



Project extension form

Yenepoya Ethics Committee-3 (YEC-3)

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.	EC Reference No: _____	
2.	Date of EC Approval: <input type="button" value="Click here to enter a date."/>	Duration of Approval months/ years
3.	Date of Start of study: <input type="button" value="Click here to enter a date."/>	Date of Completion: <input type="button" value="Click here to enter a date."/> <i>(As per the first approval granted)</i>
	Duration of Extension sought: months/ years	
	Period of Extension sought from <input type="button" value="Click here to enter a date."/>	To <input type="button" value="Click here to enter a date."/>
4.	Have there been any modifications in the budget for the extension sought? If No, skip to item no.5 Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, discuss in detail:	
5.	Does the study involve recruitment of participants? Yes <input type="checkbox"/> No <input type="checkbox"/> (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* Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> <small>* 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.</small> (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	(h) Have any participants withdrawn from this study since the last approval?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 If yes, total number withdrawn and reasons: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"/> If No, skip to item no.7
	(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 No
If yes, discuss in detail:

8. Have any ethical concerns occurred during the study? 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 the period of study?
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. Briefly explain the reason for the extension sought (up to 500 words) (Please attach the relevant documents in support of the extension.)

Signature of PI:  Click here to enter a date.