

Premature Termination/Suspension/ Discontinuation Report Format.....
(Name of the Institution)

EC Ref. No. (For office use):

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC approval: Date of start of study: 2. Date of last progress report submitted to EC: 3. Date of termination/suspension/discontinuation:

4. Tick the appropriate

Premature Termination ☐ Suspension ☐ Discontinuation ☐

Reason for Termination/Suspension/Discontinuation:

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

5. Plans for post study follow up/withdrawal²¹ (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 Consent Withdrawn:.....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Withdrawn by PI:.....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):

²¹ Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.

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

Participants lost to follow up: Any other: Number of drop outs:.....

Reasons for each drop-out:

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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 ☐ No ☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No ☐

If yes, provide details:.....

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9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No ☐

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

10. 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

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Summary of results (if any):

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Signature of PI:

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