**Full Behavioral Research Ethics Board (BREB) Application**

This is a word document of the entire Behavioral Research Ethics Board application as of Mar 1, 2020, with the exception of sections relevant to faculty/instructors conducting [course-based research projects](https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/Course-Based_Research_Project_Guidelines.pdf). Researchers can use this document to draft their ethics application before completing the online version in RISe (<https://www.rise.ubc.ca/>). Students may find it a helpful resource for planning their ethics application with their supervisor.

Note that while the document contains all possible pages in the application, when you complete it in RISe, some pages will only appear if you have answered “yes” to certain questions. For example, “Page 3: Study Conflict of Interest” only appears if you select “yes” in Box 2.6. Short-form ethics applications for research that exclusively uses surveys or secondary use of data are also embedded in the document. If you are only conducting surveys, you should only complete Pages 1-4, K and 9. If you are only conducting research using secondary use of data, you should only complete Pages 1-4, L and 9.

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* For research ethics guidance notes see: [Guidance Notes on Behavioral Applications](https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes/guidance-notes-behavioural-applications) (guidance notes are numbered to match the boxes in the application)
* For additional instructions on how to complete the application see: [Application Guidance Notes](https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/BREB_Guidance.Oct-2019.pdf) (also available in the online version of the application in RISe by clicking on the question marks )
* For more research ethics resources see: [BREB Guidance Notes](https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes)

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| Page 1: Principal Investigator & Study Team |
| **1.1. Principal Investigator** |  |
| Enter Principal Investigator’s secondary appointments or affiliations (including Health Authorities), if applicable |  |
| **1.2. Primary Contact** \*If the primary contact will also be working on the study (i.e., accessing participants and/or data), they should also be listed in Box 1.3A, 1.4A or 1.5A. Students conducting the study for their graduate project should also list themselves in Box 1.3A. |  |
| **1.3A. Co-Investigators - Online Access** |  |
| **1.3B. Describe each Co-I's role in study**e.g. statistician, supervisor, adviser, student etc. Ensure individual is entered in Box 1.3A |  |
| **1.4A. Additional Study Team Members - Online Access** |  |
| 1.4B. Describe each Additional Study Team Members' role in studye.g. staff, research assistant etc. |  |
| **1.5A. Additional Study Team Members - No Online Access** |  |
| 1.5B. Describe each Additional Study Team Members' (no online access) role in studye.g. external supervisor, consultant etc. |  |
| **1.6. Tri Council Policy Statement (TCPS) Tutorial** Have all research personnel completed the required TCPS2 tutorial? |  [ ]  Yes [ ]  No |
| **1.7. Project Title**Enter the title of this research study as it will appear on the certificate. \*The title given here must match the title on the study documents. |  |
| **1.8. Project Nickname**Enter a nickname for this study. What would you like this study to be known as to the Principal Investigator and study team? |  |
| Page 2: Study Dates and Funding |
| 2.1.A. 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 approvals are obtained.
 |  [ ]  Yes Estimated start date:  |
| **2.1.B. Estimated end date** | Estimated end date:  |
| **2.2.A. Types of Funds**Please select the applicable box(es) below to indicate the type(s) of funding you are receiving to conduct this research. You must then complete section 2.3 and/or section 2.4 for the name of the source of the funds to be listed on the certificate of approval. |  [ ]  Grant-in-aid [ ]  Grant  [ ]  For-Profit Sponsor (Industry or Pharmaceutical) [ ]  Internal Funds [ ]  No Funding [ ]  Other (Enter details in 2.3 or 2.4 as appropriate) |
| **2.2.B. For Industry Sponsored studies, please provide a sponsor contact.** |  |
| **2.3.A. Research Funding Application/Award Associated with the Study that was Submitted to the UBC Office of Research Ethics** | UBC Number (FXX-XXXXX):  |
| **2.3.B. If a research funding application was submitted to another institution besides a UBC affiliated institution, which institution is administering the funds?** |   |
| **2.4.A. Research Funding Application/Award Associated with the Study not listed in question 2.3.** |  UBC Number (FXX-XXXXX):  |
| **2.4.B. Please enter any applicable information about your funding which is not already shown in Box 2.3A or 2.4A (including funding applied for but not yet received).** |  |
| **2.5.A. Is this a DHHS grant?** |  [ ]  Yes [ ]  No |
| **2.5.B. If yes, please select the appropriate DHHS funding agency from the selection box.** |   |
| **2.6. Study Related Conflict of Interest** Conflicts of Interest (COIs) in research are situations where someone’s personal interests (financial, career, or other) could compromise or could be perceived to compromise the objective conduct of research or integrity of the data.  Conflicts of interest can arise naturally from an Investigator’s engagement inside and outside the University, 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. Do the Principal Investigator, Co-Investigators and/or their related parties have any personal interest(s) that could compromise or reasonably be perceived to compromise the objective conduct of the research or the integrity of the data generated by the study? Personal interests may include business, commercial or financial interests, dual roles (e.g. PI and Doctor), as well as personal matters and career interests. |  [ ]  Yes [ ]  No |
| Page 3: Study Conflict of Interest (This page only appears if you select “yes” in Box 2.6) |
| **3.1. 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?** 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\*: 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 (a company, partnership, or non-profit corporation) whose interests could be affected by the outcome of this research. provides services (e.g., non 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. has intellectual property rights or interests linked in any way to this study (e.g., patents, copyrights, royalties or other payments, etc). \*Note: immediate family members include partners and children (whether living in the household or not). |   |
| **3.2. 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 in the space below: |   |
| **3.3. Please advise how you propose to manage any actual, perceived, or potential COI outlined above in 3.1. or 3.2.:** |  |
| **3.4. Are all COI declarations for the Principal Investigator and Co-Investigators up to date?** |  |
| Comments: |  |
| Page 4.A: Study Type (Boxes 4.1 to 4.2C)  |
| **4.1. Application Type**Indicate whether your application is Clinical or Behavioural. |  [ ]  Behavioral [ ]  Clinical |
| **4.2.A. Institutions and Sites for Study**(including study team members' institutional affiliations under which this research is being conducted) |

