

## (Annexure 7)

## Premature Termination/ Suspension/ Discontinuation Report Format अखिल भारतीय आयुर्वेद संस्थान

## All INDIA INSTITUTE OF AYURVEDA (AIIA)

EC Ref. No. (for office use):

	Title of study: Principal Investigator (Name, Designation and Affiliation)				
1.	Date of EC Approval: Click here to enter a date.	Date of start of study: Click here to enter a date.			
<ol> <li>3.</li> <li>4.</li> </ol>	Date of Last Progress Report Submitted to EC: Date of Termination/suspension/discontinuation: Tick the appropriate Premature Termination Suspension Reason for Termination/Suspension/Discontinuation Action taken Post Termination/ Suspension/Discontinuation				
5.	Plans for post study follow up/withdrawal <sup>21</sup> (if any):				
6.	Details of study participants:  Total participants to be recruited: Screened: Screen failures:				
	Enrolled: Consent Withdrawn: Reason (Give details):				
	Withdrawn by PI: Reason (Give details):				
	Active on treatment: Completed treatment:	Participants on Follow-up:			
	Participants lost to follow up: Any other:	No. of drop outs:			
	Reasons for each drop-out:				
7.	Total Number of SAEs reported till date in the study: Have any unexpected adverse events or outcomes observed in the study been reported to the EC?  Yes $\square$ No $\square$				
8.	Have there been participant complaints or feedback about the study?  If yes, provide details				

<sup>&</sup>lt;sup>21</sup> Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.

			Yes No No Ves No No
10. Do the procedures for withdrawal of enrolled participants take into account their rights and (e.g., making arrangements for medical care of research participants): If yes, provide details Yes \( \bigcap \) No			
Summary of Results (if any):			
Signature of PI:			Click here to enter a date.
	Do the procedure (e.g., making arra	Do the procedures for withdraw (e.g., making arrangements for Summary of Results (if any):	(e.g., making arrangements for medical care of research participants):  Summary of Results (if any):