

(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: <a href="mailto:ksalisbury@loyalistcollege.com">ksalisbury@loyalistcollege.com</a>

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.

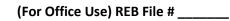
General Project Information	
Title of Research Project:	_
Today's Date	
Date of Original Ethics Approval	
Principal Investigator:	
Name	
Phone	
Email	
General Details Related to Adverse Event  Did this adverse event occur to a participant enrolled in your study or to the researcher	of the study?
☐ Participant ☐ Researcher	
Was the adverse event attributable to a study procedure? $\square$ Yes $\square$ No $\square$ Uncertain	



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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 <b>yes</b> , when and how often?
Type, when and now ortem
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.)

<u>NOTE</u>: 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					1
Age					
Address					
Date and Time of Occurrence					
Location of Event					
Detailed Description of Adverse  Describe the adverse event/inci impact from the adverse event.			tails of any physic	al injury or psycholo	gical
•					
Provide details (step-by-step) or event/incident.	f the action(s) t	taken immediate	ly following ident	ification of the adve	rse
Was medical or other intervent	ion provided?	□ Yes □ No			
		6	19 1 41	1. 1	
If <b>yes,</b> provide the name of, and	contact inform	ation for, any me	edical or other per	sonnel involved.	
Was the participant discontinue	ed from the stu	dv as a result of	the adverse event	:? □ Yes □ No	





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 detail 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 electron	nic 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





## **REB Use Only**

$\square$ Acknowledgement that the adverse event is unlike minimal	kely to occur again, and the risk to the participants rem	ains
$\square$ Acknowledgement that the likelihood of the adverthan minimal. Research must be ceased immediately	erse event is high and the risk to participants is now mo y.	ore
Comments:		
Signature of REB Chair	 Date	