

SOP Code: SOP 08/V1	Preparation of Standard Operating Procedures for Sri Manakula Vinayagar Nursing College Ethics Committee (SMVNC-EC)	Effective Date: 11.10.2023
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Title: Preparation of Standard Operating Procedures (SOP) for Sri Manakula Vinayagar Nursing College Ethics Committee (SMVNC-EC)

1. Purpose

The purpose of this SOP is to define the process for writing, reviewing, distributing and amending SOPs of the SMVNC-EC. The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with ICMR guidelines (Indian regulations) and relevant, national and international ethical guidelines.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the SMVNC-EC

3. Responsibility

It is responsibility of the Member Secretary in consultation with Chairman of the SMVNC-EC to appoint an SOP team to formulate a new SOP/S or to revise existing SOP/s. The SOP team shall do this by following the standard procedures, format and coding system that is used while drafting or editing any SOP/s of the SMVNC-EC.

3.1 Secretariat of the IEC will

- Assist Member Secretary to formulate an SOP Team.
- Co-ordinate activities of writing, reviewing, distributing and amending SOP/s.
- Ensure that all the IEC members and involved administrative staff have access to the sops. Ensure that all the IEC members and involved staff are working according to currentversion of SOP/s.
- Maintain an up-to-date distribution list for each SOP/s distributed to the SMVNC-EC members.
- Maintain a file of all current SOP's and the list of SOP/s.

- Maintain a file of all past sops of the SMVNC-EC.
- Ensure that the latest version of the SOP is uploaded at the institute website.

3.2 Member Secretary of the EC will

- Assess the need(s) for SOP/S revision.
- Consult with Chairman of the SMVNC-EC to appoint an SOP team.
- Coordinate activities of writing, reviewing distributing and amending SOPS.
- Submit the draft for approval to Chairman.

3.3 SOP team will

- Assess the request(s) for SOP/S revision in consultation with the Member Secretary and Chairman.
- Propose new/modified sops as needed.
- Draft the SOP's in consultation with the IEC members and involve administrative staff.
- Review the draft SOP before submitting to full board meeting.

3.4 Chairman of the EC will

- Appoint SOP Team.
- Approve the SOP/s.
- Sign and date the approved SOP/s.

3.5 SMVNC-EC members will

- Review and approve the draft SOPS.
- Sign and date the approved sops.
- Maintain a copy of all sops.

4. Detailed instructions

4.1 Identify the need for new or amendment of current SOP/s

Chairman, Member Secretary or any member of the EC who would feel the requirement of a revision or notices an inconsistency/ discrepancy has any suggestions on how to improve the existing SOP or requests to design an entirely new SOP can put forth his request by writing to the SMVNC-EC either as an email/letter/verbal request in

a meeting. The Chairman will inform all the SMVNC-EC members about this request at a regular full-board SMVNC-EC meeting.

If the SMVNC-EC committee agrees to the request, an appropriate SOP team will be appointed by the Chairman and designated the task to proceed with the revision process/ formulation process of the SOP. If the SMVNC-EC committee members do not agree. No further action will be taken. If the member, who made the request for modification of the SOP. is absent for regular full-board SMVNC-EC meeting then he will be informed by the Chairman.

4.2 Appointing the SOP Team

- The Chairman will constitute an SOP Team consisting of the Member Secretary and two or more members of the SMVNC-EC who have a thorough understanding of the ethical review process.
- The SOP writing team will carry out the subsequent steps as described in sections 4.3-4.7.

4.3 List all relevant procedures

- Write down step by step all the procedures of the SMVNC-EC that are to be standardized in the form of an SOP.
- Organize, divide and name each process

4.4 Write and review a new SOP

- When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairman.
- Each SOP should be given a number and a title that is self-explanatory and easily understood. A unique code number with the format SOP xx/Vy will be assigned to each SOP item by the Secretariat. "xx" will be a two-digit number assigned specifically to each activity based SOP. "V" refers to version of the SOP and "y" will be a number identifying the version. The first SOP of the current version would be SOP 01/VI i.e. it is SOP number 01 with version 1.

- Each SOP may have annexures which are forms to be filled in by various stakeholders [EC or Principal Investigator (PI)]. Each annexure will be given a unique code number with the format AX pp/SOP xx/Vy. AX refers to annexure form. pp is a two-digit number identifying the number of the annexure, while xx/Vy refers to the SOP number and its version. For example AX 01/SOP01/V1 means annexure form number 1 belonging to SOP 01/V1.
- Each SOP will be prepared according to the standard template in AX 01 SOP01 VI.
- Each page of the SOP will bear the header which will have the effective date i.e. the date of approval (aa/bb/cccc) of the SOP by the Chairman. The SOP number will be on the right hand corner with the logo of the Institution and title of the SOP while the footer will bear the page number in center as page p of q (total) pages.
- The draft SOP prepared by the SOP team will be circulated to all the EC members by the Member-Secretary.

