

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

ICMR-NATIONAL INSTITUTE FOR RESEARCH IN BACTERIAL INFECTIONS, KOLKATA

(Annexure 5)

Protocol Violation/ Deviation Reporting form (Reporting by case)

EC Ref. No. (for office use):



Title of study:

Principal Investigator (Name, Designation and Affiliation):

1.	EC approval date: <small>Click here to enter a date.</small>	Date of start of study: <small>Click here to enter a date.</small>
2.	Participant ID:	Date of occurrence: <small>Click here to enter a date.</small>
3.	Total number of deviations /violations reported till date in the study:	
4.	Deviation/Violation identified by: Principal Investigator/study team <input type="checkbox"/> Sponsor/Monitor <input type="checkbox"/> SAE Sub Committee/EC <input type="checkbox"/>	
5.	Is the deviation related to (Tick the appropriate box) :	
	Consenting <input type="checkbox"/>	Source documentation <input type="checkbox"/>
	Enrollment <input type="checkbox"/>	Staff <input type="checkbox"/>
	Laboratory assessment <input type="checkbox"/>	Participant non-compliance <input type="checkbox"/>
	Investigational Product <input type="checkbox"/>	Others (<i>specify</i>) <input type="checkbox"/>
	Safety Reporting <input type="checkbox"/>	
6.	Provide details of Deviation/Violation:	
7.	Corrective action taken by PI/Co-PI:	
8.	Impact on (if any): Study participant <input type="checkbox"/>	Quality of data <input type="checkbox"/>
9.	Are any changes to the study/protocol required? Yes <input type="checkbox"/> No <input type="checkbox"/>	
	If yes, give details	

Signature of PI:

Click here to enter a date.