**REB TEMPLATE FOR UNANTICIPATED PROBLEM 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

**QUICK LINKS TO TAB SECTIONS:**

**[TAB 1. Study State](#TAB_1_STUDY_STATE)**

**[TAB 2. Unanticipated Problem - Description](#TAB_2_UNANTICIPATED_PROBLEM_DESCRIPTION)**

[**TAB 3. Unanticipated Problem - Occurrence(s)**](#TAB_3_UNANTICIPATED_PROBLEM_OCCURENCES)

[**TAB 4. Unanticipated Problem - Mitigation**](#TAB_4_UNANTICIPATED_PROBLEM_MITIGATION)

**TAB 1. Study State**

|  |  |  |
| --- | --- | --- |
| **#** | **Question** | **Guidance Notes** |
| 1.1\*  | What is the status of participant recruitment for this study? | State if the Unanticipated Problem to be reported has caused, for example: Active recruitment to be paused; Recruitment is ongoing; Recruitment was complete, with participants engaged in another stage of the study; etc. Please describe. |
|  |
| 1.2\* | Provide a brief summary of the progress of the study up to the time of the problem. | Include whether the study was proceeding as planned and at what stage it has reached at the time of the problem. Maximum 200 Words. |
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**TAB 2. Unanticipated Problem - Description**

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| --- | --- | --- |
| **#** | **Question** | **Guidance Notes** |
| 2.1\* | Is the problem unexpected in terms of nature, severity, or frequency? | State what makes the problem significant for participants in the study. |
|  |
| 2.2\*  | As PI, in your opinion is the unanticipated problem related to the study intervention? |  |
| [ ]  Yes[ ]  Maybe[ ]  No |
| 2.3  | If the response above was "Yes" or "Maybe", please explain here. |  |
|  |
| 2.4\* | Has this type of unanticipated problem occurred in this or a related study, to your knowledge? |  |
| [ ]  Yes[ ]  Maybe[ ]  No |
| 2.5  | If the response was "Yes" or "Maybe", please provide more details here. |  |
|  |

**TAB 3. Unanticipated Problem - Occurrence(s)**

|  |  |  |
| --- | --- | --- |
| **#** | **Question** | **Guidance Notes** |
| 3.1\* | State when the unanticipated problem occurred. |  |
|  |
| 3.2  | State the site at which the unanticipated problem occurred. | Confirm if the site required and had given consent for the research activity. |
|  |
| 3.3\* | State when the research team became aware of the problem. |  |
|  |
| 3.4\* | How did the research team become aware of the problem | For example, was it reported as a problem by a participant, a research team member, member of the public, etc. |
|  |
| 3.5\* | What action, if any, has been taken or is proposed to be taken by the research team (or others) to reduce any occurrences of future unanticipated problems of this nature? | Provide a description of actions along the timeline from point of awareness of the problem to now. |
|  |
| 3.6\* | What adverse outcome(s) has occurred, or is expected for the participant(s)? |  |
|  |

**TAB 4. Unanticipated Problem - Mitigation**

|  |  |  |
| --- | --- | --- |
| **#** | **Question** | **Guidance Notes** |
| 4.1\* | Describe the current status of those affected by the unanticipated problem to your knowledge at this time. | For example, any ongoing problems being monitored. |
|  |
| 4.2\* | Describe what follow-up mitigations you recommend for study participants? | For example: Revise protocol; Informing current participants; Re-consenting current participants with an amended Consent Form; Temporarily suspending the study; No actions required.**Please note that changes to study procedures or forms may require an Amendment Form to be completed.** |
|  |
| 4.3\* | Have any members of the research team been in communication with the participants since the research team has been aware of the unanticipated problem? |  |
| [ ]  Yes[ ]  No |
| 4.4  | If "Yes" to the question above, please provide a description and include any notices shared for review. |  |
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