SOP 22	Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 22/ V3	***To Review Biomedical & Health Research during COVID-19 Pandemic***	**Effective Date: 31.12.2021**

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee will function and conduct ethics review in an emergency situation with restrictions as imposed by social distancing requirements during the COVID-19 outbreak.

2. Scope:

This SOP covers the functioning, information and procedures followed by Institutional Ethics Committee – Sri Manakula Vinayagar Medical College and Hospital (SMVMCH) during pandemic times.

3. Procedures & Responsibilities:

S.No	Procedure	Responsibility
	Submission and initial review	
a.	Submit research proposal (electronically)	Researchers
b.	Receive, record, verify completeness and allot reference no.	Secretariat/ Member Secretary
c.	Categorize depending on risk (Exempt/ Expedited, Full committee), identify need for review by experts/ independent consultants/ patient /others; and designate reviewers	Member Secretary in consultation with Chairperson
d.	Perform review of documents as described in *Table 4.3 of ICMR National Ethical Guidelines*, fill study assessment form	Reviewers
e.	Schedule virtual Meeting, Prepare Agenda, invite members (*Independent Consultants/Subject Experts/ PI/ Member secretary of local EC/ in consultation with Chairperson*).	Secretariat / Member Secretary

S.No	Procedure	Responsibility
	Virtual EC meeting	
f.	Open the meeting, determine quorum (*Section 4.8.4 of ICMR National Ethical Guidelines), COI declaration, Summaries* Agenda	Chairperson
g.	Brief presentation and/or address queries on the research proposal and leave meeting prior to decision	Researchers/ subject experts (optional)
h.	Present observations on item reviewed	Reviewers
i.	Discuss further on the item and reach consensus	SMVMCH-EC members
j.	Record Decision and rejoin member who had declared COI before moving on to subsequent item on agenda	Secretariat / Member Secretary
k.	Record minutes of meeting, ratify approved decisions of exemption/expedited review before closing meeting	Member Secretary/ Chairperson
	Post meeting activities	
l.	Communication of decision and maintaining records.	Secretariat/ Member Secretary
m.	Follow up/monitoring/ analysis of SAE/ handling of issues related to non- compliance, violation, complaints etc.	Member Secretary in consultation with Chairperson

4. Detailed instructions:

1. The Covid related research proposals will be initially reviewed by the Institutional Clinical Review Board which will verify the appropriateness of the research, investigators and their qualifications and will issue the permission letter to carry out the research in the Institution.
2. The Research Proposal then will be submitted electronically with supporting documents to SMVMCH-EC. It should contain the following documents as per SOP 06/V2.2:
   - Cover letter addressed to secretariat of the EC (AX01/SOP 06/V3)
   - Check list for proposal submission to the EC (AX02/SOP 06/V3)
   - Research project submission application form for initial review by SMVMCH – EC (AX03/SOP 06/V3)
   - Additional information to be provided with application form for clinical trials (AX04/SOP 06/V3)

- Additional information to be provided with application form for human genetics testing research (AX05/SOP 06/V3)
- Additional information to be provided with application form for socio behavioral and public health research (AX06/SOP 06/V3)
- Brief CV of all Investigators (for clinical trials) (AX07/SOP 06/V3)
- Good Clinical Practice (GCP) training of investigators (for clinical trials)
- Research Committee comments and response template
- Research Committee approval letter
- EC clearance of other centers (for multicentric research)
- Agreement between collaborating partners (for multicentric research)
- MTA (Material Transfer Agreement) between collaborating partners (for multicentric research)
- Insurance policy/certificate (if applicable)
- Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification (if applicable)
- Copy of contract or agreement signed with the sponsor or donor agency (if applicable)
- All significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol (if applicable)
- Copy of the detailed protocol as per EC template (AX08/SOP 06/V3)
- Investigators Brochure (If applicable for drug/biologicals/device trials)
- Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/Guides for Focused Group Discussions (FGDs) (English and translated) (if applicable)
- Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated) (if applicable) (AX 09/SOP06/V3)
- Assent form for minors (12-18 years) (English and Translated) (if applicable) (AX 10/SOP06/V3)
- Advertisement/material to recruit participants (fliers, posters etc) (if applicable)
- Permission from governing authorities (if required)

3. Once received, the secretariat will verify protocol for completeness (if not ask PI) and number.
4. Member Secretary to categorize research into full review, expedited review or exemption from review.
5. Member Secretary (in consultation with Chairperson) will identify need for review by subject experts, independent consultants, special invitees, patient representatives, others for prior review or to present views during the meeting.
6. The project for full review will be included in agenda of virtual full-committee meeting to be scheduled at the earliest by the Member Secretary in consultation with the Chairperson.
7. The members will be briefed about the technological requirements and virtual platform used for the conduct of the meeting.
8. Quorum requirements for review will be applicable as per Section 4.8.4 ICMR National Ethical Guidelines, 2017.
9. Review procedures as per ICMR National Ethical Guidelines will also hold good for the virtual web ethics meeting.

5. References:

1. ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants 2017

2. National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During COVID-19 Pandemic 2020

	Name	Designation	Signature
Prepared	Dr. Nishanthi. A	Member	
	Dr. Ganesh. R	Member	
Reviewed	Dr. Vimal. M	Member Secretary	
Approved	Dr. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	3/1/22