



KMCT
MEDICAL COLLEGE

APPLICATION FORM NO: 15
INSTITUTIONAL ETHICS
COMMITTEE,
KMCT MEDICAL COLLEGE
Manassery (P.O), Mukkam, Kozhikode, 673602
Project extension form

IEC 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:	Duration of Approval months/ years
3	Date of Start of study:	Date of Completion: (As per the first approval granted)
	Duration of Extension sought: months/ years	
	Period of Extension sought from	To
4	Have there been any modifications in the budget for the extension sought? If No, skip to item no.5 If yes, discuss in detail: Yes ☐ No ☐	

5	Does the study involve recruitment of participants? (f) If yes, Total number for study No. (g) Screened: No. Enrolled: No. (h) Number Completed: No. on followup: No. (i) Enrolment status – ongoing / completed/ stopped No. (j) If ongoing , Expected No. (k) Report of DSMB (l) Any other remark	Yes ☐ No ☐ Yes ☐ No ☐ NA ☐
	(m) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA ☐ If yes, total number withdrawn and reasons:	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 ☐ No ☐ If No, skip to item no.7 If yes, discuss in detail:	
7	In case of amendments in the research protocol/ICD, will re-consent be sought from participants? Yes ☐ No ☐ If yes, when / how:	

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8. 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:

9. Have any ethical concerns occurred during the study? Yes ☐ No ☐
If yes, give details

10. (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 ☐

11. Has there been any protocol deviations/violations that occurred during the period of study? Yes ☐ No ☐
If yes, number of deviations

- Have you reported the deviations to EC? Yes ☐ No ☐
If no, state reasons

12. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC

Yes ☐ No ☐ NA ☐

13. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

14. 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:

Date: