Protocol Deviation or Violation Report

To fulfil ICH-GCP requirements, any deviations or violations of the approved protocol **must** be notified to the reviewing HREC. The Principal Investigator (PI) must complete the report for their site. Two copies of the form are required: submit one copy to the Coordinating Principal Investigator (CPI) to be forwarded to the reviewing HREC; submit the other copy to the site's Research Governance Officer (RGO).
If there is a material impact on the conduct of the research project, ethical acceptability of the protocol, or safety of the participant(s), this must be explained below.

Research Project Details

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

Report Details

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

Type of Protocol Deviation or Violation

Deviation ☐ Violation ☐

Type of deviation or violation of the protocol		Date
Randomisation of ineligible participant(s)	☐	
Eligibility criteria breach	☐	
Screening procedure required by the protocol not done	☐	
Screening or on-project procedure done outside the protocol required time	☐	
Incorrect therapy given to participant(s)	☐	
On-project procedure required by the protocol not completed as determined by Principal Investigator	☐	
Visit non-compliance	☐	
Medication non-compliance	☐	
Other *(specify below)*	☐	

Number of participants directly affected by the protocol deviation or violation	

Brief explanation and risk assessment
(include any impact on conduct of research project, ethical acceptability of protocol or safety of participants)

Action(s) Recommended by the Principal Investigator

Action(s) Recommended *(tick all that apply)*		
Participant(s) to be withdrawn from project	☐	
Participant(s) to remain on project but data analysis to be modified	☐	
Change to the protocol*	☐	
Change to the Participant Information Sheet and Consent Form(s)*	☐	
Previously enrolled participants to be notified	☐	
Project to be suspended	☐	
Project to be stopped	☐	
Sponsor or collaborative group notified *(provide date of notification)*	☐	
No action	☐	
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.

Sponsor Details (if applicable)

***Reporting responsibilities**: The PI is responsible for reporting all protocol deviations and violations; however the sponsor may take action under certain circumstances. The sponsor must endeavour to obtain authorisation from the PI.*

Sponsor		Email	
Contact Person (Australia)		Telephone	
Signature		Date	

Investigator 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).

Principal Investigator		Trial Coordinator	
Signature		Signature	
Date		Date	
Organisation		Organisation	
Email		Email	
Telephone		Telephone	