July 2021

UNIVERSITY OF WATERLOO
OFFICE OF RESEARCH ETHICS

Adverse Events Report

The Principal Investigator (PI) or the Faculty Supervisor (FS), in the case of student research is responsible for reporting any injury, adverse event, or detrimental incident experienced by a research participant or other individuals 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. Note: protocol deviations are to be reported on a separate form.

The PI or FS must notify Research Ethics by e-mail about the adverse event as soon as possible, no later than 24 hours following the event. The PI or FS must complete and submit this form to Research Ethics within one business day following the event. The PI/FS is expected to respond to the adverse event immediately and according to the description originally outlined in the research ethics application for the study. For multi-site clinical trials, there may be an obligation to notify all study participants of the adverse events to provide for ongoing informed consent. Please attach additional pages as needed.

Please do not submit handwritten forms. Typewritten forms must be provided. This form is a fillable PDF.

Ethics Application #: _____ **Ethics Clearance Date (D M Y):** _____

Study Title: _____

_____

Name of Principal Investigator or Faculty Supervisor _____

_____

Name of Department/ School: _____

_____

A. EVENT DETAILS:

Date of Occurrence (D M Y): _____ Time: _____

Location of Event: _____

B. GENERAL DETAILS RELATED TO ADVERSE EVENT:

1. Did this adverse event occur to a participant enrolled in the study?

   If Yes, how many participants were affected? YES ○ NO ○

   If No, provide an explanation below outlining who was affected (e.g., researcher).

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 the Risks section of the Research Ethics Application 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, provide the title of the study, Ethics Application #, under which the previous adverse event occurred and when the adverse event last occured?

6. Has an adverse event occurred previously involving the same study participant(s) or other individuals?
   YES ◯ NO ◯
   If Yes, when did this occur?

7. Is this type of adverse event likely to occur again? YES ◯ NO ◯ Uncertain ◯

8. Have any changes to the study procedures been implemented becuase of this adverse event to reduce or eliminate this risk to study participants or other individuals? YES ◯ NO ◯
   If Yes, provide an explanation below and submit an amendment to revise the study procedures.

9. 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.

NOTES: No new participants may be involved in the respective study until any necessary revisions to the procedures and/or Information Letter-Consent Form have received ethics clearance. The PI must keep a confidential record of any adverse events that occurs as a result of their research or that of student's they supervise. These records must be kept as there may be a need to identify the specific participant(s) involved for follow-up. These records are to include a participant id code and, in a separate file, keys to connect the id codes with the actual names and contact information for the participant(s) who may need to be contacted. These records are to be kept in accordance with the guidelines on Security of Research Participants' Data.

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. (approx. 500 words)

2. Provide details (step-by-step) of the action(s) taken immediately following identification of the adverse event/incident. (approx. 500 words)

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 because 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/Faculty Supervisor Confirmation

As Principal Investigator/Faculty Supervisor on this project, I confirm that the details contained in this report are an accurate account of the adverse event(s) that occurred on the date noted above.

Signature of Principal Investigator/Faculty Investigator: _____ **Date:** _____

Print and sign the completed form and send an electronic copy to Research Ethics at reb@uwaterloo.ca

For Research Ethics/REB Use Only Review of Adverse Event Report

Action Required: ◯ Yes ◯ No further action is required

Change(s) are required to:

- ☐ Study Procedures
- ☐ Information Consent Document
- ☐ Other

Study Disposition:

- ☐ Continuation of study permitted
- ☐ Continuation of study conditional on change(s) noted above
- ☐ Suspension of study pending further review by REB

_____ _____

Julie Joza, MPH
Director, Research Ethics
University of Waterloo

Date

_____ _____

Heather Root, Ph.D
Senior Manager, Research Ethics
University of Waterloo

Date