|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [logo_wordmark](http://www.unbc.ca) |  | **Research Ethics Board**  **(REB)**  **Office of Research**  Room CJMH 1065  3333 University Way  Prince George, BC, V2N 4Z9  (250) 960-6735  Email: [reb@unbc.ca](mailto:reb@unbc.ca) |  | Protocol #:  Date Received:  Romeo #:  For Office Use Only |
| **Research Ethics Protocol For Research With Human Participants** | | | | | |
| **Renewals and Amendments**  **(Pre-Romeo)** | | | | | |

Please refer to the [UNBC Policy on Ethics Review of Research Involving Human Participants](https://www.unbc.ca/sites/default/files/sections/research/20200422ethicsreviewofresearchinvolvinghumanparticipantspolicyandresearchethicsboardtor.pdf) prior to completion and submission of this application. Reviews are conducted according to the principles and spirit of the [*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS2 (2022)*](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html). If you have questions about or require assistance with the completion of this form, please contact the Office of Research at (250) 960-6735 or [reb@unbc.ca](mailto:reb@unbc.ca).

**SECTION A**

**TYPE OF APPLICATION, please tick all that apply:**

|  |  |
| --- | --- |
|  | **Renewal**  **\*Please submit 2 months prior to the expiry of your current approval period** |
|  |  |
|  | **Amendment(s)** |
|  |  |
|  | **This application involves in-person research activities**  The research team will ensure 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. |

**HOW TO SUBMIT**

|  |  |
| --- | --- |
| 1. | Please complete sections [A](#Section_A), [B](#Section_B), [C](#Section_C), [D](#Section_D) and the [Supporting Document Checklist](#Supporting_Document_Checklist). Incomplete applications will not be processed. |
| 2. | Make sure to attach a copy of the original REB certificate or approval letter indicating the approval number, date and title of the project. |
| 3. | Please submit the completed and signed application electronically to [reb@unbc.ca](mailto:reb@unbc.ca). |

**APPLICATION DEADLINE**

Applications are reviewed on an ongoing basis. Please allow two weeks for a response from the REB.

**SECTION B**

**APPLICANT INFORMATION** (Please complete all sections that apply)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. | **Principal Investigator:**  For students, please include the name and email address of your Supervisor below | |  | | |
|  | **Program/Department/School:**  Identify institution if not at UNBC | |  | | |
|  | **Phone Number:** |  | | **UNBC Email:** |  |
|  | **Student Supervisor’s Name:** |  | | **UNBC Email:** |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 2. | **Co-Investigator(s)\*:** | |  | | | | | |
|  | \*Please append additional pages with Co-Investigator(s) names, if necessary | | | | | |  | \*Separate page(s) attached |
|  | **Program/Department/School:**  Identify institution if not at UNBC | | |  | | | | |
|  | **Phone Number:** |  | | | **Email:** |  | | |

