



INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth G. S. Medical College and KEM Hospital, Mumbai.

Annexure 1 AX 01/SOP 09/V 7 Premature Termination/Suspension/Discontinuation Report Format

Date:

IEC No. of the Project:

Study Title:

Principal Investigator (Name, Designation & 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 (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Enrolled: Consent Withdrawn: Reason (Give details):

Withdrawn by PI: Reason (Give details):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: Complete treatment: Participants on follow-up:

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



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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:

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 Principal Investigator (PI) with Date: