Summary AE/SAE/SUSAR/USADE Report

This report must be used to provide a summary 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 the report to the reviewing HREC and should provide a copy to each site's Principal Investigator (PI) and Research Governance Officer (RGO).

AE/SAE/SUSAR/USADE Reports should be attached to this Summary Report.

A brief summary of the report(s) that have a material impact on the ethical acceptability of the research must be attached to this report.

Research Project Details

HREC Reference Number		CPI for Research Project	
Local Reference Number		HREC Approval Date	
Date of this Report			
Project Title			
Mode of HREC Approval	☐ Single state only	☐ Interstate Mutual Acceptance	

SUSAR or USADE Summary Report

For further information, applicable to both drug and device research projects, refer to *Detailed Guidance on the Collection, Verification and Presentation of Adverse Drug Reaction Reports Arising from Clinical Trials or Medicinal Products for Human Use* (EU Commission, April 2006).

Is this the Annual Safety Report (ASR) based on the company calendar?	☐ Yes	☐ No
Date of ASR		

In the case of no ASR, is there an updated safety reference document (e.g. Investigator's Brochure or Product Information)	☐ Yes	☐ No

If Yes, provide the document title and version number/date

Is this a six-monthly SUSAR or USADE line listing based on the company calendar?	☐ Yes	☐ No
Date of line listing		

Sponsor Statement

Has the sponsor included a statement regarding the implications for participants and conduct of the study?	☐ Yes	☐ No
Date of document containing sponsor statement		

If the sponsor did not provide a statement, provide reason

Action recommended by the Investigator(s)

Was any action recommended by the Investigator(s)?	☐ Yes	☐ No

If Yes, indicate the action(s) recommended *(tick all that apply)*	
Change to the protocol* or monitoring	☐
Change to the Participant Information Sheet and Consent Form(s)*	☐
Previously enrolled participants to be notified	☐
Project to be suspended	☐
Project to be stopped	☐
Other *(specify below)**	☐

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		Trial Coordinator	
Signature		Signature	
Date		Date	
Organisation		Organisation	
Email		Email	
Telephone		Telephone	

HREC Acknowledgement

Name		Position	
Signature		Date	