**REB TEMPLATE FOR NEW APPLICATION FORM DEVELOPMENT**

**PLEASE DO NOT SUBMIT THIS FORM TO THE REB.**

**This form is intended for application development purposes only. For information on how to apply for ethical review, please see the UNBC REB website.**

\*ASTERISK INDICATES A MANDATORY QUESTION

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**TAB 1. STUDY DATES AND FUNDING INFORMATION**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **1.1\*** | **Please choose one of the following:** |  |
| [ ]  You plan to start collecting data immediately after obtaining ethics and any other required approvals[ ]  You plan to start data collection at a later date i.e., 2 months or more after submitting application |
| **1.2** | **Estimated Start Date of Human Participant Involvement if you selected a later start date in the question above** | If you plan to start data collection at a later date, as indicated in the question above, please click the calendar icon below to select the Start Date or enter the date manually using the “yyyy-mm-dd” format. |
| Click or tap to enter a date.  |
| **1.3\*** | **Estimated End Date of Human Participant Involvement** | Please use the calendar icon below to select the End Date or enter the date manually using the “yyyy-mm-dd” format. |
| Click or tap to enter a date.  |
| **1.4\*** | **Does this study have any funding associated with it?** |  |
| [ ]  Yes – Please answer the questions below[ ]  No – Please skip to Study-Related Conflict of Interest Question (2.1) |
|  |
| **1.5** | **Where will funding be held?** |  |
| [ ]  UNBC[ ]  Another institution (please specify below)[ ]  N/A |
| **1.6** | **If a research funding application was submitted to another institution besides UNBC, which institution is administering the funds?** |  |
|  |
| **1.7**  | **If UNBC will be administering the funds, has a funding application been submitted to the Office of Research and Innovation via ROMEO?** |  |
| [ ]  Yes – please ensure that you have linked the related award under the Project Info tab with the “Search” button[ ]  No[ ]  N/A |
| **1.8** | **If you answered "No" to the question above, please explain why not (e.g., you are using start-up funds, PD funding, etc.).** |  |
|  |
| **1.9** | **If there are any research funding applications/awards that are associated with the study that are not listed above, please provide details in the text box below.** | Please indicate the title and sponsor of the award, as well as any other applicable details. |
|  |
| **1.10** | **Other Funding Information** | Please enter any applicable information about your funding which is not already shown in the questions above, including funding applied for but not yet received. |
|  |

**TAB 2. CONFLICT OF INTEREST**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **2.1\***  | **Study-Related Conflict of Interest: (a) Do any of the immediate family members, or personal partners of the research team, occupy multiple roles with respect to potential participants? (b) Will any of the researchers, members of the research team, and/or their immediate family members, or personal partners, receive any personal benefits in connection with this study?** | Conflicts of Interest (COIs) can arise naturally from an Investigator’s engagement inside and outside their affiliated institution, and the mere existence of a COI or the perception of a COI will not necessarily present an issue for the research study. All real, potential or perceived COIs that could affect the integrity of the research must be stated, and addressed. |
| [ ]  "Yes" to either (a) or (b)[ ]  "No" to both (a) and (b)[ ]  Unsure - Please read TCPS Article 7.4 (pages 96 & 97). If needing further detail, contact the Research Ethics Officer |
| **2.2\*** | **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?**  | While not exhaustive, the below are examples that may give rise to a COI.The PI, Co-I, and/or their partners/immediate family members (partners and children either living in the same household or not):(a) has 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 (e.g., a company, partnership, or non-profit corporation) whose interests could be affected by the outcome of this research;(b) provides services (e.g., non or fee-paying consulting, advisory, board membership, etc.) to any entity (e.g., a company partnership, or non-profit corporation) whose financial interests could be affected by the outcome of this research;(c) has intellectual property rights or interests linked in any way to this study (e.g., patents, copyrights, royalties or other payments, etc.). |
| [ ]  Yes[ ]  No |
| **2.3** | **If you answered "Yes" to either of the questions above, please provide details in the text box below for each “Yes” situation.** |  |
|  |
| **2.4\*** | **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 |
| **2.5** | **If you answered "Yes" to the question above, please provide details in the text box below.** |  |
|  |
| **2.6** | **Please advise how you propose to manage any actual, perceived, or potential COI outlined in the questions above?** |  |
|  |

**TAB 3. STUDY TYPE AND RISK ASSESSMENT**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **3.1\*** | **Study Type** | Please check all that apply.Note: **Classroom Projects** involve a research methods course exercise, or other exercises designed to give students training in conducting and/or presenting research (i.e., the activity should not be an undergraduate or graduate thesis/dissertation).  |
| [ ]  Classroom Project – Graduate student[ ]  Classroom Project – Undergraduate student[ ]  Research – Faculty[ ]  Research – Graduate student (including Thesis/Dissertations/Projects)[ ]  Research – Post Doctoral Fellow[ ]  Research – Undergraduate student (including Honours Thesis)[ ]  Other (please explain below) |
