


SOP 07 B	 Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 07B/ V2.1	<i>Expedited Review of Research Study Protocols</i>	Effective Date: 23.04.2019

Title: Expedited Review of Research Study Protocols

Note: New annexure no 3 is added after approval of SMVMCH-EC members. It is amended and will be effective from 23.04.2019

Annexure 3- Additional information to be provided with Application Form for Expedited review (*Annexure 01/SOP/7B/V2.1*)

Annexure 03/SOP/7B/V2.1

For Expedited Review

Additional information to be provided with Application Form

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


Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why expedited review from EC is requested?

(Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2)

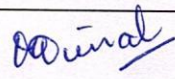
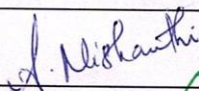
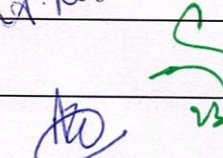
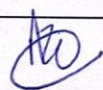
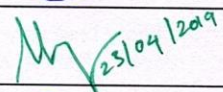
- i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
- ii. Involves clinical documentation materials that are non-identifiable (data, documents, records). ☐
- iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐
- iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal ☐
- v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
- vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
- vii. For multicentre research where a designated EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. ☐
- viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
- ix. Any other (please specify) ☐

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Signature of PI with date:

Comments of EC Secretariat:

Signature of Member Secretary 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	