

(Annexure 7)
**Premature Termination/ Suspension/
 Discontinuation Report Format**
Institutional Ethics Committee
Narayana Dental College & Hospital



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.](#) Date of start of study: [Click here to enter a date.](#)

2. Date of Last Progress Report Submitted to EC: [Click here to enter a date.](#)

3. Date of Termination/suspension/discontinuation: [Click here to enter a date.](#)

4. Tick the appropriate
 Premature Termination Suspension Discontinuation

Reason for Termination/Suspension/Discontinuation:
 Action taken Post Termination/ Suspension/Discontinuation:

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Enrolled: Consent Withdrawn: Reason(Give details):

Withdrawn by PI: Reason(Give details):

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

Participants lost to follow up: Any other: No. of drop outs:

Reasons for each drop-out:

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?
 If yes, provide details Yes No

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

9. Have there been any suggestions from the SAE Sub Committee?
If yes, have you implemented that suggestion?

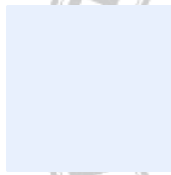
Yes No
Yes No

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare?
(e.g., making arrangements for medical care of research participants): If yes, provide details

Yes No

Summary of Results (if any):

Signature of PI:



Click here to enter a date.