| **3.2** | **If you checked "Other" or if you checked more than one box in the question above, please explain. If you checked multiple boxes, explain the relationship between the researchers as pertinent to study data management and future analysis.** |  |
|  |
| **3.3\*** | **Does your research involve another BC institution or Health Authority?** | Research Ethics BC has many member institutions, including the provincial Health Authorities.  It was formed with the purpose to harmonize a single ethics review for a multi-institutional study. If your research is multi institutional in either the makeup of the research team or data collection sites, please check to see if there are REBC members amongst them (visit <https://healthresearchbc.ca/research-ethics-bc/why-research-ethics>).  A harmonized application is completed on the Provincial Research Ethics Platform (PREP) hosted on UBC's RISe system and this ROMEO application is not transferable to PREP. |
| [ ]  Yes – Please STOP completing this application if you have confirmed REBC member institutions involved in the study. Go to PREP/RISe (rise.ubc.ca) to complete your harmonized application and delete this draft[ ]  No – Please continue with this Romeo application |
| **3.4\*** | **Have you attached a copy of the research proposal to the "Attachments" tab of this Romeo application?** | The methodology provided and reviewed in the ethics application is the methodology expected to be carried out for the study, and is the methodology the REB found to meet ethical research practices, and approved on behalf of the university.Note that a research proposal is helpful to support reviewers to gain context for questions, when the information provided in the application is not sufficiently clear. Research proposals are generated for student research, grant applications and other purposes to outline the disciplined inquiry and/or systematic investigation undertaken to extend knowledge for research review.  |
| [ ]  Yes[ ]  No |
| **3.5\*** | **Is this proposal closely linked to other proposal(s) previously/simultaneously submitted?**  |  |
| [ ]  Yes[ ]  No |
| **3.6\*** | **Have you received any information or are you aware of any rejection of this study by any Research Ethics Board?** |  |
| [ ]  Yes[ ]  No |
| **3.7** | **If you answered "Yes" to either of the two questions immediately above, please indicate the Research Ethics Board Number(s) of proposal(s) and describe the relationship between this proposal and other previously/simultaneously submitted proposal(s).** |  |
|  |
| **3.8** | **If you answered "Yes" to either 3.5 or 3.6 above, please provide known details and attach any available relevant documentation to the "Attachments" tab, using a consistent and informative naming convention.** |  |
|  |
| **3.9\*** | **Has this research proposal received any independent scientific/methodological peer review?** |  |
| [ ]  Yes – External Peer Review[ ]  Yes – Internal Peer Review[ ]  No |
| **3.10\*** | **Peer Review Details** | Please include the names of committees or individuals involved in the review, and state whether the peer review process is ongoing or completed. If the research is for an undergraduate or graduate thesis, the student's thesis committee must have reviewed and approved the research proposal before a research ethics application is submitted. If NO peer review has been conducted, explain why. |
|  |
| **3.11\*** | **To determine if your study meets the standard of Minimal Risk Research, please review the Research Risk Assessment Guidelines and, using these measures, locate the study in the following two questions. Indicate that you have reviewed the Guidelines.**  | Please refer to the posted [Research Risk Assessment Guidelines](https://www2.unbc.ca/sites/default/files/sections/office-research-and-innovation/researchriskassessmentguidelines.pdf). |
| [ ]  Yes[ ]  No |
| **3.12\*** | **Level of Research Risk** | The risks involved in participating in the research are scaled from Low to High, as defined in the posted [Research Risk Assessment Guidelines](https://www2.unbc.ca/sites/default/files/sections/office-research-and-innovation/researchriskassessmentguidelines.pdf). |
| [ ]  Low[ ]  Medium[ ]  High |
| **3.13\*** | **Level of Participant Vulnerability in the context of your study** | How vulnerable does the participants' situation or circumstances make them in the context of your study, scaled from Low to High, as defined in the posted [Research Risk Assessment Guidelines](https://www2.unbc.ca/sites/default/files/sections/office-research-and-innovation/researchriskassessmentguidelines.pdf)? |
| [ ]  Low[ ]  Medium[ ]  High |
| **3.14\*** | **Does your study meet the standard of Minimal Risk Research?** | To visualize the Risk Research Matrix, please review the [Research Risk Assessment Guidelines](https://www2.unbc.ca/sites/default/files/sections/office-research-and-innovation/researchriskassessmentguidelines.pdf) again using the information determined in questions 3.11 through 3.13. |
| [ ]  Yes – No more than one medium response in the two previous questions of Research Risk and Participant Vulnerability[ ]  No – Responses include two medium, or at least one high, response in the two previous questions of Research Risk and Participant Vulnerability |
