(For Office Use) REB File # _____

Adverse Event Form

Please complete and submit this form to Kurstin Salisbury, Research Ethics Board Coordinator at (613) 969-1913, x2275, or email to: ksalisbury@loyalistcollege.com

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 REB Coordinator and the Chair/s 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 and submit to the REB Coordinator and the Chair of the Research Ethics Board within 5 business days of the event. The Principal Investigator or Faculty Supervisor is expected to respond to the adverse event immediately and according to the description originally outlined in Sections 19 in your Application to Participate in Research.

General Project Information

Title of Research Project: _____

Today's Date	
Date of Original Ethics Approval	

Principal Investigator:

Name	
Phone	
Email	

General Details Related to Adverse Event

Did this adverse event occur to a participant enrolled in your study or to the researcher of the study?

☐ Participant ☐ Researcher

Was the adverse event attributable to a study procedure? ☐ Yes ☐ No ☐ Uncertain

If **yes or uncertain**, please explain:

Was the adverse event unexpected? ☐ Yes ☐ No

Is this adverse event described as a risk in your Research Application and in the Information Letter and Consent Form? ☐ Yes ☐ No

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

If **yes**, when and how often?

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

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 ☐ Uncertain
(If yes, please complete and submit a "Renewal and Amendment Form" for ethics review.)

Will the adverse event require any modification to the Information Letter-Consent Form? ☐ Yes ☐ No
(If yes, please complete and submit a "Renewal and Amendment Form" with an explanation, as well as a revised Information Letter-Consent Form for ethics review.)

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

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Participant Details

Participant's Name	
Age	
Address	
Date and Time of Occurrence	
Location of Event	

Detailed Description of Adverse Event and of Action Taken

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

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

Was medical or other intervention provided? ☐ Yes ☐ No

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

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

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

If **yes,** please 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 Principal Investigator(s): _____ **Date:** _____

Signature of Faculty Supervisor: _____ **Date:** _____

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

Please mail a hard copy or email a copy containing your electronic signature to the attention of:

Loyalist College Applied Arts and Technology
Kurstin Salisbury - Research Ethics Board Coordinator
376 Wallbridge-Loyalist Road
P.O Box 4200
Belleville, ON K8N 5B9
(613) 969-1913, x2275
ksalisbury@loyalistcollege.com

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☐ Acknowledgement that the adverse event is unlikely to occur again, and the risk to the participants remains minimal

☐ Acknowledgement that the likelihood of the adverse event is high and the risk to participants is now more than minimal. Research must be ceased immediately.

Comments:

_____ _____

Signature of REB Chair **Date**