone1:

Phone2:

Fax:

Mailing Address:

Institution:

Country:

Comments:

### Common Questions

##### 1. General Information

|  |  |  |
| --- | --- | --- |
| **#** | **Question** | **Answer** |
| 1.1  | Please provide a brief summary of the study, including the rationale, avoiding the use of technical terms and jargon. (max 500 words) |   |
| 1.2  | If this is a funded project, please provide the ROLA reference number and/or the grant title. |   |
| 1.3  | Has this study been submitted to any other research ethics boards (REBs)?  |   |
| 1.4  | For each team member listed in the Project Team Info tab, please list the following. Their ROLE in this study. Their RESPONSIBILITY in this study. (E.g. Sam Doe, PI, responsible for the conduct of the research study. Alex Green, Research Assistant, responsible for recruitment, interviews and analysis of data.) |   |

##### 2. Study Description

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| **#** | **Question** | **Answer** |
| 2.1  | What are the study hypotheses or, if specific hypothesis are not normally part of the methodology, what are the research questions ? Provide details of the procedures that will be used to test the hypotheses or research questions. In writing this section consider that the board needs to understand what a participant will experience as they take part in the study.  |   |
| 2.2  | Does this study include any deception or withholding of key information that may be relevant to the participant making an informed decision about participation? |   |
| 2.3  | Please explain and justify the use of deception in this study.  |   |
| 2.4  | If you are giving a debriefing, describe how and when the participants will be debriefed. Note that if you are using deception, you must always have a debriefing. Please include the debriefing letter in the Attachment tab.  |   |
| 2.5  | What is the anticipated number of participants needed to carry out this research? |   |
| 2.6  | How much time will a participant be asked to dedicate to the project? If there are multiple, separated sessions, please indicate the time needed for each session.  |   |
| 2.7  | List all study instruments (e.g., survey, data collection forms, etc.) that will be used in this research study. For each instrument, indicate whether or not you developed the instruments yourself or if it is a standard instrument in the relevant field. Please ensure that all instruments listed here are included in the Attachment tab.  |   |
| 2.8  | For each of your study procedures, list the locations where the study procedures will be conducted.  |   |
| 2.9  | What is the age range of the participants? |   |
| 2.10  | Does this study involve research with Canadian Aboriginal peoples? |   |
| 2.11  | Does this study involve online research?  |   |
| 2.12  | Will this research take place in a K-12 classroom system or child-care system?? |   |
| 2.13  | Describe the participants being selected for this study and the criteria for their inclusion. If your inclusion criteria involve characteristics/qualities that would require you to identify if a potential participant qualifies, describe how will you do that (e.g., if you require a participant to be fluent in a language, or have a certain personality characteristic, how will this be ascertained?). |   |

##### 3. Recruitment Process

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| **#** | **Question** | **Answer** |
| 3.1  | Describe your recruitment procedure. This should include how potential participants will become aware of your study, how they will secure their participation in the study and how they can get in touch with you. Ensure that all recruitment documentation is included in the Attachment tab.  |   |
| 3.2  | If you indicated that the researcher will contact the participants directly, please indicate how the researcher has access to or will obtain the contact information.  |   |
| 3.3  | Will a person who might have some influence (e.g., supervisor of employees, teacher of students, or other such relationships) be making initial contact with the potential participants.  |   |
| 3.4  | If you answered “Yes” to question 3.3, please describe the nature of the influence and what steps will be taken to ensure it does not exert undue influence on the person to participate. |   |

##### 4. Consent Process

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| **#** | **Question** | **Answer** |
| 4.1  | Which of the following forms of consent / assent will be used? Ensure that all consent documentation is included in the Attachment tab.  |   |
| 4.2  | Please elaborate on each kind of consent listed above.  |   |
| 4.3  | If you selected unable to obtain consent / requesting a consent waiver, please elaborate.  |   |
| 4.4  | Seeking consent from individuals under the age of 18 or who may have diminished capacity without obtaining parental/legal guardian consent should be based on whether or not they have the capacity to understand the significance of the research and the implications of the risks and benefits to them. Please indicate how consent will be obtained for those under 18 or who may have diminished capacity.  |   |
| 4.5  | If you indicated that no parental consent will be obtained for individuals under the age of 18 or with a diminished capacity, please explain here.  |   |
| 4.6  | Will a person who might have undue influence on the participant be consenting the participant?  |   |
| 4.7  | If you answered "Yes" to question 4.6, please explain here.  |   |
| 4.8  | Indicate if the participants may have any of the anticipated communication difficulties listed below. |   |
| 4.9  | If there is an anticipated communication difficulty, as indicated above, please describe the procedures that will be used to address this.  |   |