| **3.15** | **Justification for Your Risk Assessment** | The box below offers the opportunity to elaborate on the assessment of the study proposal level of risk, and participant vulnerability. This provides a way to justify the assessments made, especially if study context is helpful for an outsider to understand what might otherwise be considered sensitive and risky. Please write N/A if the option is not desired. |
|  |

**TAB 4. SUMMARY OF STUDY AND RECRUITMENT**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **4.1\*** | **Purpose of Research and Research Question(s)** | (a) Describe the purpose for the proposed study. Rationale for conducting the research is to be made clear, in lay language and shown to be supported through investigation of the subject;(b) State the research questions to be examined/the hypothesis to be tested. If conducting research for dissertation/thesis purposes, please state in this section. |
|  |
| **4.2\*** | **Summary of Study Methods** | Summarize the research methods to be applied in conducting the study. Outline the information to be collected, where and how it will be obtained, and how it will be analyzed. The Research Data Management Plan will be addressed in the sub tab following this one. Please consult the Library Guide: [UNBC Geoffrey R. Weller Library RDM](https://libguides.unbc.ca/rdm). |
|  |
| **4.3\*** | **Role(s) of Research Team Member(s) and Experience** | Please describe your own role in the research, and that of the other team member(s), and what the member(s) qualifications are to conduct this kind of research (e.g., describe relevant training, experience, degrees, and/or courses). If the study is to be conducted by a student researcher, ensure that the supervisor's experience is explained. |
|  |
| **4.4\*** | **Study Sites and Institutions – Where are research activities occurring?** | Please list all study sites and institutional resources involved in the study. Include:(a) UNBC sites and resources involved (e.g., secure server for data storage, research lab, office space);(b) non-UNBC locations where the research will be conducted under this Research Ethics Approval (e.g., school, classroom, community centre, name of privately owned clinic, participant's home, in the field);(c) Please include study team members' institutional affiliations under which this research is being conducted. |
|  |
| **4.5\*** | **Roles of Location for Data Collection and Necessary Consents** | In the text box below, please describe the roles of the study sites and institutions listed in the previous question. Indicate how each study site and institution will be involved (e.g., recruiting participants, analyzing data or utilizing lab space; accessing records or charts; team member affiliations for this research). \*Please note that any necessary consents pertaining to each of the research locations are to be attached to the "Attachments" tab, or have their status clarified in question 6.3. |
|  |
| **4.6\*** | **Inclusion Criteria** | Describe the participants being selected for this study and list the criteria for their inclusion. |
|  |
| **4.7\*** | **Exclusion Criteria** | Include details if otherwise eligible participants will be excluded due to other characteristics. If no exclusion criteria are applicable, enter N/A. |
|  |
| **4.8\*** | **Recruitment** | Provide a detailed description of the steps you will use to recruit participants. Include: a) Who will contact prospective participants? b) By what means will recruitment be done (e.g., public posting, third party recruitment, etc.)? c) How will prospective participants be identified? d) Include all site specific information. e) Attach all relevant materials to be used in the recruitment process, including letters of initial contact, posters, scripts and advertisements to the "Attachments" tab using a consistent and informative naming convention. |
|  |
| **4.9\*** | **Use of Records** | If pre-existing, controlled records (e.g., course grade sheets or other records/databases, health records) will be used to access information about potential participants, please describe how permission will be obtained to access, collect and use this information (if not, enter N/A). |
|  |
| **4.10\*** | **Summary of Participant’s Expected Contributions** | Describe briefly in a step-by-step manner what the researcher will be asking participants to do, after they have been recruited and consented. Please note the frequency an activity is to occur for a single participant over days, weeks and/or months, as required for the research. |
|  |

**TAB 5. SECURITY OF DATA AND CONFIDENTIALITY OF PERSONAL INFORMATION**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **5.1\*** | **Security of Data During the Course of the Study** | How will participant data be recorded and stored (e.g., computerized files, hard copy, videotape, audio recordings, personal electronic communications device, other)? How will security of the data be maintained? Note that identifiable research data retained in physical study documents must be kept in a secure locked location and storage of computer files will need to be with encryption. Data should not be stored or downloaded onto, or stored on, an unsecured computer and back up files should be stored appropriately. If any data or images are to be kept on the Web, what precautions have been taken to prevent them being accessed or copied?  |
|  |
| **5.2\*** | **Access to Data** | Provide the names of those who will have access to the raw data. How will those who have access to the data be made aware of their responsibilities concerning privacy and confidentiality? The research participants must also be told in the consent process who will have access to their data (raw data and any variations of de-identified and amalgamated data) and what use will be made of it, either now or in the future. Temporary student assistants, translators, transcriptionists, and clerks may be referred to by their role in the study, instead of by name. |
