Cambridge Clinical Trials Unit Box 111 CCTU/FRM006

Adverse Event Log

To be kept in the Pharmacovigilance section of the Trial Master File and Site File

Study Title:					
Investigator:			**Site name/no.:**		
R&D Number:		**EudraCT no.:**		**REC no.:**	

Subject ID Number	Description of AE	Date of Onset	Outcome	Date of Resolution	Severity	Causality	Is it serious?*	CI/PI signature & Date

Outcome Key: 1 = Resolved no residual effects, 2 = Resolved with residual effects, 3 = Ongoing, 4 = Death
Severity Key: 1 = Mild, 2 = Moderate, 3 = Severe
Causality Key: 1 = Not related, 2 = Unlikely, 3 = Possibly, 4 = Probably, 5 = Definitely **NB: 3–5 qualify the AE as an Adverse Reaction or AR**
Is it serious? Key: 1 = Results in death, 2 = is life threatening, 3 = requires hospitalisation or prolongation of existing hospitalisation, 4 = results in persistent disability or incapacity, 5 = consists of congenital anomaly or birth defects, 6 = none of 1 to 5
***If AE is serious please complete form CCTU/FRM001 – SAE/R Reporting Form and report to Sponsor within 24 hours.**