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| --- | --- |
| Institution | Site |
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| 4.2.B. Non-UBC Institutions and Sites for Study(including study team members' institutional affiliations under which this research is being conducted) |

|  |  |
| --- | --- |
| Institution | Site |

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| 4.2.C. Please enter any other locations where the research will be conducted under this Research Ethics Approval(e.g., Name of privately-owned clinic, community centre, school, classroom, participant's home, in the field - provide details). |  |
| Page 4.B: Behavioural Study Type (Boxes 4.2D to 4.6)  |
| **4.2.D. Roles of Study Sites and Institutions** |

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| **Study Site** | **Accessing Records or Charts** | **Analysing Data or Utilizing Lab Space** | **Recruiting Participants** | **Team Member Affiliations** |
| --- | --- | --- | --- | --- |
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| **4.3.A. 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: REB study number(s):  |
| **4.3.B. If applicable, please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.** |  |
| **4.3.C. Have you received any information or are you aware of any rejection of this study by any Research Ethics Board? If yes, please provide known details and attach any available relevant documentation in Box 9.7.** |  [ ]  Yes [ ]  No |
| Please provide known details: |   |
| **4.4.A. External peer review details:** |  |
| **4.4.B. Internal (Institution or hospital) peer review details:**\*If this is for a student project, please confirm that the research proposal has been signed off by the student’s supervisor (or committee members) if applicable. All studies above minimal risk require a peer review. The consent form should also indicate that this project is part of a graduate degree. |  |
| **4.4.C. If this research proposal has not received any independent** **scientific/methodological peer review, explain why no review has taken place.** |  |
| **4.5.A. After considering the level of risk your research involves and the vulnerability of your study population, please tick one box below that best represents the overall level of risk.** | Please check **ONE** box only:

|  |  |
| --- | --- |
| **Participant Vulnerability** | **Research Risk** |
| Low | Medium | High |
| Low | 1 [ ]  | 1 [ ]  | 2 [ ]  |
| Medium | 1 [ ]  | 2 [ ]  | 3 [ ]  |
| High | 2 [ ]  | 3 [ ]  | 3 [ ]  |