|  |
| **5.3\*** | **Protection of Personal Information** | Describe how the identity of research participants will be protected both during and after the research study, including how participants will be identified on data collection forms. If your study involves the linkage of several data sources, explain how confidentiality regarding the shared information will be preserved.A unique study code should not be derived from or related to the information about the individual (i.e., name, SIN, PHN, hospital number, DOB, address, or unique characteristic). |
|  |
| **5.4\*** | **Will any data be transferred (made available) to persons or agencies outside the University?** |  |
| [ ]  Yes[ ]  No |
| **5.5** | **If you answered "Yes" to the question above, describe in detail what identifiable information will be released, to whom, how the data will be transferred, how and where it will be stored and what safeguards will be used to protect the identity of participants and the privacy of their data.**  | If applicable, please attach the data transfer agreement to the "Attachments" tab of this Romeo application. |
|  |
| **5.6\*** | **Retention and Destruction of Data** | Please specify the intended data retention period and destruction methods for all data types to ensure confidentiality (e.g., tapes should be demagnetized, paper copies shredded). Responsibility for security of data rests with the Principal Investigator from the point of collection through to disposition. Please state how long data is to be retained, and how that period will be supported securely. In some cases, data are of such value that they should not be destroyed (e.g., oral history interviews). In these cases, please describe your plans to preserve this material. The consent process should outline these plans and describe how and when it may be appropriate for others to have access to this information. |
|  |
| **5.7\*** | **Future Use of Data** | If there is no anticipated future use for the data being collected, beyond the conclusion of this research study, state clearly here. Alternately, describe any known future use of the data beyond the conclusion of this research study, and indicate whether participant consent will be obtained in the current consent procedure, or the participant will be contacted later to obtain consent. Either possibility must be described in the consent process. If consent is to be obtained now, the future use of the data must be described in full to the participant and included with the current application. If consent for future use of the data is to be obtained later, full details must be submitted to the REB for review and approval before the research begins. The REB acknowledges that in the case of ethnographic field notes and interviews, researchers cannot be expected to know all the uses they plan to make of the data. Therefore, researchers should inform the peoples they are studying of the potential for future use of the data during the consent process.  |
|  |
| **5.8\*** | **Distribution of Results to Participants** | Describe how the results of the study will be provided to participants (e.g., provide them with the option to indicate interest in receiving a summary report by email or other means if possible, including an estimated timeline for the study completion; or provide them with the address of faculty member's webpage, where study results are to be posted, if appropriate).  |
|  |

**TAB 6. NUMBER OF PARTICIPANTS AND LOCATIONS FOR STUDY**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **6.1\*** | **What is the target number of participants to take part in this study, covered by this Research Ethics Approval?** | Target for UNBC’s researchers to recruit for this study. |
|  |
| **6.2\*** | **What is the target number of participants to take part in the entire study (i.e., worldwide)?** | If the study is completely covered by this single approval, the number entered here would be equal to that provided in the previous question. If there is a larger study, that is occurring in multiple jurisdictions beyond UNBC research team, under multiple Research Ethics Approvals, the number to be entered here would be higher than the number given in response to the previous question. |
|  |
| **6.3\*** | **Are approvals from other institution(s) and/or site(s) required?** | Please refer to TCPS2 Article 8.3 for research undertakings at sites conducted outside the research institution’s jurisdiction. Permission from the site authority at which research is to occur is required, if such an authority is in place. Researchers are to inquire directly to their selected research sites to determine how to proceed. Sites may have no such requirements, whereas others will require both their own site and ethics approvals. Refer to Article 8.3. |
| [ ]  Yes[ ]  No |
| **6.4** | **If you answered "Yes" to the question above, please indicate the institution(s) and/or site(s) in the text box below.** | \*\*Please attach a copy of the approval letter, if received, to the “Attachments” tab, using a consistent and informative naming convention. If not available to attach at this time, please also indicate what stage the request for each site approval is at in the text box below. |
|  |
| **6.5\*** | **Are approvals from another jurisdiction or country required?** | Please refer to TCPS2 Article 8.3 for further details. |
