SUSAR/USADE Site Report

SUSAR = Suspected Unexpected Serious Adverse Reaction **USADE = Unanticipated Serious Adverse Device Effect**

This report must be used to notify the reviewing HREC of a SUSAR or USADE that occurs at an approved site during a research project. The Coordinating Principal Investigator (CPI) must submit this report to the reviewing HREC as soon as possible (within 24 hours). If 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. The site PI must notify their Research Governance Officer (RGO) of the event.

This form must **only** be used for SUSAR or USADE reporting. For Adverse Event (AE) or Serious Adverse Event (SAE) reporting, use a *AE and SAE Report* form (available from www.health.vic.gov.au/clinicaltrials).

If the SUSAR or USADE occurred at a site in Victoria, the Victorian Managed Insurance Authority (VMIA) must also be notified of the event using this form. Refer to the *Clinical Trials - Insurance and Risk Management Guidelines*.

For information on safety reporting, refer to *NHMRC Australian Health Ethics Committee (AHEC) Position Statement* (2009).

Responses must be typed into the form; do not write responses by hand (except signature).

Research Project Details

HREC Reference Number		CPI for Research Project	
Local Reference Number		HREC Approval Date	
Project Title			

Sponsor Details

Sponsor		Sponsor Telephone	
Sponsor Contact (Aus)		Sponsor Email	

Site Details (Location of Event)

Site Name (Organisation)		Principal Investigator	
State/Territory		Date of this Report	

Participant Details

*For informing VMIA of an event at a **site in Victoria**, participant details must be provided.*

Initials		UR Number	
Date of Birth			

Event Details

SUSAR	☐	USADE	☐
Event ID (Local Reference)		Start Date of Event	
Description of Event			

Relationship to Investigational Product

☐ Definitely related	☐ Probably related	☐ Possibly related
☐ Unrelated	☐ Unknown	☐ Procedurally related *(USADE only)*

Has the Investigator reported the event to the sponsor?	☐ Yes	☐ No	☐ N/A

If No or N/A, specify the reason

Is the event considered to have a material impact?
Material impact is defined as "an impact which will result in a change to the ethical acceptability of the research".

☐ Definitely ☐ Possibly ☐ No

Is any action recommended by the Investigator?	☐ Yes	☐ No

If Yes, provide details

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) 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	
Signature		Signature	
Date		Date	
Organisation		Organisation	
Email		Email	
Telephone		Telephone	

HREC Acknowledgement *(Office Use Only)*

Name		Position	
Signature		Date	
Comment			