

<b>SOP Code: SOP 06/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: Standard Operating Procedures (SOP) for Resignation, Replacement or Removal of members***

**Purpose**

- The purpose of this SOP is to describe how the Institutional Ethics Committee (IEC) Manages resignation, replacement or removal of members from research study.
- Protocols may be terminated at the recommendation of the IEC, Principal Investigator, sponsor, Regulator or other authorized bodies wherein subject enrolment and subject follow-up are discontinued before the scheduled end of the study.

**Responsibility**

- It is the responsibility of the IEC to manage the resignation, replacement or removal of members from any study (recommended resignation, replacement or removal of members by Data Safety and Monitoring Board, Principal Investigator, Sponsor or other authorized bodies or by the IEC) that the IEC has previously approved.

**Procedure**

- The members can apply directly to serve as member of IEC or they can be given request letter from the chairman or member secretary/ vice chairman.
- The selection of the members of IEC will entirely depend on the requirement of the IEC and qualification of the member and would be decided by Member secretary and Chairman jointly or Chairman with consent of at least three members.



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- The applicant will be informed about their selection or rejection within one week of their application.
- Chairman can also request members to join the IEC .The Member Selection will be decided by Member secretary and Chairman jointly or Chairman with consent of at least three members.
- The duration of the membership will be 3 years.
- There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.
- The members who have resigned may be replaced at the discretion of the appointing authority for the same.
- A member can be replaced in the event of long-term non-availability [three consecutive meetings]. The member should be asked for clarification and if found non-convincing then he/she can be removed with the notice of one week.
- The members who decide to resign must provide written notification of their proposed resignation date voluntarily by informing the IEC one month prior.
- In case where member if involved in non compliance of the SOPs he/she should be asked for clarification, which can be discussed in the meeting and if found non convincing then the member can be removed with a notice of one week.
- The recommendations may be sought from the resigning member.
- It is desirable that a backup of such member should be first prepared and included in the IEC so that the membership requirement of the IEC should be maintained.
- Authority to replace/Remove the member shall be with the Chairman.
- Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
- A member may be relieved or terminated of his/her membership in case of
  - Is held to be /declares himself/herself insolvent
  - Is guilty of any professional malpractice.





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- Does not act in good faith and in bonafide discharge of their function as a member of IEC.
  - If a regular member fails to attend more than 3 meetings of IEC.
  - Has willingly suppressed withheld or concealed any information available or known to him/her, with regards to any application for approval pending before the IEC and/or of his/her personal or conflict of interest in any such trial.
  - Relocate to another city or any such matter.
- Documentation of the resignation, replacement or removal of members will be recorded in the meeting minutes of the next duly constituted IEC meeting and IEC membership circular/ roster will be revised.

**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%20Ethical%20Guidelines%202017.pdf)

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