**REB TEMPLATE FOR AMENDMENT 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.**

**In cases where the nature and/or the extent of the proposed modifications are substantial, such that the changes result in a study that deviates substantially from the originally approved study or previous modified study, the research ethics board reserves the right to require that a new application form be submitted.**

\*ASTERISK INDICATES A MANDATORY QUESTION

**QUICK LINKS TO TAB SECTIONS:**

[**TAB 1. RESEARCH TEAM**](#TAB_1)

[**TAB 2. PROJECT FUNDING**](#TAB_2)

[**TAB 3. PROJECT INFORMATION AND PROGRESS**](#TAB_3)

[**TAB 4. REQUESTED STUDY MODIFICATIONS**](#TAB_4)

**TAB 1. RESEARCH TEAM**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **1.1** | **If there is a or will be a new Principal Investigator, or the Principal Investigator's contact information has changed, please provide the name and all contact information below.** |  |
|  | | |
| **1.2\*** | **Have there been, or are there changes to be made to the members of the research team, or to their primary contact information since the last REB approval?** | Please ensure all changes to the Research Team made since the last REB approval, or to be made through this Amendment Form, are outlined in this Tab's responses. |
| Yes  No | | |
| **1.3** | **If study team members have been removed or added, or there is new contact information, please describe below.** | Please ensure contact information is provided for new team members, and any updated changes for continuing members is provided. |
|  | | |
| **1.4\*** | **Are you aware of any changes to the real, potential, or perceived conflicts of interest on the part of any personnel involved in the study that have emerged since the study protocol was initially approved?** | Include any conflicts of interest on the part of new Research Team members in this Tab’s responses. |
| Yes  No | | |
|  | | |
| **1.5** | **If you answered "Yes" to the question above, please provide details of the change in conflict of interest.** |  |
|  | | |
| **1.6\*** | **Have there been any changes to the Study Type from "Research" or "Classroom Project", by Faculty, Post Doctoral Fellow, Graduate Student, or Undergraduate Student?** | Please refer to this studies' New Application Form, Q. 3.1, to establish the original Study Type. |
| Yes  No  Other | | |
| **1.7** | **If you checked "Other", please explain. If a new relationship between the researchers has developed, as pertinent to study data management and future analysis, please explain here.** |  |
|  | | |

**TAB 2. PROJECT FUNDING**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **2.1\*** | **Have there been any changes to the funding of this protocol since the most recent ethics approval?** |  |
| Yes  No  N/A | | |
| **2.2** | **If you answered "Yes" to the question above, please provide details of the funding changes.** | Please include: (a) the funding source; (b) the Romeo file number, or a brief explanation why it has not been entered into Romeo; and (c) the Romeo Project Title (or the Project Title used in the funding application). |
|  | | |

**TAB 3. PROJECT INFORMATION AND PROGRESS**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **3.1\*** | **Date research will continue/resume:** | This date should be no sooner than one week from the Amendment Form submission. |
| Click or tap to enter a date. | | |
| **3.2\*** | **Date research is expected to be completed:** | REB approval can be granted for a maximum of 12 months. A Renewal and Study Progress Form needs to be submitted if the study is to run for longer than one year. |
| Click or tap to enter a date. | | |
| **3.3\*** | **Does this protocol involve the active recruitment of human participants? If “No”, proceed to question 3.9.** |  |
| Yes  No | | |
| **3.4** | **Is recruitment ongoing?** |  |
| Yes  No | | |
| **3.5** | **Are in-person research activities to occur?** | (a) 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 3.6; (b) If "Yes", and the research does not involve the above increased risk or have policies or protocols in place, proceed to question 3.9.; (c) If "No", proceed to question 3.9. |
| Yes  No | | |
| **3.6** | **If you answered “Yes” to both Q 3.5 and (a) in Q 3.5 Guidance Note, provide justification for commencement, resumption, or new in-person research activities during the COVID-19 pandemic.** |  |
|  | | |
| **3.7** | **If you answered "Yes" to Q 3.5 and (a) in Q 3.5 Guidance Note, 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.** |  |
|  | | |
| **3.8** | **If you answered "Yes" to Q 3.5 and (a) in Guidance Note, please complete a Safe Research Plan (SRP) which provides 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 as outlined on the Office of Research COVID-19 web page. A completed copy of the SRP is to be submitted with this ethics application amendment (using the "Attachments" tab) that involves resumption/ongoing in-person research with at risk populations. The SRP will be sent for review in a concurrent, separate process through the UNBC Office of Research and Safety Office.** |  |
| SRP uploaded, as needed  SRP uploaded, as not sure  SRP not uploaded, as not required | | |
| **3.9\*** | **An unanticipated problem may have implications for the conduct of the study or the integrity of the research data. After reading the definition of "unanticipated problems" in the guidance note, are there any unanticipated problems that have occurred?** | An unanticipated problem is defined as an incident, experience or outcome that meets all for the following three criteria: a) Unexpected (in terms of nature, severity, or frequency); b) Related or possibly related to the participation in the research; c) Suggests that the research places the research participants, or others, at a greater risk of harm than was previously known or recognized. |
| Yes  Possibly  No | | |
| **3.10** | **If you answered “Yes” to the question above, please briefly explain and complete an Unanticipated Problem Form.** |  |
|  | | |
| **3.11\*** | **Please provide a brief summary of the overall progress of the study. Include details on minor adjustments to the study implementation and its timelines.** | Please note the renewal process does not have the capacity to review changes to an approved protocol, they must be reported through this amendment process. |
|  | | |

