CONESTOGA
Connect Life and Learning

RESEARCH ETHICS OFFICE
Research Ethics Board
96 Grand Avenue South
Cambridge, Ontario N1S 2L9
Tel: (519) 748-5220 x 7108

Adverse Events Report

The Faculty Investigator or Supervisor (in the case of student research) is responsible for reporting any injury, adverse event, or detrimental incident experienced by a research participant that is/may be related to the research procedures. Any undesirable experience or response is considered an adverse event. The adverse event may be emotional, psychological or physiological in nature.

The Faculty Investigator or Supervisor must notify the Director, Office of Applied Research and the Chair of the Research Ethics Board about the occurrence of the adverse event IMMEDIATELY. In addition, the Principal Investigator or Faculty Supervisor must complete and submit an Adverse Events Report to the Director, Office of Applied Research and the Chair of the Research Ethics Board according to the same timeline. The Faculty Investigator or Faculty Supervisor is expected to respond to the adverse event immediately and according to the description originally outlined in Sections 15 and 23 in your Application to Involve Human Participants in Research.

REB Approval #: **Original Ethics Clearance Date:**

Project Title:

Faculty Investigator(s): **Department:**

Faculty Supervisor: **Department:**

Student Investigator(s): **Department:**

A. GENERAL DETAILS RELATED TO ADVERSE EVENT:

1. Did this adverse event occur to a participant enrolled in your study? Yes ☐ No ☐
2. Was the adverse event attributable to a study procedure? Yes ☐ No ☐ Uncertain ☐
   (If a relationship between the event and the study procedures can be ruled out, this form is not required).
3. Was the adverse event unexpected? Yes ☐ No ☐

4. Is this adverse event described in your Application to Involve Human Participants in Research and in the Information Letter and Consent Form? Yes ☐ No ☐

5. Has this type of adverse event previously occurred in this or a related study? Yes ☐ No ☐

   If YES, when and how often? _____ ____

6. Is this type of adverse event likely to occur again? Yes ☐ No ☐ Uncertain ☐

7. Have any changes to the study procedures been implemented as a result of this adverse event in order to reduce or eliminate this risk to study participants? Yes ☐ No ☐

   If YES, provide an explanation below and submit a Change Request Form for ethics review

8. Will the adverse event require any modification to the Information Letter-Consent Form? Yes ☐ No ☐

   If YES, provide an explanation and submit a revised Information Letter-Consent Form for ethics review.

NOTE: No new study participants may be involved in the respective study until any necessary revisions to the study procedures and/or Information Letter-Consent Form have received ethics clearance.

B. PARTICIPANT DETAILS:

Participant's Name: Age:

Address:

Date of Occurrence (D M Y): Time:

Location of Event:

C. DETAILED DESCRIPTION OF ADVERSE EVENT AND OF ACTION TAKEN

1. Describe the adverse event/incident that occurred. Include details of any physical injury or psychological impact from the adverse event.

2. Provide details (step-by-step) of the action(s) taken immediately following identification of the adverse event/incident.

3. Was medical or other intervention provided? Yes ☐ No ☐

   If yes, provide the name of, and contact information for, any medical or other personnel involved.

4. Was the participant discontinued from the study as a result of the adverse event? Yes ☐ No ☐

5. Is there any plan for follow-up contact with the participant? Yes ☐ No ☐

   If yes, explain.

Principal Investigator Confirmation

As Principal Investigator on this project, I confirm that the details contained in this report are an accurate account of the adverse event(s) that occurred on

Signature of Faculty Investigator(s): **Date:**

Signature of Faculty Supervisor: **Date:**

Signature of Student Investigator(s): **Date:**

For Office of Applied Research Ethics Use Only

Action Required: Yes ☐ No ☐

Details of Action Taken:

Details of Follow-up Action:

_____ _____

Andrew Fraser, Director
Applied Research and Innovation

Date

ACKNOWLEDGEMENT - This policy has been adopted from the University of Waterloo, Office of Research Ethics with their permission, and adapted for Conestoga College. Conestoga College gratefully acknowledges the contribution of the University of Waterloo in this regard.