(Annexure 14)
Project Extension form
अखिल भारतीय आयुर्वेद संस्थान
All INDIA INSTITUTE OF AYURVEDA (AIIA)

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 ☐ No ☐ If yes, discuss in detail:	
5.	Does the study involve recruitment of participants? Yes ☐ No ☐ (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 ☐ No ☐ NA ☐ ** 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.* (g) Any other remark	
	(h) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA ☐ If yes, total number withdrawn and reasons:	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**
	(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 ☐ No ☐

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.