

<b>SOP Code: SOP 03/V1</b>	<b>Preparation of Standard Operating Procedures for Sri Manakula Vinayagar Nursing College Ethics Committee (SMVNC-EC)</b>	<b>Effective Date: 11.10.2023</b>
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***Title: Preparation of Standard Operating Procedures (SOP) for Memberships Requirements of the Ethics Committee***

**Introduction:**

Sri Manakula Vinayagar Nursing College Institutional Ethics Committee (SMVNC- EC) reviews all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all research participants before approving the research proposals. The SMVNC- EC reviews and grants approval to the research protocols from Sri Manakula Vinayagar Medical College, Sri Manakula Vinayagar Nursing College, The SMVNC-EC reviews and it is the authority for granting ethical approval to academic studies, clinical trials and bioequivalence studies. Services of SMVNC EC are also provided to external institutions on MOU with them.

The SMVNC EC ascertains whether all cardinal principles of research ethics viz. autonomy, beneficence, non-maleficence and justice are taken care in the research involving human participants. The SMVNC EC reviews all research projects to be conducted at the institution irrespective of whether the research project is funded or non-funded, and irrespective of funding agency.

**Goals and Objectives**

- To protect the dignity, rights and well being of the current and potential research participants
- The standard operating procedure is to describe the terms of reference, which provide the framework for constitution, selection, role and responsibilities of Sri Manakula Vinayagar Nursing College Institution ethical committee (SMVNC - EC)
- Procedures for maintaining confidentiality of all activities and documents

### Scope

- This SOP applies to the EC, selection, roles and responsibilities of members of the EC and maintenance of confidentiality of all activities and documents.

### IEC Members list:

Role in IEC	Name and Educational Qualification	e-mail ID	Affiliated to SMVNC – Yes/No; if no - affiliated organization
<b>Chairperson</b>	Prof. Dr. Felicia Chitra, Ph.D Nursing	feliciachitra@mtpgrihs.ac.in	Principal, MTPGRI&HS
<b>Member Secretary</b>	Dr. S. Narmatha Ph.D Nursing	narmathas@smvnc.ac.in	Vice- Principal, SMVNC
<b>Basic Medical Scientists</b>	Dr. Rathidevi Ph.D Nursing	rathidevi@icon.ac.in	Associate Professor, ICON
<b>Clinician Affiliated</b>	Dr. R. Priyadharshini Ph.D Nursing	priyadharashinir@smvnc.ac.in	Professor, SMVNC
	Dr. Vetriselvi Ph.D Nursing	vetriselvijipmer1967@gmail.com	Assit. Professor, JIPMER
<b>Legal expert</b>	Mr. Sathish Kumar Babu, B.A., L.L.B	sathish.sathish.babu2@gmail.com	Legal Advisor, SMVNC
<b>Social Scientist</b>	Dr. N. Muthu Venkata Subramaniam, Ph.D	muthusiksha@gmail.com	Associate Professor , SMVNC
<b>Lay Person</b>	Mr. Selvam Dhanapal	selvamd6259@gmail.com	Resident, kalitheerthalkuppam
<b>Other Supporting Staff</b>	Mr. Kiubanadhan, B.Sc., M.L.I.S., D.C.A.	kirupanandana@smvnc.ac.in	Librarian, SMVNC
<b>Alternate Member</b>	Dr. R. Sridevi Ph.D Nursing	sridevir@smvnc.ac.in	Professor, SMVNC

### Policy for Updating/Training of IEC Members:

- Member Secretary will notify - all relevant information on ethics to the IEC – members
- All IEC members shall be required to undergo refresher course in Good clinical practice annually.
- The Chairperson, Member Secretary and members will be encouraged by the appointing authority to attend national and international training programs and other related activities

**Evaluation of IEC:**

- The committee will conduct periodic self-assessment annually through internal meeting of the members using the Self-Assessment Tool. The individual feedback will be provided to all members by Member Secretary.

**Selection and Responsibility IEC Members:**

- To select the committee chairperson, member secretary and IEC members will be done by expert either affiliated or non-affiliated to IEC
- It is the responsibility of all the IEC members and the secretariat to read, understand, follow and respect this SOP
- To attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
- To review, discuss and consider research proposals submitted for evaluation.
- To review the progress reports and monitor ongoing studies
- To maintain confidentiality of the documents and deliberations of IEC meetings
- To carry out the work delegated by Chairperson and Member Secretary
- To assist the Chairperson and Member Secretary in carrying out IEC work as per SOP.
- The IEC should ensure that patients' rights are not compromised regarding any payments proposed to be made in the study to the patients towards reimbursement of incidental

**Research Proposal Submission Procedure:**

- All research proposals are to be submitted to the IEC- Member Secretary in the prescribed Application format along with check list in the prescribed format and detailed study protocol at least 1 to 2 weeks in advance, especially for all clinical trials. Covering letter addressed to the IEC - Chairperson / Member Secretary  
The protocol would include the following:

- Title; Name and contact details of a) Principal Investigator (PI); b) Study Sponsor
- Protocol - Summary; research objectives and rationale for the study involving human subjects.
- Recent curriculum vitae (CV) of the investigators indicating qualification and experience; GCP certificate (< 3 years) of PI and his team members.
- Details of Funding agency / Sponsors and fund allocation for the proposed work. \*
  - Investigator's Brochure. \*
- Undertaking by the Investigator. \*
- Subject recruitment procedures or proposed methods / advertisement / notices.
- Study subjects - Inclusion and exclusion criteria.
- Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any.
- Statistical analysis in detail.
- Procedure for seeking and obtaining informed consent; with sample of patient information sheet and information consent forms in English and vernacular languages

### **Selection of Independent Consultants/Subject Experts**

- The Director of SMVNC-EC appoints independent consultants/subject experts. The subject experts sign the confidentiality agreement
- The SMVNC-EC has the procedures in place for involving the subject experts as reviewers of research proposals. The subject experts will not have voting rights.
- For the research proposals categorized for expedited review, the subject expert does the review and submits the report to the SMVNC-EC Member Secretary. For the proposals categorised under full review, the subject does the review and attends the meeting of full board of IEC.

### **Conflict of Interest and Confidentiality**

- The SMVNC-EC members are informed about the conflict of interest policy during their appointment. In the consent letter for appointment, the members declare that they will disclose any conflict of interest, and will exempt himself / herself from the review process and decision making
- During the meetings of SMVNC-EC, the chairperson asks the members to declare conflict of interest if any, and reassesses the quorum when any member withdraws from the decision making.
- The declaration of conflict of interest is recorded in the minutes of the meetings.
- The SMVNC-EC members are trained on the conflict of interest policy.

### **Tenure of Membership**

- The tenure of EC members as per Drug Controller General of India registration will be for a period of 3 years from the date of registration.

### **Training of the EC members in research Ethics**

- An individual selected as new members of the EC will be required to attend one meeting as an 'observer' before being inducted as a member of the EC
- Member secretary or an EC member will provide introductory training in research, Ethics, GCP and SOPs to the new member
- The newly inducted member should submit certificate of training.

### **References**

1. Forum for Ethics Review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22<sup>nd</sup> 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](http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf)

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