Adverse Event/Unanticipated Issue Report Form

# **Instructions**

In the situation where an adverse event and/or unanticipated issue occurs at any time throughout your research study, you are required to *IMMEDIATELY* report the incident to Seneca’s Research Ethics Board (REB) using this form. Any required changes to eliminate the immediate issue and/or risk to participants may be made if necessary but shall be reported to the REB. The REB may request to suspend the research study until required adjustments to the procedure are made.

There are three (3) sections in this report form that are to be completed by the principal investigator before submission. Please take note of the following sections:

1. Section A: General Information
2. Section B: Adverse/Unanticipated Issue Report
3. Section C: Signature

# **Submission Instructions**

The Seneca REB will only accept electronic versions of documents in Word or PDF format. Please complete all applicable sections and submit your Adverse Event/Unanticipated Issue Report to the REB Coordinator. Electronic signatures are accepted for section C. You will receive an email acknowledgement of your submission within two (2) business days.

# **Section A: General Information**

## **1.0 Project Information**

**Title of Research Project:** (Enter text here)

**Original REB Submission File#:** \*\*\*\*-\*\*

## 1.1 Principal Investigator

**Principal Investigator:** (must be same person indicated on the original application)

**School/Department:** (Enter text here)

**Position:** (Enter text here)

**Email:** (Enter text here)

**Phone:** (Enter text here)

# **Section B: Adverse Event/Unanticipated Issue Report**

## **2.0 Project Summary**

1. Please provide a synopsis of the main purpose, objectives, and methodology of the research project.

(Enter text here)

## **3.0 Adverse Event/Unanticipated Issue**

1. Please provide a detailed description of the adverse event/unanticipated issue that occurred. Outline the resulting consequences to the participant(s). Please indicate if any immediate action/attention was required.

**Date of Issue:**

**Location:**

(Enter text here)

1. Please describe any changes that has been or will be made to the study procedures to mitigate or eliminate this risk to participants.

(Enter text here)

# **Section C: Signature**

## **4.0 Required Signatures**

My signature certifies that the information in this document is true and correct to the best of my knowledge.

1. **Principal Investigator’s Signature**

Principal Investigator Signature Job Title Date

1. **Instructor/Supervisor’s Signature (Required for Student applicants only)**

Instructor/Supervisor Signature Job Title Date