**SECTION C**

**RESEARCH PROJECT DETAILS**

|  |  |  |
| --- | --- | --- |
| 1. | **Title of Project:** |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 2. | **Type of Project** |  | | | | |
|  | Undergraduate |  | Research (including Honours Thesis) | |  | Classroom Project  (Undergraduate student) |
|  | Graduate |  | Research (including Thesis/ Dissertations/ Projects) | |  | Classroom Project  (Graduate student) |
|  | Post Doctoral |  | Research | | | |
|  | Faculty |  | Research | |  | Classroom Project (Faculty) |
|  | Other (Please explain) | | |  | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 3. | **Source of Funding**  Please refer to TCPS2, Article 7.4, for more information on Financial Conflicts of Interest | | | | | | | | | | | | | |
|  | (a) | Is there funding associated with this project? | | | |  | | Yes |  | | No | |  | N/A |
|  | (b) | Funding Source(s): |  | | | | | | | | | | | |
|  | (c) | Entered into Romeo |  | Yes |  | | No | | |  | | N/A | | |
|  | (d) | Romeo File number  (if applicable) |  | | | | | | | | | | | |
|  | (e) | Romeo Project Title  (if applicable) |  | | | | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| 4. | **Project Dates** | | |
|  | (a) | Date Research will Continue/Resume:\*  \*This date should be no sooner than two weeks from the application submission | |  | | --- | | Click here to enter a date. | | mmm-dd-yyyy | |
|  | (b) | Date Research is Expected to be Completed:\*\*  \*\*REB approval is for 12 months at a time. A Renewal Application will need to be submitted if the project duration will be longer than 12 months. | |  | | --- | | Click here to enter a date. | | mmm-dd-yyyy | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 5. | **Participant Recruitment** | | | | | |
|  | (a) | Does this protocol involve the active recruitment of human participants?  If “No”, please proceed to question 7. |  | Yes |  | No |
|  | (b) | Is recruitment ongoing? |  | Yes |  | No |
|  | (c) | Are in-person research activities to occur? |  | Yes |  | No |
|  |  | * If “Yes”, and the research involves populations that may face increased risk of COVID-19, or communities where local COVID-19 policies and protocols are in place, please answer question 6; * If “Yes”, and the research does not involve the above increased risk or have policies or protocols in place, proceed to question 7. * If “No”, proceed to question 7. | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 6. | **In-Person Research Activities where research involves populations that may face increased risk of COVID-19, or communities have COVID-19 policies or protocols in place** | | | | | |
|  | (a) | Provide justification for commencement, resumption, or new in-person research activities during the COVID-19 Pandemic: | | | | |
|  | (b) | Identify any virtual methods that will be available as an option to participants in the event in-person research is again halted for COVID-19 mitigation: | | | | |
|  | (c) | 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 COVID-19 webpage](https://www.unbc.ca/research/covid-19-updates-on-research-activities-and-support-personnel). A completed copy of the SRP is to be submitted with this ethics application that involves resumption/ongoing in-person research. The SRP will be sent for review in a concurrent, separate process through the UNBC Office of Research and Safety Office. | | | | |
|  | (d) | SRP appended to this application? |  | Yes |  | No |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 7. | **Progress of study, and any amendments needed for the protocol** | | | | | |
|  | (a) | Are there any changes to be made to the protocol that most recently received clearance from the REB? |  | Yes |  | No |
|  | (b) | If “Yes”, please provide a brief summary of the changes to be made to the protocol and the overall progress of the study, with details on adjustments to the study implementation and its timelines. Please describe the nature and significance of changes, and the reason why the proposed changes are to be made: | | | | |
|  | (c) | If “No”, please provide a brief summary of the overall progress of the study, with details on adjustments to the study implementation and its timelines: | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 8. | **Risks to Participants** | | | | | |
|  | (a) | Indicate if the proposed changes will result in a change of risk for the study participants or research team beyond what was originally anticipated (if renewal of study with no changes, please indicate “No”) |  | Yes |  | No |
|  | (b) | If yes, please explain: | | | | |
|  | (c) | Does the renewal/amendment have little or no changes to the research, without increase in risk to the participants or other ethical implications for the participants, since the latest review and approval by the REB?  Please review the [Research Risk Assessment Guidelines](https://www.unbc.ca/sites/default/files/sections/research/researchriskassessmentguidelines_0.pdf) for further details. |  | Yes |  | No |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 9. | **Informed Consent** | | | | | | | |
|  | Participant Information must include a clear statement of both general and COVID-19 related risks. If in-person research activities are to occur, a clear statement of risks, along with limits to anonymity and confidentiality due to contact tracing requirements, must also be included. | | | | | | | |
|  | (a) | Do the proposed changes to the study protocol require any amendments to the consent process?  If “Yes”, ensure updated consent documentation is appended to this application |  | Yes |  | No |  | N/A |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 10. | **Unanticipated Problems** | | | | | |
|  | An unanticipated problem is any incident, experience or outcome that meets **all** of the following criteria:   * Unexpected (in terms of nature, severity, or frequency); * Related or possibly related to the participation in the research; * Suggests that the research places the research participants, or others, at a greater risk of harm than was previously known or recognized. | | | | | |
|  | (a) | After reading the definition of “unanticipated problems” above, are there any unanticipated problems that have occurred? |  | Yes |  | No |
|  | (b) | If “Yes”, please explain: | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 11. | **Summary of Changes** | | | | | |
|  | Are any of the following revised or new documents being submitted along with this renewal/amendment application? | | | | | |
|  | (a) | Revised proposal (optional) |  | Yes |  | No |
|  | (b) | Revised consent and/or assent documents |  | Yes |  | No |
|  | (c) | Updated site permissions and consents for research activities, which include any site-specific COVID-19 considerations |  | Yes |  | No |
|  | (d) | Other revised or new documents  If “Yes”, please indicate which documents are included in the “[Supporting Document Checklist](#Supporting_Document_Checklist)” at the end of this application form. |  | Yes |  | No |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 12. | **Conflicts of Interest**  Please refer to TCPS2, Article 7.4 | | | | | |
|  | (a) | Are you aware of any real, potential, or perceived conflicts of interest on the part of any personnel involved in the study that has emerged since the study protocol was initially approved? |  | Yes |  | No |
|  | (b) | If “Yes”, please describe: | | | | |

|  |  |
| --- | --- |
| 13. | **Lapsed Studies** |
|  | If the Research Ethics Board approval has expired, please provide a written explanation for the late renewal and confirmation that NO study related actions took place during the time over which there was no valid ethical approval. Explain what strategies have now been put in place: |

