# Human Research Ethics Board - Trinity Western University

# Adverse and/or Unanticipated Event Report Form

 HREB File No.:

 Date Received by HREB:

|  |  |
| --- | --- |
| **Principal Investigator:**        | **Phone:**      -     -       |
| **Department:**        | **Email:**        |
| **Address:**        |

 (Street Address or PO Box, City, Province, Postal Code)

**You are:** [ ]  Faculty [ ]  Staff [ ]  Masters Student [ ]  Doctoral Student [ ]  Research Fellow

***If you are a student/research fellow:***

|  |  |
| --- | --- |
| **Name of Supervisor:**        | **Phone:**      -     -      ext.        |
| **Department:**        | **Email:**        |
| **Address:**        |

 (Campus Office Location)

### Terms

An Adverse Event is any unfavorable change in current health status (including physical, mental, emotional, or psychological) in a person participating in a research study. This change may or may not be causally related to the study protocol.

An Unanticipated Event is any unfavourable or unintended occurrence during the course of a research study which may have immediate or potential implications for participants.

## A. General Information

### 1. Title of Project

### 2. Location

**(a) Did the event take place at TWU?**

[ ]  Yes [ ]  No

**(b) If the event took place off-campus, specify the location where the event occurred:**

**Has anyone from the site been notified?**

[ ]  Yes Date notified: mm/dd/yyyy Name of person notified:

[ ]  No

### 3. Description of Adverse and/or Unanticipated Event

**(a) Date of event.**

mm/dd/yyyy

 **(b) Date research team became aware of the event.**

mm/dd/yyyy

 **(c) Provide details regarding what occurred, including how the research team became aware of the event.**

**(d) Is the nature of the problem or event unexpected in terms of nature, severity, or frequency?**

[ ]  Yes [ ]  No

**(e) Does the nature of the problem suggest that the research places participants or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, or that were not described in the original application?**

[ ]  Yes [ ]  No

**(f) Was the problem described in the Risks section of the Consent Form?**

[ ]  Yes [ ]  No

**(g) What action (if any) has been taken, or will be taken, by the research site, and by whom?**

**(h) What action (if any) has been taken, or will be taken, by the research team?**

**(i) What actions have been taken, or will be taken, to reduce the likelihood of this happening again?**

### 4. Statement of Principal Investigator

I am aware of and understand the circumstances and/or information related to the adverse/unanticipated event referred to on this form. I have assessed the significance of this event with respect to participants involved in this research and as a result, I believe that:

The study should continue without change to the protocol:

Yes [ ]  No [ ]

The study should continue without change to the Information and Consent Form:

Yes [ ]  No [ ]

**If you answered NO to either question, please enclose the revised protocol and/or consent form for review by the Human Research Ethics Board.**

#### Please submit one original signed application with all required attachments to Elizabeth Kreiter, HREB Coordinator, Suite 101, Fosmark Centre.

## B. Signatures

I confirm that I have reviewed this report, which provides a complete and accurate description of the event, and that, upon receipt of the HREB's review, I will implement any corrective action required by the HREB, should any be recommended.

Principal Investigator Date

**AND (if applicable)**

Student’s Supervisor Date

## For HREB Use Only

❒ *No further action required. Report accepted as submitted*

❒ *Referred to Full Board*

❒ *Additional information requested. Email with details sent to Principle Investigator*

Signature of HREB Chair or alternate: Date: