Sri MANAKULA VINAYAGAR Nursing College

SOP Code: SOP 10/V1	Preparation of Standard Operating Procedures for Sri Manakula Vinayagar Nursing College Ethics Committee (SMVNC-EC)	Effective Date: 11.10.2023

Title: Standard Operating Procedures for Policy on Training on New and Existing Committee Members

Introduction to SMVNC ETHCS COMMIITTEE

SMVNC Institutional Ethics Committee 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 Institutional Ethical Committee reviews and grants approval to the research protocols from SMVNC. The Institutional Ethical Committee 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-IEC 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. The SMVNC-EC adheres to existing applicable rules and regulations for its formation and functioning. The IEC follows ICMR 2017 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

Goals and Objectives of SMVNC- EC -Goals of SMVNC-EC

- To protect the dignity, rights and wellbeing of the current and potential research participants
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs

Objectives of SMVNC-EC:

- To review the research proposals in an unbiased manner, without compromising the scientific quality, and ethical principles in conduct of biomedical, experimental and behavioral research.
- To advice and educate the researchers on ethical guidelines in conducting research involving human participants.
- To be updated with the relevant guidelines and regulations on research, research ethics and good clinical practice.
- To monitor the progress of approved research proposals with regard to compliance of protocol and ethical principles.

POLICIES OF SMVNC-EC

1. Policies and SOPs of SMVNC-EC

The policies of SMVNC-EC are defined in this document. The SMVNC-EC follows written SOPs for its different functions as per applicable rules and regulations.

The Policy document is reviewed every year, and if necessary revisions are done. The Member Secretary is responsible for the review and updating of the Policy Document. Two or three members from the IEC will be in the Policy Review Team. Inputs from Head of the institution, the Chairperson of IEC and members will be taken. The Chairperson of IEC is the Approving authority for the Policy Document.

The SMVNC-EC members are trained on the policies and SOPs of SMVNC- EC during their induction, and with every revision of these documents. There is a SOP for the preparation and review of SOPs of SMVNC-EC.

2. Constitution of SMVNC-EC

2.1. Appointment: The Head of the Institution (Chairman) appoints the members of SMVNC-EC including the Chairperson and Member Secretary based on their competence, experience and integrity. He sends an official request letter to the members who will

confirm their acceptance by providing all required information such as curriculum vitae, and certificates of training on research ethics and good clinical practice. Then the Head of the Institution (Chairman) sends a final appointment letter with terms and conditions of appointment, roles and responsibilities. The members need to sign the consent letter and confidentiality agreement. The SMVNC-EC is functional from the date of constitution and SOP training to the members.

2.2. Administrative Support and Independence for Functioning: The management of SMVNC Institutions provides support to the ethics committee activities including infrastructure, secretariat staff, financial resources and training. The management does not interfere in the functioning of SMVNC-EC including review, decision making and monitoring. The Head of the Institution (Chairman) mentions policy statement authorizing the ethics committee of its independence in functioning, in the appointment proposal letter and final appointment order of Chairperson, SMVNC-EC. This policy statement is also mentioned in the constitution letter of SMVNC-EC issued by the Head of the Institution (Chairman).

2.3. The SMVNC-EC does not have the institutional head or any official of the institution holding administrative post in the management (Director, Dean, Principal, Administrator, Medical Superintendent) as its member. the Head of the Institution (Chairman) is the appellate authority.

2.4. Composition: The SMVNC-EC will have 7 to 15 members. The present team has 10 members. The Chairperson is from outside the institution and non-affiliated to SMVNC. Any current or retired employee of SMVNC will not be the Chairperson of SMVNC-EC. The Member Secretary is Internal. The SMVNC-EC will have one of the members as joint secretary. The members include at least two clinicians, one basic medical scientist, one legal expert, one social scientist and one lay person. One of the members is selected as the Vice Chairperson. There is adequate gender representation. The Social Scientist, Legal Expert and Lay Person are not affiliated to the institution.

2.5. Tenure: The members have tenure of three years. After the tenure, at least 1/3 rd of the members are replaced by members of the same category. The Chairperson, Member secretary and members could get maximum two consecutive terms. Any member showing professional misconduct and members with continuous absence from meeting s of SMVNC-EC are terminated as and when such cases are found.

2.6. Alternate Members: SMVNC-EC has a panel of alternate members who have voting rights and who will participate in the review process and decision making in the absence of any regular member. Alternate member of the same category will replace the member in such cases. The eligibility criteria for alternate members are same as that of members.

3. Conflict of Interest and Confidentiality

3.1. 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.

