Adverse Event Reporting Form

Ethics Review Committee

Faculty of Medicine, University of Jaffna

Reference number:

Protocol title:

Principal investigator:

Sponsor's name:

Study site(s):

Patient identification number:

2. Suspected adverse drug reaction

Date of onset:	**Date of recovery:**
Description of the event:	
Outcome (tick the appropriate box)	

Recovered	Recovering	Continuing	Hospitalised	Fatal

Laboratory reports			
Seriousness (tick the appropriate box)			
Life threatening		Death	
Results in hospitalisation		Birth defect	
Prolongation of hospitalisation expected		Other (specify)	
Permanent disability			
Impairment or damage to organs			
Relevant medical history			

3. Study drug / device

Batch no.:			**Expiry date:**
Date started:			**Date stopped:**
Dosage form	**Route**	**Dose**	**Frequency**

Other drugs used						
Name	**Dosage form**	**Route**	**Dose & frequency**	**Date started**	**Date stopped**	**Reason for using**

Adverse event on discontinuation of the drug/ reduction of dose (tick the appropriate box)			
Drug stopped (date)	Dose reduced (indicate the reduced dose) (date)		
Status of adverse event (tick the appropriate box)			
Disappeared	Improved	Persisted	Not known

Reappearance of adverse events on reintroduction (tick the appropriate box)					
Yes		No		Not known	

4. Reporting person

Name:

Address:

Designation:

Status in the research team:

Contact number:

Date of reporting:

Signature:

Date: