

Please complete this form and email it to ResearchCompliance@unisa.edu.au upon notification of a serious 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 SERIOUS ADVERSE EVENT

Participant ID:			Country of Occurrence:		
Date of Birth:			Date of Adverse Event:		
Date of Report:					

Report Type (*specify below: Laboratory test result/clinical record etc*):

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Description of Event:

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Relationship of the event to the study/drug/device: (*Please provide assessment of the relationship*)

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SECTION 4: ADDITIONAL INFORMATION

Is the report sufficiently serious to oblige discontinuation of the trial?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Is the report of a sufficiently serious degree to warrant further investigation by UniSA?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Is the report of a sufficiently serious degree to warrant warning trial participants (via modification of the Participant Information Statement)?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

SECTION 5: 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>