##### 5. Risks, Benefits and Safety

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| **#** | **Question** | **Answer** |
| 5.1  | List and describe any foreseeable potential risks and harms. If there are risks or harms, describe what potential benefits there may be to individuals or society to justify these risks or harms.  |   |
| 5.2  | Please indicate how you will minimize any potential risks/harms in this study. |   |
| 5.3  | If there is a possibility that the participant may experience emotional distress, what training / qualifications does the interviewer / researcher have that equips them to recognize such distress and to know when to stop the interview? |   |
| 5.4  | If there is a possibility of distress, please comment on what resources will be available to deal with potential distress (e.g., Will a list of resources be provided? Is there someone on site to deal with distress?). |   |
| 5.5  | Please confirm that you are aware of any obligations that you may have for reporting information to outside agencies (e.g., information about abuse of minors to CAS, or other such information) that may arise in this study. This limit on confidentiality must also be clear in the Letter of Information and Consent.  |   |

##### 6. Confidentiality and Data Security - Collection of ...

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| **#** | **Question** | **Answer** |
| 6.1  | Based on the information in the Guidelines for Confidentiality and Data Security, are you collecting identifiable information for this study? |   |
| 6.2  | If yes to question 6.1, identify any personal identifiers collected for this study. Select all that apply. |   |
| 6.3  | If you have selected "Other" above, please specify.  |   |
| 6.4  | Explain and justify the use of each identifier selected above.  |   |

##### 7. Confidentiality and Data Security - Transporting o ...

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| **#** | **Question** | **Answer** |
| 7.1  | Will the transport of study records conform to the requirements of the Guidelines for Confidentiality and Data Security Section A - Transporting of Study Data? |   |
| 7.2  | If you answered "Yes" to question 7.1, who will have access to the data (identifiable or de-identified data)? |   |
| 7.3  | If you answered "Yes" to question 7.1 and the data to be transferred include identifiable information, list the type of identifiable information that will be included with the data sent off-site.  |   |
| 7.4  | If you answered "No" to question 7.1, please describe the deviations you are requesting with respect to the transport of study data containing identifiable information, and explain why these deviations are essential to being able to conduct the study? |   |

##### 8. Confidentiality and Data Security – Storage, reten ...

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| **#** | **Question** | **Answer** |
| 8.1  | How are you storing your data |   |
| 8.2  | Will the storage of study data conform to the Guidelines for Confidentiality and Data Security Section B - Storage, Retention and Destruction of Study Data? |   |
| 8.3  | If you have answered "No" to question 8.2, please describe any deviations you are requesting with respect to the storage of study data, and explain why those deviations are necessary for the conduct of the study.  |   |
| 8.4  | If someone other than the local Principal Investigator will be retaining the study data please specify who will store the data, how the data will be stored, and where the data will be stored. |   |
| 8.5  | Please confirm that data (identifiable and/or de-identifiable) will be retained for a minimum of 5 years as per regulatory guidelines (e.g., granting agency guidelines).  |   |
| 8.6  | Will you be retaining data with identifiable information for longer than 5 years |   |
| 8.7  | Will the data with identifiable information being retained for longer than 5 years be professionally archived? |   |
| 8.8  | If yes to question 8.7, please provide information on the professional archive depository and confirm that the Letter of Information and Consent contains information that data with identifiable information will be archived.  |   |
| 8.9  | If you will be retaining data with identifiable information for longer than 5 years describe (1) how long it will retained, (2) why it is necessary it be retained for longer than 5 years, and (3) how you will ensure the confidentiality of the data during the extended retention period.  |   |
| 8.10  | If you are collecting identifiable information how will you destroy that data after the retention period indicated in the above questions? |   |

##### 9. Compensation

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| **#** | **Question** | **Answer** |
| 9.1  | Will participants receive any compensation or incentive for participation? |   |
| 9.2  | Please elaborate on any compensation or incentive the participants will receive.  |   |
| 9.3  | Will participants receive any reimbursement for expenses? |   |
| 9.4  | Please elaborate on any reimbursement for expenses that participants will receive.  |   |
| 9.5  | If any compensation or reimbursement will be prorated please provide details of the prorating here and in the Letter of Information and Consent.  |   |
| 9.6  | If compensation involves entering the participant into a draw, describe how the participant will be entered into the draw and how they will be notified of winning. Ensure that the identifiable information for the draw is not associated with the data.  |   |