**Section D – Signatures**

**All researchers participating in the project must sign below in order for this application to be processed and reviewed.**

As the **Principal Investigator** on this project, my signature confirms that I will comply with the Tri-Council Policy Statement and all University of Northern British Columbia policies and procedures governing the protection of human participants in research, including but not limited to, ensuring that:

* the project is performed by qualified and appropriately trained personnel in accordance with REB protocol;
* no changes to the REB cleared protocol or consent form/statement are implemented without notification to the REB of the proposed changes and receipt of the subsequent REB clearance;
* significant adverse effects to research participants are promptly reported to the REB; and
* a further renewal application is submitted to the REB for continuation of the study beyond this 12 month renewal period.

As a **Student Researcher**, in addition to the above, my signature **also** confirms that I am a registered student in good standing. My project proposal has been reviewed and cleared by my advisory committee (where applicable), and **this application has been reviewed and approved by my Supervisor**. If my status as a student changes, I will inform the REB. ***For all students, the signature of a Faculty Supervisor is also required below.***

As a **Faculty Researcher**, in addition to the above, my signature **also** confirms that I hold an active appointment with the university to conduct this research.

|  |  |  |  |
| --- | --- | --- | --- |
| Signature of Principal Investigator: |  | Date: |  |
|  | | | |
| Signature of Co-Investigator(s): |  | Date: |  |
|  | | | |

As **Faculty Supervisor of the student(s)**, I certify that the information provided in this application is complete and correct, and I approve the scientific merit of the research project.

I understand that as principal **Faculty Supervisor of the student(s)**, I have ultimate responsibility for the conduct of the study, the ethical performance of the project and the protection of the rights and welfare of human participants. I agree to comply with the Tri-Council Policy Statement and all University of Northern British Columbia policies and procedures governing the protection of human participants in research, including, but not limited to, ensuring that:

* the project is performed by qualified and appropriately trained personnel in accordance with REB protocol;
* no changes to the REB cleared protocol or consent form/statement are implemented without notification to the REB of the proposed changes and receipt of the subsequent REB clearance;
* significant adverse effects to research participants are promptly reported to the REB
* a further renewal application is submitted to the REB for continuation of the study beyond this 12-month renewal period.

|  |  |  |  |
| --- | --- | --- | --- |
| Signature of Faculty Supervisor: |  | Date: |  |
|  | | | |

**Supporting Document Checklist**

Please indicate which of the following supporting documents are appended to this application (please add extra lines where necessary). **Include only those documents that have been revised or that are entirely new to this application** (*any* *changes/revisions must be clearly underlined and highlighted*). Please ensure that all documents are **clearly labeled**, that all pages are **clearly numbered**, and attach them **in the order in which they are listed below**.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Additional pages with Co-Investigator(s) names and details | | |
|  | Copy of the original REB certificate or approval letter indicating the approval number, date and title of the project | | |
|  | Other REB approvals | | |
|  | TCPS 2: CORE Certificate | | |
|  | UNBC Institutional consents (e.g. Vice-President Research / Program / Department / School) | | |
|  | Consents from Aboriginal groups or organizations | | |
|  | Other consents (please specify): | |  |
|  | Safe Research Plan for In-Person Research involving populations that may face increased risk of COVID-19, or communities where local policies and protocols are in place regarding the pandemic | | |
|  | Research contract(s) | | |
|  | Participant information letter(s) | | |
|  | Participant consent form(s) | | |
|  | Research assistant/transcriber confidentiality agreement(s) | | |
|  | Participant recruitment materials (e.g. posters, letters, email scripts, and media advertisements) | | |
|  | Interview protocols, questionnaires, survey instruments  (As per TCPS2, Article 10.5, in studies using emergent design in data collection, final versions of questionnaires or interview schedules **must** be submitted to the REB as soon as they become available) | | |
|  | Research proposal | | |
|  | Other (please specify): |  | |
|  | Other (please specify): |  | |
|  |  | | |

***Applicants are reminded that research with human subjects***

***cannot be undertaken prior to***

***obtaining approval by the Research Ethics Board***

***per* *TCPS2, Article 6.11***