

## **Adverse Event Form**

Please complete and submit this form to Dr. Jessica Becking, Research Ethics Board Coordinator at (613) 969-1913, x2406, or email to: jbecking@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.

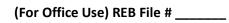
The Principal Investigator or Faculty Supervisor must notify the REB Coordinator and the Chair/s of the Research Ethics Board about the occurrence of the adverse event IMMEDIATELY. In addition, the Principal Investigator or Faculty Supervisor must complete and submit an Adverse Events Report and submit 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.

<b>General Project</b>	Information			
Title of Research	Project:			
Today's Date				
Date of Origina	l Ethics Approval			
Principal Investi	gator:			
Name				
Phone				
Email				
General Details I	Related to Adverse Ev	rent		
Did this adverse	event occur to a parti	icipant enrolled in your stu	idy or to the researcher of	the study?
☐ Participant	☐ Researcher			
Was the adverse event attributable to a study procedure? $\square$ Yes $\square$ No $\square$ Uncertain				



If <b>yes or uncertain</b> , 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? $\ \Box$ Yes $\ \Box$ No					
Has this type of adverse event previously occurred in this or a related study? ☐ Yes ☐ No					
If <b>yes</b> , 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.





## **Participant Details**

Participant's Name	
Age	
Address	
Date and Time of Occurrence	
Location of Event	
Detailed Description of Adverse  Describe the adverse event/inci impact from the adverse event.	Event and of Action Taken  dent that occurred. Include details of any physical injury or psychological
impact from the adverse event.	
Provide details (step-by-step) o event/incident.	f the action(s) taken immediately following identification of the adverse
Was medical or other intervent	ion provided? ☐ Yes ☐ No contact information for, any medical or other personnel involved.





Is there any plan for follow-up contact with the participant?	□ Yes □ No
If <b>yes,</b> please explain.	
Principal Investigator Confirmation	
As Principal Investigator on this project, I confirm that the detai 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 electro	nic signature to the attention of:
Dr. Jessica Becking - Research Ethics Board Coordinator Loyalist College Applied Arts and Technology 376 Wallbridge-Loyalist Road P.O Box 4200	

Belleville, ON K8N 5B9 (613) 969-1913, x.2406





jbecking@loyalistcollege.com

REB Use Only	
$\hfill \square$ Acknowledgement that the adverse event is unlike minimal	ely to occur again, and the risk to the participants remain
$\hfill \square$ Acknowledgement that the likelihood of the adversion than minimal. Research must be ceased immediately.	rse event is high and the risk to participants is now more
Comments:	
Signature of REB Chair	Date