SOP Code: SOP 05/V1	Preparation of Standard Operating Procedures for Sri Manakula Vinayagar Nursing College Ethics Committee (SMVNC-EC)	Effective Date: 11.10.2023

Title: The conditions of appointment and the quorum required for the Sri Manakula Vinayagar Nursing College Ethics Committee (SMVNC-EC)

The SMVN-EC is formed by the Chairman of SMVNC-EC (Principal, SMVNC) in accordance with the guidelines laid Biomedical Research on Human Participants by ICMR guidelines (Indian regulations, 2017) and relevant, National and International ethical guidelines.

The minimum of 50% + 1 member are required to compose a quorum. All decisions will be taken in meetings and not by circulation of project proposals. For clinical trial, the five members of quorum must be from Medical scientist, Clinician, Legal expert, Social scientist or representative of a Non-Governmental voluntary agency or a philosopher or an ethicist or a theologian or a similar person and one Layperson from the community as per ICMR guidelines (Indian regulations, 2017) and relevant, National and International ethical guidelines.

The responsibilities of the SMVNC-EC Members will be to ensure that all the human research and trial projects are approved and conducted within the specified clinical trial site and have the following qualities:

- Projects are sound in scientific design, have adequate statistical significance and are in accordance with ICMR guidelines (Indian regulations, 2017) and relevant, National and International ethical guidelines.
- Biomedical research projects do not compromises the safety, rights and well being of the study subjects.
- Trial is conducted and supervised by adequately qualified and experienced medical personnel.
- Recruit patients who voluntarily sign the informed consent and fulfill the inclusion and exclusion criteria specified in the protocol and are randomized appropriately.

- Do not expose the study subjects to more than minimal risk.
- To review proposed trial with regard to the following;
    - The trial objectives.
    - The qualification and competence of the investigators.
    - The sample size calculation.
    - The proposed analysis of data.
    - The subject inclusion and exclusion criteria.
    - The exposure of participants to risk.
    - The extent of medical and laboratory examination proposed.
    - The storage of data and laboratory samples.
    - The procedures proposed to achieve informed consent.
    - The proposed mechanisms to ensure confidentiality.
- The member secretary in consultation with the Chairman organizes the meeting.
- The Member Secretary will maintain the minutes of the meeting. Both the Chairperson and the Member Secretary will sign the minutes of the meeting.
- Once the minutes of the meeting are signed, the Member Secretary will circulate to all the members and issue approval or disapproval letter to the concerned Principal Investigator.
- The Chairperson will preside over the meeting.
- Both the Chairman & Member Secretary will sign off the Approval Letter.
- The committee will review all new research projects and also the ongoing research projects at intervals appropriate to the degree of risk to the study subjects.
- In the case of Non availability of the Chairman, the Vice Chairman will chair the meeting.
- The committee will maintain a list of projects submitted, approved / disapproved and the outcome of each project.

References

1. Forum for Ethics Review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http://www.ferci.org/sops/
2. Ethical Guidelines for biomedical Research on Human Participants (2017). India Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR Ethical Guidelines 2017.pdf

	Name	Designation	Signature
Prepared	Dr.R.Priyadharshini	Clinician	
	Mrs.S.manimekalai	IRC member	
Reviewed	Dr.S.Narmatha	Member Secretary	
Approved	Prof.Dr.G.Muthamilselvi	Chairman	
Issued	Dr.A.Ayee	SOP Incharge	