


SOP 11	 Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 11/ V2.1	<i>Review of Protocol Deviations / Violations</i>	Effective Date: 23.04.2019

Title: Review of Protocol Deviations / Violations
Note: Annexure 1 on Page no 4 to 5 of SOP 11/V2 is amended and approved on 23.04.2019

Annexure 1 - Protocol Violation / Deviation Reporting Form (Reporting by case)
(Annexure 01/SOP/11/V2.1)

Annexure 01/SOP/11/V2.1

Protocol Violation / Deviation Reporting Form (Reporting by case)

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. Participant ID: _____ Date of occurrence: _____
3. Total number of deviations /violations reported till date in the study: _____
4. Deviation/Violation identified by:

Principal Investigator/study team	<input type="checkbox"/>
Sponsor/Monitor	<input type="checkbox"/>
SAE Sub Committee/EC	<input type="checkbox"/>
5. Is the deviation related to (Tick the appropriate box) :

Consenting	<input type="checkbox"/>	Source documentation	<input type="checkbox"/>
Enrollment	<input type="checkbox"/>	Staff	<input type="checkbox"/>
Laboratory assessment	<input type="checkbox"/>	Participant non-compliance	<input type="checkbox"/>
Investigational product	<input type="checkbox"/>	Others (specify)	<input type="checkbox"/>
Safety reporting	<input type="checkbox"/>		

6. Provide details of Deviation/Violation:

7. Corrective action taken by PI/Co-PI:

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8. Impact on (if any): Study participant ☐ Quality of data ☐
9. Are any changes to the study/protocol required? Yes ☐ No ☐

If yes, give details

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	 23/6/19
Approved	Dr. T. Thiagarajan	Chairman	 23/04/2019
Issued	Dr. D. Rajagovindan	Director, SMVMCH	