murdoch children's research institute

EXPEDITED SAFETY REPORT FORM

Reporting requirement

All sites to report to the Sponsor-Investigator all *SAEs, SUSARs and USMs within **24 hours** of site staff becoming aware of the event.
**Except those identified in the protocol as not needing immediate reporting*

HREC Reference #			
Project title			
SAFETY EVENT TYPE	☐ SAE	☐ SUSAR	☐ USM

Section A: Local Site Details	
Site Name:	
Site Principal Investigator:	
Date site staff became aware of the safety event:	

Section B: Participant Details	
Participant Enrolment OR Randomisation No.:	
Participant Initials:	
SEX: (please tick)	
Date of Birth (DD/MMM/YYYY)**:**	
Weight (XXX.X Kg)**:**	

Section C: Event Details	
SAE Term: *(verbatim, as it appears in the source document, e.g. participant's medical notes)*	
Severity Grade: *(According to the grading scale provided in the study protocol)*	

Date of Onset (DD/MMM/YYYY)**:**	
SAE Category: *(Tick all that apply)*	☐ Results in Death ☐ Is Life Threatening ☐ Requires or prolongs inpatient hospitalisation ☐ Results in persistent or significant disability or incapacity ☐ Is a congenital anomaly or birth defect ☐ Other significant medical event
Contributing Factor(s): *(Tick all that apply)*	☐ Study Intervention ☐ Concomitant Intervention; *specify*_____ ☐ Concurrent/Concomitant Medication; *specify*_____ ☐ Concurrent Disorder; *specify*_____ ☐ Concurrent Clinical Trial*; *specify Clinical Trial;* _____ ☐ Other; *specify*_____
Trial Stage:	☐ Screening ☐ Treatment ☐ Follow-up ☐ Other, *specify*_____
Event description and management: *(Use additional pages if necessary, provide relevant redacted reports/supplementary information)*	

Section D: Intervention Details	
Intervention Name:	
Intervention Administration Details: **(dose, frequency etc)**	
Safety Event Relationship to the Intervention:	☐ Unrelated ☐ Unlikely to be related ☐ Possibly related ☐ Probably related ☐ Definitely related

Section D: Action Taken	
Action Taken:	☐ None ☐ Intervention reduced ☐ Intervention delayed ☐ Intervention delayed & reduced ☐ Withdrawn from Intervention
Was an Urgent Safety Measure (USM) instigated? *A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.*	* ☐ Yes ☐ No *Report to local RGO within 72 hours of becoming aware of event (if applicable)
Treatment Given for SAE: *(if applicable)*	
SAE Outcome:	☐ Recovering/Resolving (outcome to be updated later) ☐ Recovered/Resolved ☐ Recovered/Resolved with sequelae; *specify sequelae:* _____ ☐ Fatal; *specify cause of death* _____ ☐ Unknown; *specify reason unknown*_____

Section E: Investigator Signature	
Investigator Name:	
Investigator Signature:	
Date:	

Please email one signed copy to the Sponsor–Investigator <*insert name and email address***) and retain the signed original in the Site Investigator File**