(Annexure 12)
Study completion/ Final 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.

2. Date of Start of Study: Click here to enter a date.   Date of study completion:Click here to enter a date.

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3. Provide details of:
   a) Total no. of study participants approved by the EC for recruitment:
   b) Total no. of study participants recruited:
   c) Total number of participants withdrawn from the study (if any):
   Provide the reasons for withdrawal of participants[23]:

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)

5. Describe the main Ethical issues encountered in the study (if any)

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

   Deviations: Violation: Amendments:

7. Describe in brief Plans for archival of records / Record Retention:

8. Is there a plan for post study follow-up   Yes ☐ No ☐

   If yes, describe in brief:

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?

   If yes, describe in brief: Yes ☐ No ☐

10. Is there a plan for post study benefit sharing with the study participants?   Yes ☐ No ☐

    If yes, describe in brief:

11. Describe results (summary) with Conclusion[24]:

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[23] *Explanation for the withdrawal of participants whether by self or by the P*
[24] *For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.*

12. Number of SAEs that occurred in the study:

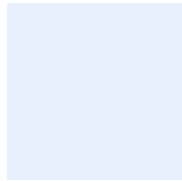13. Have all SAEs been intimated to the EC: Yes ☐ No ☐

14. Is medical management or compensation for SAE provided to the participants?   Yes ☐ No ☐

   If yes, provide details

Signature of PI: Click here to enter a date.