Institutional Ethics Committee
Of
KLE Academy of Higher Education and Research
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State India
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FORM NO: 34-SAE REPORTING TEMPLATE

Principal Investigator (Name, Designation and Affiliation)
Title of study
Protocol no:
IEC Protocol Code:

01	**Participant details :**						
	Subject Initial and No		Age at the time of Event		Gender		Weight in Kgs
					M	F	
02	Report Type		Initial		Follow up		Final
	What was the assessment of relatedness to the trial in the initial report?						
	By PI		By Sponsor		By IEC		
	Related	Unrelated	Related	Unrelated	Related	Unrelated	
3	Describe the event and specify suspected SAE diagnosis:						
4	Date of onset of SAE:				Date of reporting:		
5	Onset lag time after administration of IMP				Location of SAE (Clinic/Ward/Home/Other)		
6	Details of suspected study drug/device/investigational procedure causing SAE:						
	a. Suspect study drug (include generic name) device/intervention:						
	b. Indication(s) for which suspect study drug was prescribed or tested:						
	c. Route(s) of administration, daily dose and regimen, dosage form and strength:						
	d. Therapy start date: Stop date:						
7	Was study intervention discontinued due to event?						
	Yes				No		
8	Did the reaction decline after stopping or reducing the dosage of the study drug / procedure?						
	Yes				No		
9	Did the reaction reappear after reintroducing the study drug / procedure?						
	Yes		NO		NA		
10	Concomitant study drugs history and lab investigations: a. Concomitant study drug (s) and date of administration: b. Relevant test/laboratory data with dates: c. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)						
11	Have occurred any similar SAE in the particular study						
	Yes				No		
12	Seriousness of the SAE						

13	Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).					
14	Outcome of SAE:					
	Fatal		Continuing		Recovering	
	Recovered		Unknown		If any	
15	Was the research subject continued on the trial?					
16	Provide the details about PI final assessment of SAE relatedness to trial.					
17	Has this information been communicated to sponsor/CRO/regulatory agencies?					
18	Does this report require any alteration in trial protocol?					
19	Provide details of compensation provided/ to be provided the participants (include information on who pays, how much, and to whom) Signature of PI:					