

**Institutional Ethics Committee – Biomedical & Health Research (IEC-BMHR)**  
**ICMR-NATIONAL INSTITUTE FOR RESEARCH IN BACTERIAL INFECTIONS, KOLKATA**



**(Annexure 6)**  
**Serious Adverse Event Reporting Format**  
**(Biomedical Health Research)**

EC Ref. No. (for office use):

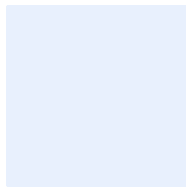
Title of study:

Principal Investigator (Name, Designation and Affiliation)

1.	Participant details :			
	Initials and ID	Age at the time of event	Gender Male <input type="checkbox"/> Female <input type="checkbox"/>	Weight: (Kgs)  Height: (cms)
2.	Suspected SAE diagnosis:			
3.	Date of onset of SAE: <a href="#">Click here to enter a date.</a>		Describe the event <sup>19</sup> :	
	Date of reporting SAE: <a href="#">Click here to enter a date.</a>			
4.	Details of suspected intervention causing SAE <sup>20</sup>			
5.	Report type: Initial <input type="checkbox"/> Follow-up <input type="checkbox"/> Final <input type="checkbox"/>			<a href="#">Click here to enter a date.</a>
If Follow-up report, state date of Initial report				
6.	Have any similar SAE occurred previously in this study? If yes, please provide details. Yes <input type="checkbox"/> No <input type="checkbox"/>			
7.	In case of a multi-centric study, have any of the other study sites reported similar SAEs (Please list number of cases with details if available).			
8.	Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)			
9.	A. Expected event <input type="checkbox"/> Unexpected event <input type="checkbox"/>			
	B.			
	Hopitalization <input type="checkbox"/>	Increased Hospital Stay <input type="checkbox"/>	Death <input type="checkbox"/>	Congenital anomaly/birth <input type="checkbox"/>

						defect	
	Persistent or significant disability/incapacity	<input type="checkbox"/>	Event requiring intervention (surgical or medical) to prevent SAE	<input type="checkbox"/>	Event which poses threat to life	<input type="checkbox"/>	Others <input type="checkbox"/>
	C. No permanent/significant functional/cosmetic impairment						<input type="checkbox"/>
	Permanent/significant functional/cosmetic impairment						<input type="checkbox"/>
	Not Applicable						<input type="checkbox"/>
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.	Provide 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	<input type="checkbox"/>		Recovered	<input type="checkbox"/>		
	Continuing	<input type="checkbox"/>		Unknown	<input type="checkbox"/>		
	Recovering	<input type="checkbox"/>		others( <i>specify</i> )	<input type="checkbox"/>		
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.						

Signature of PI:



[Click here to enter a date.](#)

<sup>19</sup>Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious

<sup>20</sup>Refers 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)