


SOP 14	 Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 14/ V2.1	<i>Management of Premature Termination / Suspension / Discontinuation of the study</i>	Effective Date: 23.04.2019

Title: Management of Premature Termination / Suspension / Discontinuation of the study

Note: Annexure 1 on Page no 4 to 5 of SOP 14 / V2 is amended and approved on 23.04.2019

Annexure 1 - Premature Termination/Suspension/ Discontinuation Report Format
(Annexure 01/SOP/14/V2.1)

Annexure 01/SOP/14/V2.1

Premature Termination/Suspension/ Discontinuation Report Format

SMVMCH-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/withdrawal (Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study) (if any):

6. Details of study participants:


Total participants to be recruited: _____ Screened: _____ Screen failure: _____

Enrolled: _____ Consent Withdrawn: _____

Reason (Give details):

Withdrawn by PI: _____

Reason(Give details):

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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:

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 ☐

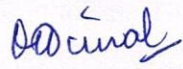
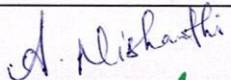


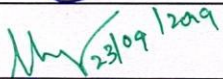
8. Have there been participant complaints or feedback about the study? Yes ☐ No ☐
If yes, provide details:

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

Summary of results (if any):

Signature of PI with date:

	Name	Designation	Signature
Prepared	Dr. Vimal. M	Member	
	Dr. Nishanthi. A	Member	
Reviewed	Dr. R. N. Kagne	Member Secretary	
	Dr. Amol Dongre	Member	
Approved	Dr. T. Thiagarajan	Chairman	
Issued	Dr. D. Rajagovindan	Director, SMVMCH	