RESEARCH ETHICS BOARD (REB) REPORTING

ADVERSE EVENTS FORM

**An adverse event includes, but is not limited to, a complaint or any undesirable experience or response that was not expected and not stated in the informed consent and original protocol. This includes any emotional, psychological, and/or physiological incidents.**

**The principal investigator must immediately report to the REB any adverse or unexpected events that occur during the conduct of research. The principal investigator or faculty supervisor is required to submit this completed Adverse Event Form within one (1) business day of the incident.**

**Instructions:**

1. Please complete this form electronically and submit as SINGLE document (.doc, .docx or .pdf) to ethics@yukonu.ca
2. Do not leave any question blank. If a question is not applicable to your situation, please enter N/A in the response.

*\** *All appendices MUST be clearly labeled and reflect how they are referenced in the form.* *Please note that your form will be returned to you for completion if all of the above criteria are not met.*

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| Applicant Information  |
| **REB Reference Number:** Click here to enter text.  |
| **Applicant Name:** Click here to enter text. |
| **Title of Study:** Click here to enter text. |
| **Name of Principal Investigator (if different from above):** Click here to enter text. |
| **Position at Yukon University:** Choose an item.**If Adjunct or Other (list position and home institution):** Click here to enter text. |
| **Email address:** Click here to enter text. |
| **Phone number:** Click here to enter text. |
| **Name of Co-Investigator(s) and/or Student(s):** Click here to enter text. |
| **Email address:** Click here to enter text. |
| Adverse Event Information  |
| **Date of this report:** Click here to enter a date. |
| **Report completed by:** Click here to enter text. |
| **Date of Adverse Event:** Click here to enter a date. |
| **Location of Adverse Event:** Click here to enter text. |
| **Please describe the nature of the adverse event. Include details of any resulting physical, emotional, psychological and physiological impact (attach any relevant documentation to this report).**  Click here to enter text. |
| **Did this adverse event occur to a participant enrolled in your study?**  | [ ]  **Yes** [ ]  **No** |
| **Was the adverse event related the procedure of the study?**  **If Yes, please describe:** Click here to enter text. | [ ]  **Yes** [ ]  **No**  |
| **Was this event described as a possible risk in the Information letter/Consent Letter?**  | [ ]  **Yes** [ ]  **No**  |
| **Has this type of event occurred before in this study or in a related study?**  | [ ]  **Yes** [ ]  **No**  |
| **Is this type of adverse event likely to occur again?**  | [ ]  **Yes** [ ]  **No**  |
| **Describe the actions (if any) taken following the identification of the adverse event. How was the situation handled or resolved?** Click here to enter text. |
| **Was medical or any other intervention required and provided to the participant?** **Provide details:** Click here to enter text. | [ ]  **Yes** [ ]  **No** |
| **Was the participant withdrawn from the study as a result of this adverse event?**  | [ ]  **Yes** [ ]  **No** |
| **Is there any plan for follow up contact?** **Please explain:** Click here to enter text. | [ ]  **Yes** [ ]  **No** |
| **Should any changes be made to the study as a result of this adverse event in order to reduce or eliminate risk to participants?** **If Yes, please explain and complete the Study Modification Form and indicate the changes on your original submission. Attach all modified materials.**  Click here to enter text. | [ ]  **Yes** [ ]  **No** |
| **Will the adverse event require you to modify the existing informed consent letter?** **If Yes, please explain and complete the REB Study Modification Form** Click here to enter text. | [ ]  **Yes** [ ]  **No** |
| **What actions will you be taking regarding the study participants as a result of this adverse event? Please select all that apply**[ ]  **Re-consenting current participants with an amended consent form**[ ]  **Informing current study participants ASAP**[ ]  **Revising consent/assent forms**[ ]  **Protocol revisions/amendments**[ ]  **Updating participant information sheet**[ ]  **Temporarily suspending study**[ ]  **No Action required**[ ]  **Other, describe:** Click here to enter text. |
| **If there is another REB involved in this project, please provide the details that were sent to them regarding the adverse event.** Click here to enter text. | [ ]  **Yes** [ ]  **No** |
| Signature and agreement |
| **My/Our signature(s) below confirms that the details contained in this report are an accurate and true account of the adverse event that occurred on**  Click here to enter a date. **(date)** |
| **Signature of Principal Investigator** | **Name of Principal Investigator:** Click here to enter text. | **Date:** Click here to enter a date. |
| **Signature of Co-Investigator** | **Name of Co-Investigator:**Click here to enter text. | **Date:** Click here to enter a date. |
| **Signature of Student Investigator** | **Name of Student Investigator:** Click here to enter text. | **Date:** Click here to enter a date. |