

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



(Annexure 7)
**Premature Termination/
 Suspension/Discontinuation Report Format**

EC Ref. No. (for office use):

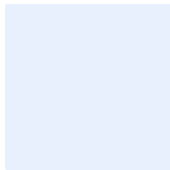
Title of study:
 Principal Investigator (Name, Designation and Affiliation):

1.	Date of EC Approval: <small>Click here to enter a date.</small>	Date of start of study: <small>Click here to enter a date.</small>
2.	Date of Last Progress Report Submitted to EC:	<small>Click here to enter a date.</small>
3.	Date of Termination/suspension/discontinuation:	<small>Click here to enter a date.</small>
4.	Tick the appropriate Premature Termination <input type="checkbox"/> Suspension <input type="checkbox"/> Discontinuation <input type="checkbox"/> Reason for Termination/Suspension/Discontinuation: Action taken Post Termination/ Suspension/Discontinuation:	
5.	Plans for post study follow up/withdrawal ²¹ (if any):	
6.	Details of study participants: Total participants to be recruited: Screened: Screen failures: Enrolled: Consent Withdrawn: Reason(Give details): Withdrawn by PI: Reason(Give details): Active on treatment: Completed treatment : Participants on Follow-up: Participants lost to follow up: Any other: No. of drop outs: Reasons for each drop-out:	
7.	Total Number of SAEs reported till date in the study: Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes <input type="checkbox"/> No <input type="checkbox"/>	
8.	Have there been participant complaints or feedback about the study? If yes, provide details Yes <input type="checkbox"/> No <input type="checkbox"/>	

²¹ Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.

9.	Have there been any suggestions from the SAE Sub Committee? If yes, have you implemented that suggestion?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
10.	Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? (e.g., making arrangements for medical care of research participants): If yes, provide details Summary of Results (if any):	Yes <input type="checkbox"/> No <input type="checkbox"/>

Signature of PI:



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