

(Annexure 6) Serious Adverse Event Reporting Format (Biomedical Health Research) Institutional Ethics Committee Narayana Dental College & Hospital



EC Ref. No. (for office use):

Title of study: Principal Investigator (Name, Designation and Affiliation)									
Timospar investigator (Nume, Designation and Attinution)									
1.	Participant details : Initials and ID Age at the time of Gender event Male Female	Weight:	(Kgs)						
2.	Suspected SAE diagnosis:	Height:	(cms)						
3.	Date of onset of SAE: Click here to enter a date. Describe the event 19:								
	Date of reporting SAE: Click here to enter a date.								
4.	Details of suspected intervention causing SAE ²⁰								
5.	Report type: Initial Follow-up Final If Follow-up report, state date of Initial report Click here	to enter a dat	te.						
6.	Have any similar SAE occurred previously in this study? If yes, please provide d	etails. Yes	No 🗖						
7.	In case of a multi-centric study, have any of the other study sites reported siminumber of cases with details if available).	lar SAEs (Pleas	se list						
8.	Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intand NOT disease process) A. Expected event Unexpected event	ervention beir	ng evaluated						

¹⁹Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious

²⁰Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)

	В.											
	Hopitalization		Increased Hospital Stay		Death		Congenital anomaly/bir th defect					
	Persistent or significant disability/incapacity	i (Event requiring intervention (surgical or medical) to prevent SAE		Event which poses threat to life		Others					
	In case of death, state probable cause of death: C. No permanent/significant functional/cosmetic impairment Permanent/significant functional/cosmetic impairment Not Applicable											
9.	 Describe the medical management provided for adverse reaction (if any) to the research participants. (include the information on who paid, how much was paid and to whom) 											
10.	 Proide details of compensation provided/ to be provided to participants (include the information on who paid, how much was paid and to whom) 											
11.	Outcome of SAE Fatal Continuing Recovering			U	ecovered nknown thers(<i>specify</i>)	MINIM						
12.	12. Provide any other relevant information to that can facilitate assessment of the case such as medical history											
13. Provide details about PI's final assessment of SAE relatedness to trial.												
S	ignature of PI:					Clic	k here to enter	a date.				