SOP 25/ AN-04: SAE reporting form

1.	NIEC Registration No:	
2.	Study/Protocol No.	
3.	Title of project:	
4.	Principal Investigator:	
5.	Date of onset of SAE: Report date:	
6.	Report type (tick any one)	a) Initial b) Follow up If Follow-up report, state date of Initial report ---------- c) Final
7.	Subject Initials and Subject ID. DOB / Age Gender:	
8.	Describe the SAE in detail (if this is a follow-up report, include follow-up information only):	
9.	Describe the medical treatment provided (if any) to the research subject	
10.	If there was a research related injury/ hospitalization, the cost of treatment/ hospitalization was borne by:	Patient [ ] Institute [ ] Sponsor/CRO [ ]

11.	Tick whichever is applicable for SAE	A. Expected event [ ] Unexpected event[ ]
		☐ Death ☐ Congenital-anomaly ☐ Life threatening ☐ Disability ☐ Hospitalization/Prolonged ☐ Other Medically important In case of death, state probable cause of death:
12.	SUSPECT DRUG INFORMATION	
13.	Suspect drug (include generic name) / device / intervention:	
14.	Dose: Route(s) of administration: Dosage Form: If available: Batch no. Mfg date: Exp date:	
15.	Therapy dates (from / to): Therapy duration:	
16.	Did the reaction decline after stopping the drug / procedure (Dechallenge & Rechallenge information):	YES [ ] NO [ ] NA [ ]
17.	CONCOMITANT DRUGS AND HISTORY	
18.	Concomitant drug(s) and date of administration:	

19.	Patient relevant history (e.g. diagnosis, allergies):	
20.	Outcome was	Recovered [ ] Not recovered [ ] Recovering [ ] Fatal [ ] Recovered with sequalae [ ] Unknown [ ]
21.	Was the research subject continued on the research study?	Yes [ ] No [ ] NA [ ] (Mark "NA" in case of death)
22.	Is this SAE information communicated to sponsor/CRO/regulatory agencies?	Yes [ ] No [ ] Provide details if communicated:

Name of PI _____ Date_____
Signature of PI