

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

### ICMR-NATIONAL INSTITUTE FOR RESEARCH IN BACTERIAL INFECTIONS, KOLKATA (Annexure 14)



#### Project extension form

EC Ref. No. (for office use):

**\*The project extension must be duly submitted no later than 30 days before the approval expires.**

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1.	CECHR Reference No.: CECHR ---- / ----	
2.	Date of EC Approval: <a href="#">Click here to enter a date.</a>	Duration of Approval          months/ years
3.	Date of Start of study: <a href="#">Click here to enter a date.</a>	Date of Completion: <a href="#">Click here to enter a date.</a> <i>(As per the first approval granted)</i>
	Duration of Extension sought:          months/ years	
	Period of Extension sought from <a href="#">Click here to enter a date.</a>	To <a href="#">Click here to enter a date.</a>
4.	Have there been any modifications in the budget for the extension sought?  <b>If No, skip to item no.5</b> <span style="float: right;">Yes <input type="checkbox"/> No <input type="checkbox"/></span>  If yes, discuss in detail:	
5.	Does the study involve recruitment of participants? <span style="float: right;">Yes <input type="checkbox"/> No <input type="checkbox"/></span> (a) If yes, Total number for study          No. (b) Screened:          No.    Enrolled:          No. (c) Number Completed:          No. on followup:          No. (d) Enrolment status – ongoing / completed/ stopped          No. (e) If ongoing , Expected          No. (f) Report of DSMB* <span style="float: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/></span> <i>* In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.</i> (g) Any other remark	

	(h) Have any participants withdrawn from this study since the last approval? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> If yes, total number withdrawn and reasons:
6.	Have there been any amendments in the research protocol/informed consent document (ICD) for the extension sought? Yes <input type="checkbox"/> No <input type="checkbox"/> <b>If No, skip to item no.7</b>
	(a) If yes, discuss in detail:
	(b) In case of amendments in the research protocol/ICD, will re-consent be sought from participants? If yes, when / how: Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, discuss in detail:
8.	Have any ethical concerns occurred during the study? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, give details
9.	(a) Have any adverse events been noted since the last review? Yes <input type="checkbox"/> No <input type="checkbox"/> Describe in brief: (b) Have any SAE's occurred since last review? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, number of SAE's :      Type of SAE's: (c) Is the SAE related to the study? Yes <input type="checkbox"/> No <input type="checkbox"/> Have you reported the SAE to EC? If no, state reasons      Yes <input type="checkbox"/> No <input type="checkbox"/>
10.	Is any new information available that changes the benefit -risk analysis of human participants involved in this study? If yes, discuss in detail: Have any ethical concerns occurred during the study? Yes <input type="checkbox"/> No <input type="checkbox"/>

