

Please complete this form and email it to ResearchCompliance@unisa.edu.au upon notification of an adverse event regarding your research.

SECTION 1: RESEARCHER DETAILS

Title:			
Surname:			
First Name(s):			
Institute/Centre/Division:			
School:			

SECTION 2: DETAILS OF PROJECT

Project Title:			
Protocol Number:			
Original Approval Date:			

SECTION 3: DETAILS OF ADVERSE EVENT

Date of Adverse Event:		Participant ID:	
Description of Event:			

Likely Cause of Event *(please tick)*:

<input type="checkbox"/>	Study Drug / Treatment	<input type="checkbox"/>	Progressive Disease
<input type="checkbox"/>	Standard Treatment	<input type="checkbox"/>	Concurrent medication
<input type="checkbox"/>	Other <i>(please specify below)</i> :	<input type="checkbox"/>	Concurrent disorder

Relationship to Study *(please tick)*:

<input type="checkbox"/>	Directly related	<input type="checkbox"/>	Not related
<input type="checkbox"/>	Possibly related		

Outcome (please tick):		
<input type="checkbox"/>	Fatal	<input type="checkbox"/> Hospitalisation required / prolonged
<input type="checkbox"/>	Life threatening	<input type="checkbox"/> Permanent or significant disability / incapacity
<input type="checkbox"/>	Other (please specify below):	

Additional Information (please answer each of the following):			
Do you believe that that adverse event was directly related to the research?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Was this event anticipated in the original Research Protocol?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Was this event described in the Participant Information Sheet?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does this report raises additional safety concerns for the participants of this research?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will there be changes made to your protocol as a result of this event?			
<input type="checkbox"/> No			
<input type="checkbox"/> Yes - If yes, please submit an Ethics Amendment Form to ResearchCompliance@unisa.edu.au			
Has the participant been withdrawn from the research due to an adverse event?			
<input type="checkbox"/> Yes			
<input type="checkbox"/> No <i>If no, has medical advice been sought to determine if the participant is medically fit to continue?</i>			
<input type="checkbox"/>	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Further Comments:

SECTION 4: CERTIFICATION		
<i>Principal Researcher Signature</i>	<i>Printed Name</i>	<i>Date</i>
<i>Supervisor's Signature (If applicable)</i>	<i>Printed Name</i>	<i>Date</i>