

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

ICMR-NATIONAL INSTITUTE FOR RESEARCH IN BACTERIAL INFECTIONS, KOLKATA (Annexure 4)

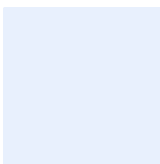


Application/ Notification form for Amendments

EC Ref. No. (for office use):

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

1.	Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.																				
2.	Details of amendment(s) <table border="1"><thead><tr><th>S.No</th><th>Existing Provision</th><th>Proposed Amendment</th><th>Reason</th><th>Location in the protocol/ICD¹⁸</th></tr></thead><tbody><tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr><tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr><tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr></tbody></table>	S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD ¹⁸															
S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD ¹⁸																	
3.	Impact on benefit-risk analysis If yes, describe in brief: Yes <input type="checkbox"/> No <input type="checkbox"/>																				
4.	Is any re-consent necessary? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, have necessary changes been made in the informed consent? Yes <input type="checkbox"/> No <input type="checkbox"/>																				
5.	Type of review requested for amendment: Expedited review (No alteration in risk to participants) <input type="checkbox"/> Full review by EC (There is an increased alteration in the risk to participants) <input type="checkbox"/>																				
6.	Version number of amended Protocol/Investigator's brochure/ICD:																				

Signature of PI:		Click here to enter a date.
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¹⁸Location implies page number in the ICD/protocol where the amendment is proposed.