AE and SAE Report

AE = Adverse Event **SAE = Serious Adverse Event**

This report must be used to notify the reviewing HREC of AEs or SAEs that occur at an approved site during a research project. The Coordinating Principal Investigator (CPI) must submit a SAE 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 a SAE, the PI may submit the report directly to the reviewing HREC. If the AE or SAE 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. This form must be used **only** for AE and SAE reporting. For Suspected Unexpected Serious Adverse Reaction (SUSAR) or Unanticipated Serious Adverse Device Effect (USADE) reporting, use a *SUSAR/USADE Site Report* form (available from www.health.vic.gov.au/clinicaltrials). **Responses must be typed into the form; do not write responses by hand** (except signature).

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	Has Investigator reported event to sponsor? *If No or N/A, give details below.*	Is event considered to have a material impact*?	Site of Event *Provide site name and indicate location.*	Event reported as required by the: *Tick all that apply.*	Is any action recommended by Investigator? *If Yes, give details below.*
1				☐ Definitely related ☐ Probably related ☐ Possibly related ☐ Unrelated ☐ Unknown ☐ Procedurally related†	☐ Yes ☐ No ☐ N/A	☐ Definitely ☐ Possibly ☐ No	☐ Victorian ☐ Non-Victorian	☐ HREC ☐ Investigator ☐ Sponsor	☐ Yes ☐ No
2				☐ Definitely related ☐ Probably related ☐ Possibly related ☐ Unrelated ☐ Unknown ☐ Procedurally related†	☐ Yes ☐ No ☐ N/A	☐ Definitely ☐ Possibly ☐ No	☐ Victorian ☐ Non-Victorian	☐ HREC ☐ Investigator ☐ Sponsor	☐ Yes ☐ No
3				☐ Definitely related ☐ Probably related ☐ Possibly related ☐ Unrelated ☐ Unknown ☐ Procedurally related†	☐ Yes ☐ No ☐ N/A	☐ Definitely ☐ Possibly ☐ No	☐ Victorian ☐ Non-Victorian	☐ HREC ☐ Investigator ☐ Sponsor	☐ Yes ☐ No
4				☐ Definitely related ☐ Probably related ☐ Possibly related ☐ Unrelated ☐ Unknown ☐ Procedurally related†	☐ Yes ☐ No ☐ N/A	☐ Definitely ☐ Possibly ☐ No	☐ Victorian ☐ Non-Victorian	☐ HREC ☐ Investigator ☐ Sponsor	☐ Yes ☐ No

†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

Sponsor Notification

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

Recommended Action

Report No.	If Yes was selected in the *Event Details* 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) 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		Comment	
Signature		Date			