Continuing Review/ Annual report format

Yenepoya Ethics Committee-3 (YEC-3)

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.	EC Reference No.:	
2.	Date of EC Approval: Click here to enter a date.	Duration of Approval months/ years
3.	Date of Start of study: Click here to enter a date.	Proposed date of Completion: Click here to enter a date.
	Period of Continuing ReportClick here to enter a date.	To Click here to enter a date.
4.	Does the study involve recruitment of participants? Yes ☐ No ☐ (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 ☐ No ☐ NA ☐ (d) Any other remark	
	(e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA ☐ If yes, total number withdrawn and reasons:	
5.	Is the study likely to extend beyond the stated period[17]? Yes ☐ No ☐ 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? **If No, skip to item no.6** Yes ☐ No ☐	
	(a) If yes, date of approval for protocol and ICD : Click here to enter a date.	
	(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? If yes, when / how: Yes ☐ No ☐	

[16] *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.*

[17] *Problems 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.