

**Research Ethics Board**

**Adverse Event** **Report**

The Principal Investigator or Faculty 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 Principal Investigator or Faculty Supervisor must notify the Research Ethics Board about the occurrence of the adverse event IMMEDIATELY. In addition, the Principal Investigator or Faculty Supervisor must complete and submit a signed Adverse Events Report to the Chair of the Research Ethics Board according to the same timeline. The Principal Investigator or Faculty Supervisor is expected to respond to the adverse event immediately and according to the description originally outlined in your Research Protocol.

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 **MCREB #:** Click here to enter text. **Date of MCREB Approval:** Click here to enter text.

**Title:** Click here to enter text.

 **Principal Investigator:** Click here to enter text. **Department:** Click here to enter text.

 **Faculty Supervisor:** Click here to enter text. **Department:** Click here to enter text.

**A. GENERAL DETAILS RELATED TO ADVERSE EVENT:**

1. Did this adverse event occur to a participant enrolled in your study? YES [ ]  NO [ ]

1. 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).

1. Was the adverse event unexpected? YES [ ]  NO [ ]

Explain your response: Click here to enter text.

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 [ ]

1. Has this type of adverse event previously occurred in this or a related study? YES [ ]  NO [ ]

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

1. Is this type of adverse event likely to occur again? YES [ ]  NO [ ]  Uncertain [ ]

Explain your response: Click here to enter text.

1. 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](http://reb.mohawkcollege.ca/forms/MCREB%20Amendment%20Request%20Form%2015Jan2014.docx) for ethics review.

Click here to enter text.

1. 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.

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.**

**B. PARTICIPANT DETAILS:**

Participant’s Name: Click here to enter text. Age: Click here to enter text.

Address: Click here to enter text.

Date of Occurrence (D M Y): Click here to enter text. Time: Click here to enter text.

Location of Event: Click here to enter text.

**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. 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? Yes [ ]  No [ ]

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

 Click here to enter text.

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. Click here to enter text.

**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 text.

**Signature of Principal Investigator: Date:**

**Signature of Faculty Supervisor:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**

*For Research Ethics Board Use Only*

Action Required: Yes [ ]  No [ ]

Details of Action Taken:

Details of Follow-up Action:

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Valya Roberts, Chair Date

Mohawk Research Ethics Board