


SOP 09	 <b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital	
SOP code: SOP 09/ V2.1	<i>Review of Resubmitted and Amended Protocols and Protocol-related Document</i>	Effective Date: 23.04.2019

**Title:** Review of Resubmitted and Amended Protocols and Protocol-related Document

**Note:** Annexure 1 on Page no 7 to 8 – of SOP 09/V2 is amended and approved on 23.04.2019

Annexure 1- Notification form for Amendments (*Annexure 01/SOP-9/V2.1*)

### Annexure 01/SOP-9/V2.1

#### Notification form for Amendments

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. Details of amendment(s)

S. No	Existing Provision	Proposed Amendment	Reason	Location in the protocol / ICD ( <i>Location implies page number in the ICD/protocol where the amendment is proposed.</i> )

3. Impact on benefit-risk analysis

Yes ☐ No ☐

If yes, describe in brief:

.....  
 .....


4. Is any re-consent necessary?

Yes ☐ No ☐

If yes, have necessary changes been made in the informed consent?

Yes ☐ No ☐



<b>SOP 09</b>	<p style="text-align: center;">   <b>Sri MANAKULA VINAYAGAR</b>              Medical college and Hospital           </p>	
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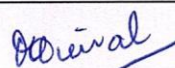
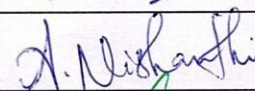



5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants) ☐

Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure/ICD: .....

Signature of PI with date:

	Name	Designation	Signature
<b>Prepared</b>	<b>Dr. Vimal. M</b>	<b>Member</b>	
	<b>Dr. Nishanthi. A</b>	<b>Member</b>	
<b>Reviewed</b>	<b>Dr. R. N. Kagne</b>	<b>Member Secretary</b>	
	<b>Dr. Amol Dongre</b>	<b>Member</b>	 23/4/19
<b>Approved</b>	<b>Dr. T. Thiagarajan</b>	<b>Chairman</b>	 23/04/2019
<b>Issued</b>	<b>Dr. D. Rajagovindan</b>	<b>Director, SMVMCH</b>	