**TAB 4. REQUESTED STUDY MODIFICATIONS**

|  |  |  |
| --- | --- | --- |
| **Q #** | **Question** | **Guidance Notes** |
| **4.1\*** | **Please outline the proposed modification(s) to the study, including the rationale for these changes.** | Please outline the details and rationale for the changes. If changes were/are made to the Research Team Members in Tab 1, ensure all relevant participant facing support documents are updated. Please ensure that all modified and/or new documents, including recruitment materials, advertisements, consent forms, questionnaires, surveys, etc., are uploaded to the "Attachments" tab with any changes clearly displayed and an updated version number in the file name, and any document footer of any participant facing documents. Have any new text highlighted and underlined, and use cross out for any text that is to be removed from the original. |
|  | | |
| **4.2\*** | **Does the proposed amendment make any modifications to recruitment of participants?** |  |
| Yes  No | | |
| **4.3** | **If you answered "Yes" to the question above, please provide details of the modifications to recruitment, including your rationale for each of the changes. Ensure to attach copies of revised support documents.** | Please attach copies of revised recruitment scripts, letters, advertisements, invitations, etc. to the "Attachments" tab. Ensure that all documents uploaded to the "Attachment" tab have clearly displayed all changes made from the originally approved document, and an updated version number in the file name, and any document footer of any participant facing documents. Have any new text highlighted and underlined, and use cross out for any text that is to be removed from the original. |
|  | | |
| **4.4\*** | **Does the proposed amendment make any modifications to participant selection criteria (e.g., individuals' characteristics, associations, target number of, pool, group, etc.)?** |  |
| Yes  No | | |
| **4.5** | **If you answered "Yes" to the question above, please provide details of the modifications to participant selection criteria, including your rationale for each of the changes.** | If there is a change in the level of vulnerability of the participant groups(s) include any modifications to the protocol to address this change. Please attach copies of revised recruitment tools, consent forms, advertisements, etc. to the "Attachments" tab. Ensure that all documents uploaded to the "Attachment" tab have clearly displayed all changes made from the originally approved document, and an updated version number in the file name, and any document footer of any participant facing documents. Have any new text highlighted and underlined, and use cross out for any text that is to be removed from the original. |
|  | | |
| **4.6\*** | **Does the proposed amendment make any modifications to the method(s) of data collection, transfer, storage, or disposition/destruction?** |  |
| Yes  No | | |
| **4.7** | **If you answered "Yes" to the question above, please provide details of the modifications to the data collection method, including your rationale for the changes.** | Please attach copies of revised instruments, surveys, interview or focus group questions to the "Attachments" tab. Ensure that all documents uploaded to the "Attachment" tab have clearly displayed all changes made from the originally approved document, and an updated version number in the file name, and any document footer of any participant facing documents. Have any new text highlighted and underlined, and use cross out for any text that is to be removed from the original. |
|  | | |
| **4.8\*** | **Does the proposed amendment make any modifications to the consent process, or require any past participants to re-consent to accommodate the amendments for the protocol?** |  |
| Yes  No | | |
| **4.9** | **If you answered "Yes" to the question above, please provide details of the modifications to the consent process, including your rationale for the changes, and any ongoing or re-consent activities required.** | Please attach copies of revised consent forms, scripts, or letter of information for implied consent to the "Attachments" tab. Please clarify how past participants are to be re-consented, if the protocol modifications make this necessary. Ensure that all documents uploaded to the "Attachment" tab have clearly displayed all changes made from the originally approved document, and an updated version number in the file name, and any document footer of any participant facing documents. Have any new text highlighted and underlined, and use cross out for any text that is to be removed from the original. |
|  | | |
| **4.10\*** | **Will the proposed amendments result in any change to risk for the study participants and/or research team beyond what was originally anticipated?** |  |
| Yes  No  Unsure – Please contact the REB (reb@unbc.ca) | | |
| **4.11** | **If you answered "Yes" to the question above, please provide details of the change to risk for the study participants and/or research team.** | Please provide the following information: (a) What are the changes to the study's risks, and why are they necessary? (b) What changes to the protocol have been made to mitigate or prevent the risks? (c) Have you conveyed the changes to the study's risks and your mitigation strategies to the participants? |
|  | | |
| **4.12** | **Please describe any other modifications proposed for this study not already described above.** | Please also attach any relevant documents to the “Attachment” tab. |
|  | | |