



आयुर्वेद शिक्षण एवं अनुसंधान संस्थान

Institute of Teaching and Research in Ayurveda

राष्ट्रीय महत्व का संस्थान, आयुष मंत्रालय, भारत सरकार

Institute of National Importance, Ministry of Ayush, Government of India

Website: <https://itra.ac.in> Email: ethics@itra.edu.in

Premature Termination/Suspension/ Discontinuation Report Format

1. Title of the study:

2. IEC ref no:

3. PI – Name, Designation and Affiliation

4. Date of EC approval:

5. Date of Start of study:

6. Date of last progress report submitted to IEC:

7. Date of termination/suspension/discontinuation:

8. Reason for Termination/Suspension/Discontinuation

9. Action taken post Termination/Suspension/Discontinuation (if any):

10. Plans for post study follow up/withdrawal (if any):

11. Details of study participants

Total number of participants to be recruited:

Screened:

Screen failures:

Consent withdrawn – reason:

Withdrawn by PI- reason:

Active on treatment / Completed treatment/ Participants on follow-up:

Participants lost to follow up:

Number of drop outs:

Reasons for each drop-out:

Any other:

12. Total number of SAEs reported till date in the study:

13. Have any unexpected adverse events or outcomes observed in the study been reported to the IEC? Yes/No

14. Have there been participant complaints or feedback about the study? Yes/No

If yes provide details

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15. Have there been any suggestions from the SAE Sub Committee? Yes /No

If yes, have you implemented that suggestion? Yes/No

16. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes No

(e.g., making arrangements for medical care of research participants):

If yes, provide details

Summary of results:

Signature of PI / Research scholar

Signature of Guide

(in case of research scholar)