| [ ]  Yes[ ]  No |
| **6.6** | **If you answered "Yes" to the question above, please indicate the jurisdiction or country in the text box below.** | \*\*Please attach a copy of the approval letter, if received, to the “Attachments” tab, using a consistent and informative naming convention. If not available to attach at this time, please also indicate what stage the request for each approval is at in the text box below. |
|  |
| **6.7** | **If applicable, has a Request for Ethics Approval been submitted to the institution or responsible authority in the other jurisdiction or country?**  | \*\* Please attach a copy of the documentation to the "Attachments" tab, using a consistent & informative naming convention, once it is received. |
| [ ]  Yes[ ]  No[ ]  N/A |
| **6.8\*** | **Does this research focus on any global Indigenous peoples, communities or organizations?** | If you answer "Yes", and research is within Canada, please refer to TCPS2 Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada. Please attach a copy of the research agreement with the community (if available) to the “Attachments” tab. If you answer "Yes", and research is including any global Indigenous peoples, communities or organizations, please provide details of how the research engagement is to be approached with respect to the local expectations in a summary uploaded to the "Attachments" tab. |
| [ ]  Yes[ ]  No |
| **6.9\*** | **Will the research be conducted on any global Indigenous reserves, Métis settlement(s), or lands governed under a self-government agreement or an Inuit or First Nations land claims agreement?** |  |
| [ ]  Yes[ ]  No |
| **6.10\*** | **If you answered "No" to both Questions 6.8 and 6.9, please insert “N/A” in the text box below and move on to sub tab 7. If you answered "Yes" to either of the questions above, please provide details in the text box below.**  |  |
|  |
| **6.11** | **Do any of the criteria for participation include membership in an Indigenous community, group of communities, or organization, including urban Indigenous populations?**  |  |
| [ ]  Yes[ ]  No |
| **6.12** | **If you answered "Yes" to the question above, please provide details.** |  |
|  |
| **6.13** | **Does the research seek input from participants regarding a community’s cultural heritage, artifacts, traditional knowledge or unique characteristics?** |  |
| [ ]  Yes[ ]  No |
| **6.14** | **If you answered "Yes" to the question above, please provide details.** |  |
|  |
| **6.15** | **Will Indigenous identity or membership in an Indigenous community be used as a variable for the purposes of analysis?** |  |
| [ ]  Yes[ ]  No |
| **6.16** | **If you answered "Yes" to the question above, please provide details.** |  |
|  |
| **6.17** | **Will the results of the research refer to Indigenous communities, peoples, language, history or culture?** |  |
| [ ]  Yes[ ]  No |
| **6.18** | **If you answered "Yes" to the question above, please provide details.** |  |
|  |
| **6.19** | **If you answered "Yes" to any of the previous five Yes/No questions (occurring within 6.9 - 6.18), have you initiated or do you intend to initiate an engagement process with the Indigenous collective, community or communities for this study?** |  |
| [ ]  Yes[ ]  No[ ]  N/A - The proposed research does not focus on peoples, communities or organizations that are defined by Indigenous origin |
| **6.20** | **Please explain your answer to the question above. If you answered "Yes", 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. If you answered "No", 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.** | \*\*Please attach any documentation of consultations (i.e. formal research agreement, letter of approval, email communications, etc.) to the "attachments" tab, using a consistent and informative naming convention. |
|  |

**TAB 7. PARTICIPANT INFORMATION AND CONSENT PROCESS**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **7.1\*** | **Time to Participate** | Indicate how much time (minutes &/or hours over how many weeks &/or months) participants will be asked to dedicate to each study procedure/activity/phase and provide the total time required of a participant to fully participate in the study (including time to (1) review study information, ask questions and give consent; (2) participate in any optional study activities offered; record maximum total time estimated to fully participate in the study to be stated). If your study involves no direct interaction with participants (e.g., naturalistic observation) please respond "N/A".Ensure that you also include this information in the consent process and that the amount of time stated is consistent in the application, recruitment letters, posters, and consent information. |
|  |
| **7.2\*** | **Risks and Mitigation** | Describe the potential risks of the proposed research for participants and how each will be managed, mitigated, or minimized. Include information about any of the following that the participants are likely to experience as a result of taking part in the study:a) physical;b) psychological;c) social; ord) legal risks.  |
|  |
| **7.3\*** | **Potential Benefits** | Describe any potential direct benefits to participants from their involvement in the study.Describe any potential benefits to the community (e.g., capacity building).Comment on the potential benefits to the scientific/scholarly community or society that would justify the involvement of participants in this study. |
|  |
