



(Annexure 3)
Continuing Review/ Annual report form
अखिल भारतीय आयुर्वेद संस्थान
ALL INDIA INSTITUTE OF AYURVEDA (AIIA)

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: <small>Click here to enter a date.</small>	Duration of Approval <small>months/ years</small>
3.	Date of Start of study: <small>Click here to enter a date.</small>	Proposed date of Completion: <small>Click here to enter a date.</small>
	Period of Continuing Report <small>Click here to enter a date.</small>	To <small>Click here to enter a date.</small>
4.	Does the study involve recruitment of participants? Yes <input type="checkbox"/> No <input type="checkbox"/> (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 <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> (d) Any other remark	
	(e) How many participants withdrawn from this study since the last approval?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 If yes, total number of participants withdrawn and reasons:	
5.	Is the study likely to extend beyond the stated period ¹⁷ ? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please provide reasons for the extension	
6.	Have there been any amendments to the research protocol/informed consent documents (ICD) during the previous approval period? If No, skip to item no.6 Yes <input type="checkbox"/> No <input type="checkbox"/> (a) If yes, date of approval for protocol and ICD : <small>Click here to enter a date.</small>	
	(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? If yes, when / how: Yes <input type="checkbox"/> No <input type="checkbox"/>	

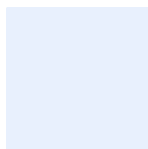
¹⁶In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.

¹⁷Problems 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 IEC
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.](#)