3.2. The members are informed about the need for maintaining confidentiality of all documents, discussions and deliberations during their appointment. The members and secretariat staff sign the confidentiality agreement.

4. Selection of Independent Consultants/Subject Experts

4.1. The Head of the Institution (Chairman) 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.

4.2. The SMVNC-EC has a subject expert panel including both affiliated and non-affiliated.

4.3. Representatives of vulnerable groups are invited for review in the research protocols involving vulnerable populations.

5. Allowing Observers or Guests

The SMVNC-EC has a mechanism to allow observers or guests to its office and meetings .The observers need to take prior permission, and sign an agreement of confidentiality

6. Submission of Documents for Review

The SMVNC-EC has a documented procedure for guiding the investigators on submission of documents to SMVNC-EC for review. The submitted documents are scrutinized and categorized for review. The research protocol should be accompanied by protocol submission form, budget proposal, informed consent documents, permission from regulatory authorities and other documents as applicable. The investigator needs to submit the protocols at least ten days prior to the scheduled meeting of SMVNC-EC

7. Review Procedures

7.1. The SMVNC-EC follows documented procedures for initial review of the research protocols and related documents. The proposals are reviewed as per applicable rules and regulations.

7.2. The proposals are categorized as: exempted from review, expedited review and full review. Research protocols with less than minimal risk are categorized as: exempted from review.

7.3. The proposals and attached documents are sent to the members and subject experts at least once week before the scheduled meeting of FMIEC. Review forms are used to assess scientific validity and ethical issues, along with checklists for reviewing informed consent

documents, clinical trial contract, budget, insurance agreement, and risk-benefit assessment.

8. Meetings of SMVNC-EC and Decision Making

8.1. The SMVNC-EC meets once in a month on every second Saturday. Additional meetings and emergency meetings are held if required.

8.2. The Member Secretary prepares the agenda for the meetings of SMVNC-EC and circulated to all members at least one week prior to the scheduled IEC meeting.

8.3. The meetings are conducted by the Chairperson who ensures quorum. The SMVNC-EC has well-defined criteria for quorum; no decision is taken without the quorum. For review of each protocol the quorum of IEC should be at least 5 members with basic medical scientist, clinician, legal expert, social scientist/philosopher and lay person. The chairperson or his/her designee should be present during the meeting.

8.4. The decision in SMVNC-EC is based on risk assessment, scientific validity and adherence to ethical principles. Decisions are taken by consensus, as: approved, approved with suggestions, resubmit with revision or rejected. The decision of SMVNC-EC is communicated to the principal investigator in writing.

8.5. Deliberations and decisions made during the meetings are documented, circulated to all IEC members, approved by the chairperson and maintained as minutes of meeting.

9. Continuing Review

The SMVNC-EC does continuing review of research protocols to periodically monitor the progress of the study, to ensure continuous protection of the rights and welfare of research participants. Based on the reports submitted by the investigator and the discussions in the full board meeting, SMVNC-EC decides for continuation of the study, recommend for modifications, or discontinuation of the study.

10. Review of Protocol Amendments and Resubmitted Documents

10.1. The SMVNC-EC reviews protocol amendments and resubmitted documents. Protocol amendments are categorized for expedited or full review. The resubmissions are categorized as exempted from review, expedited review or full review.

10.2. Review of amendments to the originally approved protocol, consent forms and investigator's brochure are done in formal meetings to evaluate the risk to trial subjects. The IEC evaluates all amendments to the approved protocol and assesses if there is an alteration in the risk benefit ratio.

11. Monitoring the Research Protocols

11.1. The SMVNC-EC has procedures in place for regular monitoring of all the proposals approved at the site. This is done by on-site monitoring, and review of source documents, the informed consent process, visit details, investigational product storage, case records, and monitoring reports from the sponsor, DSMB (Data and Safety Monitoring Board) recommendations, interview with investigator/site staff. The monitoring plan to oversight assures safety of subjects and compliance to applicable rules and regulations.

11.2. The on-site monitoring is done by a team of SMVNC-EC members headed by the Chairperson (or his designee). A checklist is used to record the observations.

11.3. The SMVNC-EC has the authority to communicate and verify with the trial subjects.

11.4. For-cause assessments are conducted following non-compliance and/or complaints for the trials approved by SMVNC-EC.

11.5. The FMIEC (*Federal Financial Institutions Examination Council's*) suggests any areas that need to be improved based on the findings of monitoring reports.

12. Review of Protocol Deviations and Violations

12.1. The SMVNC-EC reviews the protocol deviations and violations, evaluates them and takes appropriate actions as per rules and regulations.