 |
| **4.5.B. Provide explanations for the assessments of research risk and participant vulnerability reported above.**  |  |
| **4.5.C. Does your application fall under minimal risk (i.e., was it assigned an overall risk level of 1 or a blue box on the minimal risk matrix above)?** |  [ ]  Yes [ ]  No |
| **4.6. Does this study require review and approval by another Canadian REB outside of Research Ethics British Columbia (REBC)? (Note that you CANNOT change your response to this question after the study has been approved, i.e. through an amendment.)** |  [ ]  Yes [ ]  No |
| Page 4.C: Behavioural Study Type (Boxes 4.7 to 4.8)   |
| **4.7.A Creation of a Research Database or Registry Does this study involve the creation of a research database or registry with a local custodian for future unspecified research?** |  [ ]  Yes [ ]  No |
| **4.7.B. Is the purpose of this application exclusively to obtain approval for the creation of a research database or registry? [Note: if the creation of the database or registry is part of a bigger project also included in this application, you must answer no below.]**(Note if you select “yes” here you only need to complete pages 1-4, B and 9.) |  [ ]  Yes [ ]  No |
| **4.8. Course-based research project Please review the guidance on submitting course-based research projects before responding, to confirm that your application will meet the criteria.  Is this application intended to cover projects conducted for pedagogical purposes within a course?**(Note that only faculty/instructors can submit course-based research projects. This document does not include pages relevant to these types of projects, please see the online version of the application in RISe.) |  [ ]  Yes [ ]  No |
| If yes, please state whether your department has a Departmental Ethics Officer (DEO) and, if so, indicate their name below. |  |
| **4.9. Survey Research Is this a minimal risk study exclusively using a survey for data collection?**(Note if you select “yes” here you only need to complete pages 1-4, K and 9.) |  [ ]  Yes [ ]  No |
| **4.10. Secondary Use Is this a minimal risk study exclusively analyzing previously collected data?**(Note if you select “yes” here you only need to complete pages 1-4, L and 9.) |  [ ]  Yes [ ]  No |
| Page B: Creation of a Research Database (This page only appears if you select “yes” in Box 4.7.A) |
| **B.1. What is the scope and purpose of the registry?** |  |
| **B.2. What are the anticipated benefits of the registry?** |  |
| **B.3. Over what period of time will data be collected?** |  |
| **B.4. Sources B.4.A. What information source(s) are you accessing?** |  |
| **B.4.B. Provide specific details about the source(s), including the name of the registry, type of records, location etc.** |  |
| **B.5. Confidentiality B.5.A. Are you collecting personally identifying information?** |  [ ]  Yes [ ]  No |
| **B.5.B. Describe the type of personally identifying information you will be collecting and provide a justification for its inclusion in the registry.** |  |
| **B.5.C. How long will data remain identifiable (i.e., when, if ever, will it be irreversibly anonymized)? Explain why data would need to remain identifiable, if applicable.** |  |
| **B.6. Consent B.6.A. Will participants consent to be included in the registry and to have their data used for research purposes?** | [ ]  Yes [ ]  No |
| **B.6.B. Who will explain the consent form and invite participants to contribute? Where will consent be obtained and under what circumstances?** |  |
| **B.7. If you do not plan to obtain individual participant informed consent, please click on the question mark and provide justification using the criteria listed.** |  |
| **B.8. Participant access to data and withdrawal B.8.A. Will individual participants have the right to access their data, or to amend or withdraw their information?** | [ ]  Yes [ ]  No |
| **B.8.B. If you answered no, please provide a justification; if you answered yes, go to B.8.C.** |  |
| **B.8.C. Provide details of the process for accessing and/or withdrawing data, including what data can be withdrawn.** |  |
| **B.9. What entity or who will have custodianship of the registry?** |  |
| **B.10. What steps will be taken to ensure the security of the data?** |  |
| **B.11. Describe any risks associated with the possible disclosure of the data.** |  |
| **B.12. Data Transfer B.12.A. Will data be sent outside of the institution? If No, skip to B.13.** | [ ]  Yes [ ]  No |
| **B.12.B. Explain why it will be necessary to send the data outside of the institution. Indicate what data will be sent, where it will be sent, who it will be sent to, how it will be transferred (faxed, emailed, couriered, encrypted electronic transfer, etc.) and where it will be stored.** |  |