| **7.4\*** | **Participant compensation** | Describe any compensation that is to be offered to participants as either incentives to participate, or recognition/appreciation of their contribution to the research, or reimbursement for expenses incurred. Provide full details of the amounts, payment schedules, method of delivery, and value of gifts-in-kind. Please refer to TCPS2 Article 3.1 for further information. If no participant compensation is to be offered, please justify the decision here. |
|  |
| **7.5\*** | **Obtaining Consent** | Include details of where and when consent will be obtained and how it will be documented. Include the following details:(a) Who would approach the participant to obtain consent? (b) Who would inform and take the consent from the participant? (c) What is the relationship of the person obtaining consent to the participant? The REB recognizes that written consent is not necessarily appropriate for certain types of research. Researchers wishing to obtain oral consent should describe the alternative means of obtaining and documenting consent. A physical or digital copy of an Information Letter may be desired in some oral consent processes, to support participants access to study details. \*\*Please upload all Information Letter and Consent Form documents, and scripts of the oral consent process, used to support the informed consent process to the "Attachments" tab, using a consistent and informative naming convention. |
|  |
| **7.6\*** | **Time to Decide** | How long after being provided with detailed information about the study will the participant have to decide whether or not to participate? Provide your rationale for the amount of time given.  |
|  |
| **7.7\*** | **Will participants have the capacity to give fully informed consent on their own behalf?** | Please refer to TCPS2 Chapter 3, Section C for more information on the Consent Process, and Chapter 4, Section B for more information on Research Involving Children, and Participants Who Lack the Capacity to Consent for Themselves. If your study involves no direct interaction with participants (e.g., secondary data use) please respond “N/A”. |
| [ ]  Yes – Please skip to question 7.11[ ]  No[ ]  N/A |
| **7.8** | **If you answered "No" to the question above, provide details of the nature of the incapacity, and how will the issue of consent be addressed?** | For instance, children and cognitively impaired people. Outline:(a) who will give consent on their behalf;(b) how they are to be informed.\*\*Please attach a copy of the relevant Consent Form for the parent/guardian, substitute decision maker, legally authorized representative, if applicable, to the "Attachments" tab, using a consistent and informative naming convention. |
|  |
| **7.9** | **If a participant does not have the capacity to give fully informed consent, will they be able to give assent to participate?** |  |
| [ ]  Yes[ ]  No[ ]  N/A |
| **7.10** | **If you answered "Yes" to the question above, explain how assent will be sought**  | \*\*Please attach a copy of the Assent Form, if applicable, to the "Attachments" tab, using a consistent and informative naming convention. |
|  |
| **7.11\*** | **Will consent be obtained from each participant either in writing or recorded by the researcher in a systematic and retrievable manner?** |  |
| [ ]  Yes[ ]  No |
| **7.12** | **If "No" to above, please provide justification for why consent will not be obtained, and/or will not be recorded in a retrievable manner, in the text box.**  |  |
|  |
| **7.13\*** | **Does the project employ any partial disclosure or deception?** | Please see TCPS2, Chapter 3, Section B for information on Departures from General Principles of Consent. |
| [ ]  Yes[ ]  No |
| **7.14** | **If "Yes" to question above, please justify the use of partial disclosure or deception and indicate how disclosure and/or debriefing will be addressed.** | Please ensure all criteria outlined in TCPS2 Articles 3.7.A and B are addressed.  |
|  |
| **7.15\*** | **Ongoing Consent** | Describe any situation in which the renewal of consent for this research might be appropriate, and how this would take place. Renewal of consent might be particularly appropriate in the context of longitudinal, ethnographic, or other research methods involving multiple contacts with participants. Please mark "N/A" if not applicable. |
|  |
| **7.16\*** | **Provisions for Consent**  | What provisions are planned for participants, or those consenting on a participant's behalf, to have special assistance, if needed, during the consent process (e.g., consent forms in Braille, or in languages other than English)? If no provisions are to be provided, please make note here, and ensure these limitations for potential participants are included in the response for study exclusion criteria (Question 4.7).\*\*Please attach copies of translated documents to the "Attachments" tab, using a consistent and informative naming convention. |
|  |
| **7.17\*** | **Restrictions on Disclosure** | Describe any restrictions regarding access to, or disclosure of, information (during, or at the end of the study) that the financial sponsor of this project, or other involved community or organization, has placed on the investigator(s), including those related to the publication of results, if applicable. If not, please enter "N/A". |
|  |

**TAB 8. CLASS-BASED PROJECTS**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **8.1** | **Is this study a minimal risk class-based research project conducted for pedagogical purposes?** | For example, a research methods course exercise, or other exercises designed to give students training in conducting and/or presenting research. The activity should not be an undergraduate or graduate thesis/dissertation.  |
| [ ]  Yes – Please answer the additional questions on this tab[ ]  No – Please skip the rest of this tab and proceed to the next tab |