12.2. The action on protocol deviations and violation is based on the nature and seriousness, frequency of deviations and violations in the study in the past, and frequency of deviation/ violation in previous studies conducted by the same PI/ Co-PI or in the same department.

12.3. Protocol deviations and violations are reviewed in the full board meeting of IEC. The decision could be allowing the study to be continued, allowing the study with modifications and discontinuation of the ethical approval issued.

13. Review of Study Completion or Final Reports

The study completion report is expected from the investigator within 1 month of completion of the study at the site. The report is discussed in the full board meeting of IEC. The decision of IEC could be: a) noted / approved b) request for additional information / clarification.

14. Training of SMVNC-EC Members

14.1. The members of SMVNC-EC are trained with the SOP of SMVNC-EC during the first one month of their induction. The members will get opportunity only after the completion of this induction training on SOP, GCP and relevant guidelines.

14.2. The SMVNC-EC has the training schedule, and every member undergoes annual training on GCP, bioethics and guidelines for conduct of research on human participants.

15. Review of Serious Adverse Events

Serious adverse events are addressed, adequate medical care is provided and an appropriate reporting mechanism is followed as per applicable rules and regulations. The IRC subcommittee initially analyzes the IRC, prepares a report which is presented and discussed in the full board meeting of SMVNC-EC.

16. Waiver of Consent

The SMVNC-EC grants waiver of consent if the research cannot practically be carried out without the waiver and the waiver is scientifically justified; for retrospective studies, where the participants are de-identified or cannot be contacted; research on anonymized biological samples/data; certain types of public health studies/surveillance programmes /programme evaluation studies; research on data available in the public domain; or research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

17. Management of Premature Termination or Suspension of a Study:

The SMVNC-EC reviews the reports of premature termination or suspension of a study, and communicates to the PI, after the meeting acknowledging the approval of termination/ letter seeking clarifications/information regarding the premature termination.

18. Review of Research Involving Vulnerable Populations

18.1. Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. They are the individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.

18.2. The SMVNC-EC allows research on vulnerable population .While reviewing the research proposals involving vulnerable populations, the SMVNC-EC evaluates following aspects in addition to the aspects reviewed routinely. The protocol should be reviewed to assess if the following points are addressed: can the research be performed in any other non-vulnerable participants? ; Is there justification to use vulnerable population? ; Do the benefits justify the risks; Are the participants selected equitably; and Have the measures to protect Autonomy of the vulnerable population been described.

18.3. In addition to all members of the IEC, the Chairperson and Member Secretary include one or two experts who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols. A representative of the vulnerable population also will be included.

19. Grievance Redressal Process:

The SMVNC-EC has a grievance redressal mechanism in place. The SMVNC-EC readily accepts complaints/grievances from participants, or gets the inputs from interviews with patients during the site monitoring. The patient information sheet has the contact numbers of Member Secretary and Chairperson of SMVNC-EC, who could be contacted through e mail, telephone or direct walk-in meet. The complaints and concerns of participants are addressed and managed appropriately.

20. Record Keeping and Archival:

The SMVNC-EC has a documented procedure for record keeping archival. Security, confidentiality and integrity of all proposals and associated documents is reviewed from time to time and administrative communication is maintained. Documentation is dated, filed and archived as per the SOP. Confidentiality is maintained during the archival and retrieval. The document storage has restricted access with pest-control and fire safety.

21. Self-Assessment of SMVNC-EC:

The SMVNC-EC conducts self-evaluation. It conducts two internal audits in a year using a checklist. The SMVNC-EC evaluates the appropriateness of its composition. By doing self-assessment, SMVNC-EC members make themselves accountable.

22. Financial Transparency:

There is financial transparency of the SMVNC-EC activities and functioning. The SMVNC-EC maintains financial records of honorarium payment to each of the members, and other expenses incurred. The Accounts Department maintains the records of these transactions. There is a specified fees for the review of clinical trial proposals. This is mentioned in the

SOP (Submission of research proposals). The transactions related to this are maintained in the Accounts Department of SMVNC. The details and records of payments done to subjects of clinical trials is maintained in the Accounts Department of SMVNC.

23. Communications:

The SMVNC-EC has a process for communication with all stake holders. The communication modes could be printed letters, e mail, or telephonic calls. The Chairperson does the communications to Head of the Institution and Regulatory authorities. He/she is also responsible for communicating to members in case of any queries on disciplinary grounds. The Member Secretary does most of the communications. He/she is responsible for communications to members of IEC and principal investigators. The effective communications within and by SMVNC-EC assure co-ordination between all research stake holders and with the regulatory authority.

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	