

## Institutional Ethics Committee – Biomedical & Health Research (IEC-BMHR)

### ICMR-NATIONAL INSTITUTE FOR RESEARCH IN BACTERIAL INFECTIONS, KOLKATA (Annexure 9)



**icmr** **NIRBI**  
INDIAN COUNCIL OF MEDICAL RESEARCH | NATIONAL INSTITUTE FOR RESEARCH IN BACTERIAL INFECTIONS

## Serious Adverse Event Reporting Format (Clinical trials)

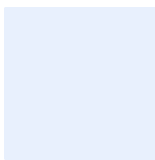
**EC Ref. No. (for office use):**

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1.	Participant details :			
	Initials and Case No./Subject ID	Age at the time of event	Gender Male <input type="checkbox"/> Female <input type="checkbox"/>	Weight: (Kgs)  Height: (cms)
2.	Report type:      Initial <input type="checkbox"/> Follow-up <input type="checkbox"/> Final <input type="checkbox"/>			
	If Follow-up report, state date of Initial report <span style="float: right;"><a href="#">Click here to enter a date.</a></span>			
	What was the assessment of relatedness to the trial in the initial report?			
	By PI- Related <input type="checkbox"/>	By sponsor - Related <input type="checkbox"/>	By EC - Related <input type="checkbox"/>	
	Unrelated <input type="checkbox"/>	Unrelated <input type="checkbox"/>	Unrelated <input type="checkbox"/>	
3.	Describe the event and specify suspected SAE diagnosis:			
4.	Date of onset of SAE: <a href="#">Click here to enter a date.</a>		Date of reporting: <a href="#">Click here to enter a date.</a>	
5.	Onset lag time after administration of intervention:		Location of SAE (Clinic/Ward/Home/Other)	
6.	Details of suspected study drug/device/investigational procedure causing SAE:			
	I. Suspect study drug (include generic name) device/intervention:			
	II. Indication(s) for which suspect study drug was prescribed or tested:			
	III. Route(s) of administration, daily dose and regimen, dosage form and strength:			
	IV. Therapy start date: <a href="#">Click here to enter a date.</a>		Stop date: <a href="#">Click here to enter a date.</a>	

7.	Was study intervention discontinued due to event? Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.	Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, provide details about the reduced dose.		
9.	Did the reaction reappear after reintroducing the study drug / procedure? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> If yes, provide details about the dose.		
10.	Concomitant study drugs history and lab investigations:  I. Concomitant study drug (s) and date of administration: <a href="#">Click here to enter a date.</a>  II. Relevant test/laboratory data with dates: <a href="#">Click here to enter a date.</a>  III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)		
11.	Have any similar SAE occurred previously in this study? If yes, please provide details. Yes <input type="checkbox"/> No <input type="checkbox"/>		
12.	Seriousness of the SAE:		
	Death <input type="checkbox"/>	Congenital anomaly <input type="checkbox"/>	
	Life threatening <input type="checkbox"/>	Required intervention to prevent permanent impairment / damage <input type="checkbox"/>	
	Hospitalization-initial or prolonged <input type="checkbox"/>	Others (specify) <input type="checkbox"/>	
	Disability <input type="checkbox"/>		
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 <input type="checkbox"/>	Recovered <input type="checkbox"/>	
	Continuing <input type="checkbox"/>	Unknown <input type="checkbox"/>	
	Recovering <input type="checkbox"/>	Other (specify) <input type="checkbox"/>	
15.	Was the research subject continued on the trial? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>		
16.	Provide the details about PI final assessment of SAE relatedness to trial.		

17.	Has this information been communicated to sponsor/CRO/regulatory agencies? Provide details if communicated (including date)	Yes <input type="checkbox"/> No <input type="checkbox"/>
18.	Does this report require any alteration in trial protocol?	Yes <input type="checkbox"/> No <input type="checkbox"/>
19.	Provide details of compensation provided/ to be provided the participants (include information on who pays, how much, and to whom)   Click here to enter a date.	