

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

**ICMR-NATIONAL INSTITUTE FOR RESEARCH IN BACTERIAL INFECTIONS, KOLKATA
(Formerly, ICMR- NICED, Kolkata)**



(Annexure 3) Continuing Review/ Annual report format

EC Ref. No. (for office use):

***The annual report must be duly submitted no later than 30 days before the annual year's completion.**

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1.	CECHR Reference No.: CECHR ---- / ----	
2.	Date of EC Approval: <small>Click here to enter a date.</small>	Duration of Approval months/ years
3.	Date of Start of study: <small>Click here to enter a date.</small>	Proposed date of Completion: <small>Click here to enter a date.</small>
	Period of Continuing Report <small>Click here to enter a date.</small>	To <small>Click here to enter a date.</small>
4.	Does the study involve recruitment of participants? Yes <input type="checkbox"/> No <input type="checkbox"/> (a) If yes, Total number expected No. Screened: No. Enrolled: Number Completed: No. on followup: . (b) Enrolment status – ongoing / completed/ stopped (c) Report of DSMB ¹⁶ Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> (d) Any other remark	
	(e) Have any participants withdrawn from this study since the last approval?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 If yes, total number withdrawn and reasons:	
5.	Is the study likely to extend beyond the stated period ¹⁷ ? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please provide reasons for the extension	
6.	Have there been any amendments in the research protocol/informed consent document (ICD) during the past approval period? Yes <input type="checkbox"/> No <input type="checkbox"/> If No, skip to item no.6	
	(a) If yes, date of approval for protocol and ICD : <small>Click here to enter a date.</small>	
	(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? If yes, when / how: Yes <input type="checkbox"/> No <input type="checkbox"/>	

¹⁶In 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.

¹⁷Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC

7. Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes No
If yes, discuss in detail:
8. Have any ethical concerns occurred during this period? Yes No
If yes, give details
9. (a) Have any adverse events been noted since the last review? Yes No
Describe in brief:
(b) Have any SAE's occurred since last review? Yes No
If yes, number of SAE's : Type of SAE's:
(c) Is the SAE related to the study? Yes No
Have you reported the SAE to EC? If no, state reasons Yes No
10. Has there been any protocol deviations/violations that occurred during this period? If yes, number of deviations
Have you reported the deviations to EC? If no, state reasons Yes No
11. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC Yes No NA
12. Are there any publications or presentations during this period? If yes give details Yes No
13. Brief Summary of the Study (up to 500 words) (to briefly describe the status, findings, activities undertaken, any deviations or changes, special mentions etc.)

Signature of PI:

Click here to enter a date.