##### 10. Online Research

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| **#** | **Question** | **Answer** |
| 10.1  | All questions in an online survey must be optional as participation is voluntary.  |   |
| 10.2  | Identifiable information, including IP address, cannot be collected or stored with the data at any time.  |   |
| 10.3  | If you will be entering the participants into a draw at the end of the survey, the participants must be able to skip all questions and still gain access to be entered into the draw.  |   |

##### 11. Research with Canadian Aboriginal Peoples

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| **#** | **Question** | **Answer** |
| 11.1  | Will the research be conducted on Canadian Aboriginal lands, include Canadian Aboriginal people or seek input from participants regarding a Canadian Aboriginal community’s cultural heritage, artefacts, traditional knowledge or unique characteristics?  |   |
| 11.2  | Will interpretation of research results refer to Canadian Aboriginal communities, peoples, language, history or culture?  |   |
| 11.3  | Please describe the nature and extent of your engagement with the Aboriginal community(s) being researched. The nature of community engagement should be appropriate to the unique characteristics of the community(s) and the research. The extent of community engagement should be determined jointly by the researchers and the relevant communities. Include any information/advice received from or about the Aboriginal community under study.  |   |

##### 12. K-12 Classroom

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| **#** | **Question** | **Answer** |
| 12.1  | Have you consulted with the Research Services department at the school board that you wish to enter before submitting this application? Please include any relevant correspondence with the Research Services department and/or principal which indicates you can collect data at their school.  |   |
| 12.2  | Please confirm that your research project will be submitted to the appropriate school boards once Western approval has been granted and that all school board approval notices will be forwarded to the Office of Research Ethics. |   |
| 12.3  | Have the research team members that will be directly interacting with K-12 students received a police check to enter into the classroom and work with children? |   |
| 12.4  | If the research is happening during school hours, what will the children who have not been consented/assented to participate in the research do during this time? |   |
| 12.5  | Indicate which of the groups you will recruit from the school. Please select all that will apply.  |   |
| 12.6  | If you have selected "other" above, please specify here.  |   |
| 12.7  | If you have indicated that you are recruiting students above, please select the age range(s) of the students from one of the following groups. Please select all that apply.  |   |
| 12.8  | If you will be requesting any information from the school or the board (e.g., student achievement scores, report card grades), indicate which information and how parent consent for this information will be sought.  |   |
| 12.9  | If research procedures require individual students to participate by being alone with the researcher in a private room/area, there must be at least two researchers present during these times. Does your study include any such conditions?  |   |
| 12.10  | If you have answered "Yes" to question 12.9 please confirm that the requirement of having at least two researchers present will be met.  |   |
| 12.11  | Is the project in any way testing or evaluating a new curriculum or pedagogy? |   |
| 12.12  | If you answered "Yes" to question 12.11, is the new procedure only being introduced as a result of the research project (i.e. It is not part of the normal curriculum that would be occurring even if the research was not being conducted?) |   |
| 12.13  | If you answered "Yes" to question 12.12 please explain.  |   |
| 12.14  | How will you distribute materials and collect informed consent when children are involved? |   |

##### 13. Conflict of Interest

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| --- | --- | --- |
| **#** | **Question** | **Answer** |
| 13.1  | Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits (for example a financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options etc.) as a result of or by being connected to this study?  |   |
| 13.2  | If you answered "Yes" in question 13.1, please describe the benefits below (do not include conference and travel expense coverage, possible academic promotion, or other benefits that are integral to the conduct of research generally). |   |
| 13.3  | If applicable, describe any restrictions regarding access to or disclosure of information (during or at the end of the study) that the sponsor has placed on the researcher(s). |   |

##### 14. Confirmation of Responsibility

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| --- | --- | --- |
| **#** | **Question** | **Answer** |
| 14.1  | I confirm that I have read all study documents, assume full responsibility for the scientific and ethical conduct of this research and agree to conduct this study as outlined in the approved Western Protocol and documents approved by the REB in compliance with the TCPS2 guidelines.  |   |
| 14.2  | Have you exported a copy of this submission to Word using the "Export to Word" button? Note that you will be unable to submit your response or future amendments if this is not done.  |   |

Bottom of Form