

Questions in the form below are mirrored in the eProtocol Protocol Violation Report Form (PVR). As such, this form can be completed and provided to the research staff at the site to submit via a PVR Form in eProtocol.

SERIOUS BREACH REPORT FORM (SPONSOR)			
This form should be completed when the study sponsor is reporting a Serious Breach to the Human Research Ethics Committee (HREC) or when a sponsor is providing additional/follow-up information following a third-party report of a confirmed Serious Breach.			
HREC reference number:		Date of this report:	
Project title:			
HREC:		Principal Investigator:	
Sponsor:		Sponsor Contact (Aus):	
Initial Report ☐ Follow up Report ☐			
Details of the organisation/individual committing the Serious Breach:			
Details of the serious breach			
Indicate the impact of the Serious Breach on any of the following:			
Participant safety:			
Participant rights:			
Reliability and robustness of data:			
Provide: 1) An explanation of where, how and when the serious breach occurred and how it was identified 2) Any other relevant information (e.g. project status)			
Details of any action taken to date*			
Include: - Any investigations you/others are conducting - The outcome of those investigations if completed (or details of when they will be available/reported) - How the Serious Breach will be reported in the Final Report/publication - Any corrective and preventative action implemented to ensure the serious breach does not occur again *If the investigation or the corrective/preventative action is ongoing at the time of this report, please indicate your plans with projected timelines for completion and provide any further information in a follow-up report.			