

**Annexure 1**  
**AX 01 / SOP 09/V6.1**

(Annexure 7)



**Premature Termination/Suspension/ Discontinuation Report Format**

**INSTITUTIONAL ETHICS COMMITTEE (IEC)**

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No. ....

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/withdrawal<sup>2</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 Consent Withdrawn:.....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Withdrawn by PI:.....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): .....

<sup>2</sup> 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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