| **8.2**  | **If medium vulnerability or medium research risk was selected on the risk matrix, but the student project(s) still fall within the minimal risk category, please provide further information on how the additional risks are to be mitigated and the experience of the students to deal with them.** | If the student projects will be low risk and with low vulnerability populations, please answer "N/A" to this question.  Important consideration: As the course instructor, final responsibility for the conduct of the student projects rests with you to ensure that the student projects meet the minimal risk criteria.  If any of the projects do not meet the minimal risk criteria, and you are willing to allow the project to proceed, a separate application for the project must be submitted using the normal application form and channels, with the instructor as the PI and the student as the co-Investigator.  Please note if the course is to be completed in a single term, the process from study origin to completion may exceed the dates of the term. |
|  |
| **8.3**  | **Describe the purpose of the assignment, e.g., to learn and practice research techniques.** | Please attach copies of the course outline and any assignment materials to the "Attachments" tab, using a consistent and informative naming convention. |
|  |
| **8.4** | **Describe the types of methods the students will be using in the class projects (e.g., surveys, participant observation, interviews, mixed-method studies, etc.) and general types of data students will be collecting.** | If the students will potentially be using a range of methodologies, all should be listed here. |
|  |
| **8.5** | **Describe how you will ensure that the methodology described for the research will be followed by the students.**  |  |
|  |
| **8.6** | **What instructions will you be providing to students regarding recruitment?** | List the types of recruitment methods students will be using and how they will be trained to execute the recruitment strategy as proposed. |
|  |
| **8.7** | **What instructions will you be providing to students regarding obtaining consent from study participants?** | \*\*Please attach a template consent document to the "Attachments" tab, using a consistent and informative naming convention. |
|  |
| **8.8** | **What instructions will you be providing to students on explaining participants’ right to withdraw from the research study?** | This information is generally part of the template consent document. If to be communicated in an alternate way, please outline here. |
|  |
| **8.9**  | **What instructions will you be providing students regarding feedback for participants about the study (where applicable)?** | For some types of student projects it may be appropriate to provide feedback to participants, as research studies are to make efforts to report the outcomes back to participants.   |
|  |
| **8.10**  | **What instructions will you be providing to students on assessing and minimizing risk to participants?** | Students should be made aware of how risks are to be mitigated, such as potential for minor upset, or confidentiality risks. |
|  |
| **8.11**  | **Please describe how the subject of ethics in research involving human participants will be covered within the course.** | This may be done through lecture on ethics, assigned readings, class discussion, etc.  |
|  |
| **8.12** | **Please describe how you will ensure that students in the course have completed the Tri Council Policy Statement tutorial (CORE 2022)** | Students who are conducting research with human participants are expected to be familiar with the Tri Council Policy Statement and are required to complete the TCPS2 CORE 2022 Tutorial. Viewing the dated completion certificate would be one method. |
|  |
| **8.13** | **Please describe how you, as course instructor, will review and approve the course projects proposed by your students, if they are not using the same standardized materials.** | This might take the form of a research proposal that students are required to submit, or individual meetings with the course instructor, etc. |
|  |
| **8.14** | **Please explain how you intend to deal with the study materials (e.g. research proposals, signed consent forms, research data, etc.) for storage, transfer, disposition, etc.** |  |
|  |
| **8.15** | **Please confirm your acceptance of each of the following.** | Please check each box to indicate your awareness of your responsibilities as the course convenor / instructor with this research. |
| [ ]  The students will complete the on-line TCPS2 CORE tutorial and provide me with a copy of their Certificate of Completion prior to engaging in their research project.[ ]  The students will conduct their research projects in accordance with the TCPS2 (2018), and the UNBC Policy and Terms of Reference on Ethics Review of Research Involving Human Participants.[ ]  The students will only conduct research that involves minimal risk to participants, as defined in Chapter 2, Section B, of the TCPS2 (2018).[ ]  If the research involves Indigenous peoples, the students will ensure their research follows the guidelines in Chapter 9 of the TCPS2 (2018).[ ]  The students' participant information sheets and consent forms will include all relevant information of their research project.[ ]  I am familiar with and agree to abide by the ethical guidelines and policies of the Research Ethics Board, including the Tri-Council Policy Statement and of my profession or discipline.[ ]  I will actively monitor the progress of student projects and I will make myself available, should problems arise during the course of the research, to supervise the students and assist in solving such problems.[ ]  If I have questions about the ethical conduct of this research, I will contact the Research Ethics Board.[ ]  I agree to notify the REB and Research Ethics Officer (if applicable) of any unanticipated ethical problems encountered by the student investigators in the course of their research. |