| **B.12.C. Will there be a data transfer agreement?** |  |
| **B.13. Data Linking B.13.A. Do you plan to link the data to any other registries? If No, skip to B.14.A.** | [ ]  Yes [ ]  No |
| **B.13.B. Identify the data set, how the linkage will occur, and provide a list of data items in the other registry. Also identify what personal information will be used to link the registries and how confidentiality regarding this shared information will be preserved.** |  |
| **B.14. Data Retention B.14.A. How long are you planning to keep the data?** |  |
| **B.14.B. If the data will be destroyed, indicate the planned method for erasure/destruction.** |  |
| **B.15. Future Use B.15.A. Will the information in the registry be retained as an ongoing registry (or as part of an ongoing registry) for future research?** | [ ]  Yes [ ]  No |
| **B.15.B. Provide a full description of the data stewardship process.** |  |
| Page K: Survey Research (This page only appears if you select “yes” in Box 4.9) |
| **K.1. Provide a brief description of the project, including the study purpose, in lay language.** |  |
| **K.2.A. Describe the criteria for participation.** |  |
| **K.2.B. How many participants are expected to take part in this study?** |  |
| **K.3. Describe your recruitment methods. Attach the relevant documents to page 9.** |  |
| **K.4.A. Are you collecting personal identifiers?** |  [ ]  Yes [ ]  No |
| **K.4.B. What identifiers are you collecting?** |  |
| **K.4.C. What safeguards will be in place to protect the confidentiality and security of the data? (e.g. data will be anonymized or de-identified)** |  |
| **K.5.A. How will the survey(s) be administered? (Check all applicable options)** |  [ ]  Web-based  [ ]  Paper |
| **What platform will be used?**\*The UBC hosted version of Qualtrics is recommended. |  |
| **Who will distribute the surveys and how will the surveys be distributed?** |  |
| **If Other is selected, please describe** |  |
| **K.5.B. In what countries will the data be stored during collection?** |  |
| **K.6. How will consent be obtained? Attach the relevant documents to page 9.** |  |
| **K.7. Remuneration. Describe if any reimbursement/remuneration will be provided to participants.** |  |
| **K.8.A. Specify how long the data will be retained, where it will be stored, who will have access to it, and how it will be kept secure during the lifecycle of the study.**\*Specify your long-term storage methods for electronic and paper-based data, who will be responsible for the data and how long it will be retained. For the full requirements see [UBC Policy SC6](https://research.ubc.ca/support-researchers/conducting-your-research/responsible-conduct-research-scholarly-integrity) on Scholarly Integrity. |  |
| **K.8.B. If the data will be destroyed after the required storage period, describe the destruction process for each storage format.** |  |
| **K.9. Are there plans for future use of the data?** |  [ ]  Yes [ ]  No |
| Explain who will have access to the data in the future and for what purpose. |   |
| Page L: Secondary Use of Data (This page only appears if you select “yes” in Box 4.10) |
| **L.1.A. Provide a brief description of the project, including the study purpose, in lay language.** |  |
| **L.1.B. Describe the datasets being used.** |  |
| **L.1.C. Who is the data custodian (original data owner)?** |  |
| **L.1.D. Is permission to access the data required?** |  [ ]  Yes [ ]  No |
| If yes, describe what type of permission is needed to access data. |  |
| If permission is required to access data, has it been received? |  [ ]  Yes [ ]  No |
| **Attach approval** |  |
| If no, describe the status of your access request. |  |
| **L.1.E. Is the data that the researcher has access to identifiable?** |  [ ]  Yes [ ]  No |
| **What identifiers will be included?** |  |
| **How will identities of participants be protected?** |  |
| **L.1.F. Will there be any data linkages?** |  [ ]  Yes [ ]  No |
| **Who will be responsible for the data linkage and how will this be done?** |  |
| **Is there a possibility that the data linkage will generate identifiable information?** |  [ ]  Yes [ ]  No |
| Describe what identifiers would be generated by the data linkage. |  |
| **L.2. Was consent obtained from participants for secondary use of data?** |  [ ]  Yes [ ]  No |
| If no, the following conditions will need to be met. If any of these conditions cannot be met, please include a justification in the text box below with regards to why they cannot be met. (This question only appears if you select “no” in Box L.2 **AND** “yes” in Box L.1.E) |  [ ]  The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information [ ]  The researchers have obtained any other necessary permission for secondary use of information for research purposes [ ]  The researchers will comply with any known preferences previously expressed by individuals about any use of their information [ ]  Identifiable information is essential to the research [ ]  It is impossible or impracticable to seek consent from individuals to whom the information relates [ ]  The use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates |
