


SOP 10	 Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 10/ V2.1	<i>Continuing Review of Study Protocols</i>	Effective Date: 23.04.2019

Title: Continuing Review of Study Protocols
Note: Annexure 2 on Page no 5 to 8 of SOP 10/V2 is amended and approved on 23.04.2019

Annexure 2 - Continuing Review / Annual report format (*Annexure 02/SOP10/V2.1*)


Annexure 02/SOP10/V2.1
Continuing Review / Annual report format

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

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC Approval: _____ Validity of approval: _____
2. Date of Start of study: _____ Proposed date of Completion: _____
Period of Continuing Report: _____ - to - _____
3. Does the study involve recruitment of participants?
 - a. If yes, Total number expected..... Number Screened: Number Enrolled:
Number Completed:..... Number on follow up:.....
 - b. Enrolment status – ongoing / completed/ stopped
 - c. Report of DSMB Yes ☐ No ☐ NA ☐
(In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA)
 - d. Any other remark
- e. Have any participants withdrawn from this study since the last approval?
If yes, total number withdrawn and reasons:
4. Is the study likely to extend beyond the stated period? (*Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*)
If yes, please provide reasons for the extension

SOP 10	 Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 10/ V2.1	<i>Continuing Review of Study Protocols</i>	Effective Date: 23.04.2019

5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

If No, skip to item no. 6

Yes ☐ No ☐

a. If yes, date of approval for protocol and ICD :

b. In case of amendments in the research protocol/ICD, was re-consent sought from participants?

Yes ☐ No ☐

If yes, when / how

6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study?

Yes ☐ No ☐

If yes, discuss in detail:

7. Have any ethical concerns occurred during this period?

Yes ☐ No ☐

If yes, give details:

8. a. Have any adverse events been noted since the last review?

Yes ☐ No ☐

Describe in brief:

b. Have any SAE's occurred since last review?

Yes ☐ No ☐

If yes, number of SAE's:..... Type of SAE's:

c. Is the SAE related to the study?

Yes ☐ No ☐

Have you reported the SAE to EC? If no, state reasons

Yes ☐ No ☐

9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations

Have you reported the deviations to EC? If no, state reasons

Yes ☐ No ☐


10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ?

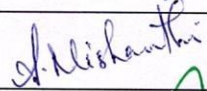
Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

Any other comments:

Signature of PI with date:

SOP 10	<div style="text-align: center;">  <p>Sri MANAKULA VINAYAGAR Medical college and Hospital</p> </div>	
SOP code: SOP 10/ V2.1	<i>Continuing Review of Study Protocols</i>	Effective Date: 23.04.2019

	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	