



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:

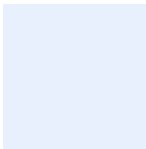
Principal Investigator (Name, Designation and Affiliation)

1.	EC Reference No: _____	
2.	Date of EC Approval: Click here to enter a date.	Duration of Approval _____ months/ years
3.	Date of Start of study: Click here to enter a date.	Date of Completion: Click here to enter a date. (As per the first approval granted)
	Duration of Extension sought: _____ months/ years	
	Period of Extension sought from Click here to enter a date.	To 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"/> <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	

	<p>(h) Have any participants withdrawn from this study since the last approval? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/></p> <p>If yes, total number withdrawn and reasons:</p>
6.	<p>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"/></p> <p>If No, skip to item no.7</p> <p>(a) If yes, discuss in detail:</p>
	<p>(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"/></p>

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.