| **Conditions Not Met Justification** |  |
| **L.3.A. Where will the data be retained, and for how long will it be retained?** |  |
| **L.3.B. If the data will be destroyed, describe how.** |  |
| **L.4. Are there plans for future use of the data resulting from this study?** |  [ ]  Yes [ ]  No |
| If yes, explain who will have access to the data in the future and for what purpose. |  |
| Page 5: Summary of Study and Recruitment |
| **5.1.A. Provide a brief statement about the project written in lay language. Do not exceed 100 words and do not cut and paste directly from the study proposal.** |  |
| **5.1.B. Summarize the research proposal, including study purpose, hypothesis, study population, and research method.** |  |
| **5.2. Inclusion Criteria Describe the participants being selected for this study, and list the criteria for their inclusion.** |  |
| **5.3. Exclusion Criteria Include details if otherwise eligible participants will be excluded due to other characteristics. If no exclusion criteria are applicable, enter n/a.** |  |
| 5.4. 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 materials, including letters of initial contact, posters, scripts and advertisements, to Box 9.4.\*If your study employs snowball sampling, it must conform to [BREB’s Third Party Recruitment Guidelines](https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes/guidance-notes-behavioural-applications#5pt4pt4). Contacts should not give the researchers the names and contact information or any other detail about potential participants without first obtaining permission from those participants, unless a strong justification is provided. |  |
| **5.5. Use of 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 permission to access this information, and to collect and use this information, will be obtained.** |  |
| **5.6. 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.** |  |
| 5.7. Research Types Select all that apply to your study.Please review the research methods descriptions before responding. If none apply, please select None of these Methods |  [ ]  Action Research (researchers investigating their own practice) [ ]  Autobiography/Auto-Ethnography  [ ]  Community Based Research (collaboration with community on design and methods) [ ]  Data Linkage [ ]  Deception [ ]  Ethnographic Fieldwork [ ]  Expert Interviews [ ]  Focus Groups [ ]  Masters Research [ ]  Naturalistic Observation [ ]  Participant Pools [ ]  PhD Dissertation Research [ ]  Secondary Use of Data [ ]  Undergraduate Research [ ]  Use of Medical Records [ ]  Videotaping [ ]  None of these Methods |
| Page 6: Participant Information and Consent Process |
| **6.1. Time to Participate**\*Ensure the time to participate given here matches that given in the study documents. |  |
| **6.2. Risks and Mitigation** |  |
| **6.3. Potential Benefits** |  |
| **6.4. Impacts on Community** |  |
| **6.5. Reimbursement and Incentives**\*Ensure the remuneration mentioned here matches that given in the study documents. |  |
| **6.6. Obtaining Consent Include details of where and when consent will be obtained and how it will be documented.** |  |
| **6.6.A. Waiver of Consent** |  |
| **6.7. Time to Decide** |  |
| **6.8. Capacity to Consent Will participants have the capacity to give fully informed consent on their own behalf?** |  |
| **6.8.A. Provide details of the nature of the incapacity (for instance, young age, mental or physical condition).** |  |
| **6.8.B. If a participant does not have the capacity to give fully informed consent, who will consent on their behalf? Ensure the relevant consent form (parent/caregiver, substitute decision maker, legally authorized representative) is attached to page 9.** |  |
| **6.8.C. If a participant does not have the capacity to give fully informed consent, will they be able to give assent to participate?** |  |
| **6.8.D. If yes, explain how assent will be sought.  Please be sure to attach copies of the assent form to page 9.** |  |
| **6.9. Ongoing Consent** |  |
| **6.10. Provisions for Consent (e.g., special assistance, Braille, translations/translator)** |  |
| **6.11. Restrictions on Disclosure** |  |
| Page 7: Number of Participants |
| **7.1. External Approvals****A. Other Institutions:** |  [ ]  Yes [ ]  No |
| **B. Please select Add to enter the name of the institution and attach the approval letter if received.** |

