The Principal Investigator or course instructor (in the case of course-based 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 Principal Investigator or course instructor is expected to respond to the adverse event immediately. The Principal Investigator or course instructor must immediately notify the Dean of Applied Research and Innovation and the Chair of the Research Ethics Board about the occurrence of the adverse event by completing this form.

**Date:** Click here to enter a date. **LAM#:**

**Section A: general Information**

**Title of Research Project/Course:** Click here to enter project title.

**Date of Original REB Approval:** Click here to enter a date.

**Principal Investigator Name:** Click here to enter first and last name.

**School/Department:** Click here to enter School/Department.

**Telephone:** Click here to enter phone number.

**Email:** Click here to enter e-mail address.

**Section B: General Details related to adverse event**

1. Did this adverse event occur to a participant enrolled in your study?  
   **Please select one.**
2. Was the adverse event attributable to a study procedure? Note: (If a relationship between the event and the study procedures can be ruled out, this form is not required).  
   **Please select one.**
3. Was the adverse event unexpected?  
   **Please select one.**
4. Is this adverse event described in your Application to Involve Human Participants in Research and in the Information Letter and Consent Form?  
   **Please select one.**
5. Has this type of adverse event previously occurred in this study?  
   **Please select one.**

a. If **YES**, when and how often?  
Click here to enter text.

1. Is this type of adverse event likely to occur again?  
   **Please select one.**
2. 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?  
   **Please select one.**

a. If **YES**, provide an explanation below and submit a Change Request Form for ethics review  
Click here to enter text.

1. Will the adverse event require any modification to the Information Letter-Consent Form?  
   **Please select one.**

a. If YES, provide an explanation and submit a revised Information Letter-Consent Form for ethics review.  
Click here to enter text.

**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.**

**section c: detailed description of adverse event and action taken**

1. Describe the adverse event/incident that occurred. Include details of any physical injury or psychological impact from the adverse event.  
   Click here to enter text.
2. Provide details (step-by-step) of the action(s) taken immediately following identification of the adverse event/incident.  
   Click here to enter text.
3. Was medical or other intervention provided??  
   **Please select one.**

a. IF **YES**, provide the name of, and contact information for, any medical or other personnel involved.  
Click here to enter text.

1. Was the participant discontinued from the study as a result of the adverse event?  
   **Please select one.**
2. Is there any plan for follow-up contact with the participant?  
   **Please select one.**

a. If **YES**, please explain.  
Click here to enter text.

**SECTION D: 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

Click here to enter full name. Click here to enter date.

Name of Principal Investigator Date:

Signature

**Submission:**

Please send a copy to the attention of the Lambton College REB Chair.

REB Chair

1457 London Road

Sarnia, ON N7S 6K4

Phone: 519-542-7751

E-mail: [reb@lambtoncollege.ca](mailto:reb@lambtoncollege.ca)

***The Following Section is For Office Use Only***

***REQUIRED ACTIONS***

Action Required:  
Click here to enter text.

Details of Action Taken:  
Click here to enter text.

Details of Follow-up Action:  
Click here to enter text.

**Signatures:**

Click here to enter date.

Dean - Applied Research and Innovation Date

Click here to enter date.

Chair - Research and Ethics Board Date