


SOP 13	 <b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital	
SOP code: SOP 13/ V2.1	<i>Review of Study Completion Reports</i>	Effective Date: 23.04.2019

**Title:** Review of Study Completion Reports  
**Note:** Annexure 1 on Page no 3 & 4 of SOP 13 / V2 is amended and approved on 23.04.2019

Annexure 1 - Study Completion / Final report format (*Annexure 01/SOP/13/V2.1*)

**Annexure 01/SOP-13/V2.1**  
**Study Completion / Final report format**

SMVMCH-EC Ref. No. (for office use) :

Title of study:


Principal Investigator (Name, Designation and Affiliation):

1. Date of EC approval :
2. Date of start of study: Date of study completion:
3. Provide details of:
  - a. Total number of study participants approved by the EC for recruitment:
  - b. Total number of study participants recruited:
  - c. Total number of participants withdrawn from the study (if any):

Provide the reasons for withdrawal of participants (*Explanation for the withdrawal of participants whether by self or by the PI*) :
4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)
5. Describe the main ethical issues encountered in the study (if any)
6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period
 

Deviations: Violation: Amendments:
7. Describe in brief plans for archival of records / record retention:
8. Is there a plan for post study follow-up? Yes No ☐ ☐  
 If yes, describe in brief:



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9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?

If yes, describe in brief:

Yes ☐ No ☐

10. Is there a plan for post study benefit sharing with the study participants?

If yes, describe in brief:

Yes No ☐ ☐

11. Describe results (summary) with Conclusion (For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready) :

12. Number of SAEs that occurred in the study:

13. Have all SAEs been intimated to the EC ?


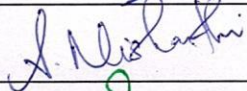

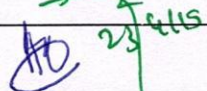
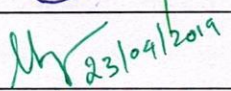
Yes ☐ No ☐

14. Is medical management or compensation for SAE provided to the participants?

If yes, provide details

Yes No ☐ ☐

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	