

# AE/SAE/SUSAR/USADE Report

This report must be used to notify the reviewing HREC of Adverse Events (AEs), Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs) or Unanticipated Serious Adverse Device Effects (USADEs) that occur during a research project. The Coordinating Principal Investigator (CPI) must submit SAE and SUSAR reports to the reviewing HREC **as soon as possible** (within 24 hours). In the event that the site Principal Investigator (PI) is not able to urgently contact the CPI regarding an event, the PI may submit the report directly to the reviewing HREC.

## Research Project Details

HREC Reference Number		Project Title			
Local Reference Number					
CPI for Research Project		Sponsor		Sponsor Telephone	
Date of this Report		Sponsor Contact (Aus)		Sponsor Email	

## Event Details

Report Number	Event ID (Local reference number)	Start Date of Event	Description of Event	Relationship to Investigational Product	Is this event a SUSAR or USADE?	Has Investigator reported event to sponsor? <i>If No or N/A, give details below.</i>	Is event considered to have a material impact*?	Site of Event <i>Provide site name and indicate location.</i>	Event reported as required by the: <i>Tick all that apply.</i>	Is any action recommended by Investigator? <i>If Yes, give details below.</i>
1				<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Unrelated <input type="checkbox"/> Unknown <input type="checkbox"/> Procedurally related <sup>†</sup>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Definitely <input type="checkbox"/> Possibly <input type="checkbox"/> No	<input type="checkbox"/> Victorian <input type="checkbox"/> Non-Victorian	<input type="checkbox"/> HREC <input type="checkbox"/> Investigator <input type="checkbox"/> Sponsor	<input type="checkbox"/> Yes <input type="checkbox"/> No
2				<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Unrelated <input type="checkbox"/> Unknown <input type="checkbox"/> Procedurally related <sup>†</sup>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Definitely <input type="checkbox"/> Possibly <input type="checkbox"/> No	<input type="checkbox"/> Victorian <input type="checkbox"/> Non-Victorian	<input type="checkbox"/> HREC <input type="checkbox"/> Investigator <input type="checkbox"/> Sponsor	<input type="checkbox"/> Yes <input type="checkbox"/> No
3				<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Unrelated <input type="checkbox"/> Unknown <input type="checkbox"/> Procedurally related <sup>†</sup>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Definitely <input type="checkbox"/> Possibly <input type="checkbox"/> No	<input type="checkbox"/> Victorian <input type="checkbox"/> Non-Victorian	<input type="checkbox"/> HREC <input type="checkbox"/> Investigator <input type="checkbox"/> Sponsor	<input type="checkbox"/> Yes <input type="checkbox"/> No
4				<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Unrelated <input type="checkbox"/> Unknown <input type="checkbox"/> Procedurally related <sup>†</sup>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Definitely <input type="checkbox"/> Possibly <input type="checkbox"/> No	<input type="checkbox"/> Victorian <input type="checkbox"/> Non-Victorian	<input type="checkbox"/> HREC <input type="checkbox"/> Investigator <input type="checkbox"/> Sponsor	<input type="checkbox"/> Yes <input type="checkbox"/> No

<sup>†</sup>Applicable for medical device research only

\*Material impact is defined as an impact which will result in a change to the ethical acceptability of the research

If the event definitely or possibly has material impact, the responsible PI or CPI should submit this report to **both** the reviewing HREC **and** the Research Governance Officer (RGO) at the site of the event. If the event has no material impact, the PI should contact their site RGO to determine the requirements regarding the notification process.

### Sponsor Notification

Report Number	If No or N/A was selected in the <i>Event Details</i> table above, specify the reason the sponsor was not notified of the event by the Investigator
1	
2	
3	
4	

### Recommended Action

Report Number	If Yes was selected in the <i>Event Details</i> table above, provide the action(s) recommended by the Investigator
1	
2	
3	
4	

If changes are made to the Protocol, Participant Information Sheet and Consent Form(s), or any other documents approved by the HREC, the CPI must submit the amended document(s) together with a HREC Amendment Form (available from [www.health.vic.gov.au/clinicaltrials](http://www.health.vic.gov.au/clinicaltrials)) for review by the HREC.

### Declaration

I confirm that this project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved). I confirm that the project is being conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (NHMRC, 2007) or as amended. I confirm that I have not received any information in any form from anyone involved in the trial to suggest this report does not accurately reflect the progress of the project at the above site(s).

CPI or PI (as applicable)		Trial Coordinator		<b>HREC Acknowledgement</b>	
Signature		Signature		Signature	
Date		Date		Date	
Organisation		Organisation		Name	
Email		Email		Position	
Telephone		Telephone			