|  |  |
| --- | --- |
| Name of Institution:  |  |

  |
| **C. Other Jurisdiction or Country (if NO, go to 7.1.G):** |  [ ]  Yes [ ]  No |
| **D. Please select Add to enter the name of the jurisdiction or country and if you have already received approval attach the approval letter.** |

|  |  |
| --- | --- |
| Name of Jurisdiction or Country:  |  |

 |
| **E. Has a Request for Ethics Approval been submitted to the institution or responsible authority in the other jurisdiction or country? (Append a copy of any such document to this application once it is received).** |  [ ]  Yes [ ]  No |
| **F. If a Request for Approval has not been submitted, provide the reasons below:** |   |
| **G. Does this research focus on Indigenous peoples, communities or organizations?**  |  [ ]  Yes [ ]  No |
| Section G: Indigenous Peoples, Communities or Organizations (Questions G.1.A-G.3 only appear if you select “yes” in Box G) |
| **G.1.A. Will the research be conducted on Indigenous reserves, 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: |   |
| **G.1.B. 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: |   |
| **G.1.C. Does the research seek input from participants regarding a community’s cultural heritage, artifacts, traditional knowledge or unique characteristics?** |  [ ]  Yes [ ]  No |
| If yes, please provide details: |   |
| **G.1.D. Will Indigenous identity or membership in an Indigenous community be used as a variable for the purposes of analysis?** |  [ ]  Yes [ ]  No |
| If yes, please provide details: |   |
| **G.1.E. Will the results of the research refer to Indigenous communities, peoples, language, history or culture?** |  [ ]  Yes [ ]  No |
| If yes, please provide details: |   |
| **G.2. Community Engagement G.2.A. If you answered yes to questions a), b), c), d), or e), have you initiated or do you intend to initiate an engagement process with the Indigenous collective, community or communities for this study?** |   |
| **G.2.B. If you answered Yes to question G.2.A., 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. Attach any documentation of consultations (i.e. formal research agreement, letter of approval, email communications, etc.) below.** |   |
| Attachment: |   |
| **G.3. No community consultation or engagement If you answered no to question G.2.A., 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.** |   |
| **H. Registration for Publication of Clinical Trials.** |  [ ]  Yes [ ]  No |
| If 'Yes', click 'Add' to enter the following information. |

|  |  |  |  |
| --- | --- | --- | --- |
| Has it been registered? | Indicate the Authorized Registry used: | Enter your Clinical Trial unique identifier: |  |

 [ ]  Yes [ ]  No \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **7.2. Number of Participants****A. How many participants will take part in the entire study (i.e., world-wide)?** |  |
| **B. How many participants will take part at institutions covered by this Research Ethics Approval?** |  |
| **7.3. Principal Investigator and Research Team Experience**\*The qualifications of all researchers involved (including the principal investigator) as it relates to their role in this research project should be described, including training and experience relevant to conducting qualitative research, rather than degrees completed. |  |
| Page 8: Confidentiality |
| **8.1. Security of Data During the Course of the Study**\*Identifiable electronic data must be stored on a secure server, such as the UBC server, or on a secure device that is both password protected and encrypted. |  |
| **8.2. Access to Data** |  |
| **8.3. Protection of Personal Information**\*If a master list will be created linking codes to names, it must be password protected, encrypted and stored separately from the rest of the data. |  |
| **8.4. Transfer of Data Will any data be transferred (made available) to persons or agencies outside the University?** |  |
| If yes, 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. Attach the data transfer agreement if applicable. |  |
| **8.5. Retention and Destruction of Data**\*Specify your long-term storage methods for electronic and paper-based data, who will be responsible for the data, how long it will be retained and, if the data will be destroyed, your data destruction methods. For the full requirements see [UBC Policy SC6](https://research.ubc.ca/support-researchers/conducting-your-research/responsible-conduct-research-scholarly-integrity) on Scholarly Integrity. |  |
| **8.6. Future Use of Data** |  |
| **8.7. Feedback to Participants** |  |
| Page 9: Documentation \*Each document attached must contain a version date (mm/dd/yy) in the footer that matches that given on page 9. Copyrighted questionnaires should use the date of publication. For document guidelines see, <https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes>  |
| **9.1. Research Proposal** |  |
| **9.2. Documentation of Consent** |  |
| **9.3.  Documentation of Assent** |  |
| **9.4. Advertisement to Recruit Participants** |  |
| **9.5. Questionnaire, Questionnaire Consent Cover Letter, Tests, Interview Scripts, etc.** |  |
| **9.6. Letter of Initial Contact** |  |
| **9.7. Other Documents** |  |
| **9.8. Websites and Social Media** |   |
| **Page 10: Fee for Service** |
| How to submit Please indicate which of the following methods of payment will be used for this application: |   |
| Contact information regarding where to send the invoice. |   |
| Page 11: Hospital/Health Authority\*If any hospital/health authority sites are selected in questions 4.2A or 4.2B you will be asked to complete an additional page 11 for each site selected. |
| Page 12: Save Application |
| In the online version of the application in RISe, you will have the options to:1. **Submit your application** – By clicking “Continue” in the application, then “Submit Application” on the study homepage (note only the PI can submit the application)
2. **Save your work and return to it later** – By clicking “Continue” in the application

The application will stay in “Pre-Submission” state until it has been submitted by the PI. Once submitted, it will change to “Department Review” state. See below for a map of the review process. |

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