4.5 Write and review a revised SOP

- If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form (AX 02/SOP01/V3) along with description of the main change/s.
- The rest of the steps are as described in Section 4.4.

4.6 Prepare submit final draft

- The new/revised SOP will be reviewed at SMVNC-EC meeting.
- The suggestions that are agreed upon by the SMVNC-EC members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.
- The SOP team would stand automatically dissolved once the SMVNC-EC takes final decision regarding the SOP.

4.7 Approve the new/revised SOP

- The final version will be presented to the Chairman for review and approval.

- The authors, reviewers and the Chairman will sign and date the SOP on the first page of the SOP document. Chairman and Member Secretary will sign and date the last page of each new/reviewed SOP/S and Secretariat of the SMVNC-EC office will put the stamps of Chairman and Member Secretary below their signature with SMVNC-EC office round stamp. This date of approval will be declared as the effective date from which the SOP will be implemented. The face page may also contain signature of Head of the Institution as having accepted the document.

4.8 Implement, distribute and file SOPs

- The approved SOP will be implemented from the effective date.
- The Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.
- The approved SOP will be distributed to the SMVNC-EC members and a log will be maintained as per the annexure- AX 03/SOP 01.
- One complete original set of current SOP will be filed in the SOP Master file, by the EC Secretariat in the EC office
- When the revised version is distributed, all the SOP Committee members will be requested to destroy their earlier version. Only one copy of the earlier version will be filed in the file entitled 'Past SOPs of the SMVNC-EC' by the EC Secretariat in the EC office.
- The SMVNC-EC members will review the SOPs once in every 3 years.

5. Reference to the other SOP: NIL

6. Annexures

Annexure 1 AX 01/SOP 01/V3- Template for SOPs.

Annexure 2 AX 02/SOP 01/V3- Documentation of History of the SOPs

Annexure 3 AX 03/SOP 01/V3- Log of the IEC members receiving

Annexure 4 AX 04/SOP 01/V3-List of SOPs of the EC.

Annexure 1: AX 01/SOP 01/V3**Template for Standard Operating Procedures****Title****Main Text:**

- 1. Purpose:** Summarizes and explains the objectives of the procedure
- 2. Scope:** States the range of activities that the SOP applies to
- 3. Responsibility:** Refers to person(s) assigned to perform the activities involved in the SOP
- 4. Detailed instructions:** Describes procedures step by step in short and clear sentences
- 5. Reference to other applicable SOP:** Refers in the cross references in the SOP version 2
- 6. Annexure:** Forms to capture information pertaining to the SOP instructions
- 7. Flow chart:** Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity.
- 8. Reference:** Refers to the references used for framing the SOP

Annexure 2: AX 02/SOP01/V3**Documentation of History of the SOPs****Details of superseded SOP**

Name of the team. of authors	Version	Effective date: (dd- mm-yyyy)	Remarks

Annexure 3: AX 03/SOP01/V3**Log of the EC members receiving SOPs**

Sl. No.	Name of Recipients	Designation	SOP Code Number	No. of Copies	Signature and Date

Annexure 4: AX 04/SOP 01/V3**List of SOPs of the Institutional Ethics Committee**

No	Title of the Standard Operating Procedures (SOPs)	SOP No.

7. Flow Chart

No	Activity	Responsibility
1.	Identify the need for new or amendment of current SOP	Any member of SMVNCH-EC, Member Secretary/Chairman
2.	Appoint the SOP Team(s)	Chairman
3.	List all relevant procedures	SOP Team
4.	Write and review a new SOP	SOP Team
5.	Write and review a revised SOP	SOP Team
6.	Prepare and submit final draft	SOP Team

7.	Final decision regarding the SOP	All member present for SMVNC-EC meeting along with Chairman and Member Secretary
8.	Approve the new/revised SOP	Chairman
9.	Implement, distribute and file SOPs	IEC members and Secretariat

8. References

1. Forum for Ethics review Committees in India (FERCI) Standard Operating Procedures of Institutional Ethics Committee (cited 22 October 2018) Available from: <http://www.ferci.org/sops/>
2. Ethical guidelines for biomedical research on human participants (2017) Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf.

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