**TAB 9. COVID-19**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **Please note that if this application involves in-person research activities, the research team is required to ensure that both on-campus and off-campus research meets the latest provincial health guidelines in relation to the COVID-19 pandemic. Researchers are expected to complete a Safe Research Plan for populations that may face increased risk of COVID-19, or communities where local policies and protocols are in place. Please see the most recent** [**REB Chair Bulletin**](https://www2.unbc.ca/office-research-and-innovation/covid-19-and-research-ethics) **for further details.** |
| **9.1\*** | **Is this protocol COVID-19 related?** | Is the COVID-19 global pandemic a factor or variable in the research? |
| [ ]  Yes[ ]  No |
| **9.2\*** | **Are in-person research activities to occur?** |  |
| [ ]  Yes – Please answer question 9.3 below[ ]  No – Please skip to the next tab |
| **9.3** | **If you answered "Yes" to question 9.2 above, does the research involve populations that may face increased risk of COVID-19, or communities where local COVID-19 policies and protocols are in place?** |  |
| [ ]  Yes – Please answer the remaining questions on this tab[ ]  No – Please skip to the next tab |
| **9.4** | **Provide justification for commencement, resumption, or new in-person research activities during the COVID-19 Pandemic.** |  |
|  |
| **9.5** | **Identify any virtual methods that will be available as an option to participant in the event in-person research is again halted for COVID-19 mitigation.** |  |
|  |
| **9.6** | **Has a Safe Research Plan (SRP) been attached to this application?** | Please provide a detailed overview of risk and mitigation strategies for the research location, study population and research team that addresses both general and COVID-19 risks by completing the Safe Research Plan (SRP) as outlined on the [Office of Research and Innovation's COVID-19 webpage.](https://www2.unbc.ca/office-research-and-innovation/covid-19-and-research-ethics) A completed copy of the SRP is to be submitted with this ethics application that involves resumption/ongoing in-person research with the population of potential increased risk or communities with policies in place. The SRP will be sent for review in a concurrent, separate process through the UNBC Office of Research and Innovation and Safety Office.\*\*Please attach the Safe Research Plan, if applicable, to the "attachments" tab, using a consistent and informative naming convention. |
| [ ]  Yes[ ]  No |

**TAB 10. DECLARATIONS**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **\*If the lead researcher on this project is a student researcher, in pursuit of their thesis/final project, the following declarations are to be made by the student researcher, who is acting as the Principal Applicant (PA) under the supervision of their faculty supervisor, who is listed as the Principal Investigator (PI) on this application. Please recognize that the application will need to be submitted for review by the faculty supervisor, who will appear as the PI in the Project Team Info Tab at the time of submission. The student researcher will need to be listed as the PA in the "Other Project Member Info" section of the “Project Team Info” tab. The submission by the faculty supervisor as PI is to facilitate the application review and approval by the faculty supervisor, who is ultimately responsible for the conduct of the study.    Both the student researcher and the faculty supervisor are to be in agreement with the declarations.**  |
| **10.1\*** | **As the Principal Applicant for this project, I confirm that I will comply with the TCPS2 and all UNBC policies and procedures governing the protection of human participants in research.** |  |
| [ ]  I agree |
| **10.2\*** | **As the Principal Applicant for this project, I will ensure that the project is performed by qualified and appropriately trained personnel in accordance with the UNBC Integrity in Research & Scholarship policy.** |  |
| [ ]  I agree |
| **10.3\*** | **As the Principal Applicant for this project, I will ensure that any significant changes needed for the REB cleared protocol (including support documents such as consent form/statements) are first submitted to the REB as an amendment and are approved prior to implementation.**  |  |
| [ ]  I agree |
| **10.4\*** | **As the Principal Applicant for this project, I will ensure that any significant adverse effects to research participants are promptly reported to the REB.** |  |
| [ ]  I agree |
| **10.5\*** | **As the Principal Applicant for this project, I will ensure a renewal application is submitted to the REB three weeks prior to the end of the initial approval period if the project is to continue beyond the initial approval period.**  |  |
| [ ]  I agree |
| **10.6\*** | **As the Principal Applicant for this project, I confirm that all research personnel that will have access to data collected during this project have successfully completed the required Tri Council Policy Statement (TCPS) tutorial.**  |  |
| [ ]  I agree |