


SOP 21	 <p style="text-align: center;">Sri <b>MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 21/ V4	<i>Training and Assessment of Ethics Committee Members &amp; Assessment of IEC Functioning</i>	<b>Effective Date: 02.01.2024</b>

**Title: Training and Assessment of Ethics Committee Members & Assessment of IEC Functioning**

**1. Purpose**

The purpose of this SOP is to describe requirements and methodology for training and performance assessment of the SMVMCH-EC members and the Secretariat.

**2. Scope**

The SOP applies to all the EC members and the Secretariat.

**3. Responsibility**

It is the responsibility of the EC Chairman with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the EC members and the Secretariat. The Chairman is responsible for assessment of all EC members and completes a self-assessment exercise at prescribed intervals.

**4. Detailed instructions**


**4.1. Topics for training**

EC members should have knowledge of the following:

- ✓ Relevant research ethics and regulatory guidelines
- ✓ Roles and Responsibilities of EC members
- ✓ Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy Recent Developments in relevant health science specialties
- ✓ SOPs of the EC

Secretariat should have knowledge and relevant skills for conducting the following activities:

- ✓ Competency in working on Microsoft word, Excel, EC office software
- ✓ Maintenance of EC Database
- ✓ Communication skills- written and verbal
- ✓ Knowledge about the SOPs

SOP 21	 <p style="text-align: center;"><b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 21/ V4	<i>Training and Assessment of Ethics Committee Members &amp; Assessment of IEC Functioning</i>	<b>Effective Date: 02.01.2024</b>


#### ***4.2. Training of new EC Members***

- Every time a new committee is constituted, the members must undergo initial training on ethics in clinical research and good clinical research and SOPs. One training every year at the minimum should be provided.
- An individual selected as a new member 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 an introductory training to the new member. The new EC members would be encouraged to undergo online EC training programme too.
- The EC Member Secretary, member, Chairman will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
- The EC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the EC Members. At the end of the training program, a post test will be conducted to document the learning.
- The EC may sponsor or reimburse the expenses of an EC member or prospective members for attending conference, continuing education session workshop and/ or training program (if applicable).
- Any amendments and recent developments in the field of bioethics will be shared by EC Members in the full board meeting.

#### ***4.3. Training of the Secretariat***

The EC Member Secretary along with other members will train the Secretariat on SOPs. There will be initial training and at least one training session per year on SOPs. The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairman.

#### ***4.4. Assessment of EC members***

SOP 21	 <b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital	
SOP code: SOP 21/ V4	<b><i>Training and Assessment of Ethics Committee Members &amp; Assessment of IEC Functioning</i></b>	<b>Effective Date: 02.01.2024</b>

- The EC members' performance should be evaluated once a year using an assessment form (*AX 01/SOP 21/V4*) by the Chairman.
- The Chairman should do self-assessment once a year

#### ***4.5. Assessment of EC Functioning***

- Periodic self-assessment of the EC will be conducted with the help of the assessment form (*AX 03/SOP 21/V4*), along with Root Cause Analysis and Corrective and Preventive Action.

#### ***4.5. Maintenance of training records of the EC Members and the Administrative Staff***

The Secretariat should maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual EC members. The copies will be filed in the individual members' files. The records regarding training copies of the Secretariat will also be maintained in their respective files.

#### **5. Reference to other applicable SOP: NIL**


#### **6. Annexures**

*Annexure 1 AX 01/SOP 21/V4 - Self Assessment Form for EC Member Secretary/Member*

*Annexure 2: AX 02/SOP 21/V4 - Self Assessment Form for EC Chairman*

*Annexure 3: AX 03/SOP 21/V4 - Self Assessment Form for IEC Functioning*


*Annexure 4: AX 04/SOP 21/V4 – Annual report for IEC Functioning*

SOP 21	 <p style="text-align: center;">Sri <b>MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 21/ V4	<i>Training and Assessment of Ethics Committee Members &amp; Assessment of IEC Functioning</i>	<b>Effective Date: 02.01.2024</b>

*Annexure 1: AX 01/SOP 21/V4*

*Assessment Form for Ethics Committee Members*


1. Current tenure
2. Terms served
3. Training received
4. Type of training received
5. No of meetings attended
6. No of projects reviewed per meeting as primary reviewer
7. No of projects reviewed per meeting as secondary reviewer
8. Participation in SAE report review process- yes/no
9. Participation in site monitoring visits - yes/no
10. Number and type of continuing training workshops organised for EC members  
(applicable to Member Secretary)
11. Number and type of continuing training workshops organised for staff of the EC  
secretariat (applicable to Member Secretary)
12. Any other significant contribution to the field of research ethics
13. Remarks by the Chairman on the self-assessment

SOP 21	 <p style="text-align: center;"><b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 21/ V4	<i>Training and Assessment of Ethics Committee Members &amp; Assessment of IEC Functioning</i>	<b>Effective Date: 02.01.2024</b>

*Annexure 2: AX 02/SOP 21/V4*


*Self-Assessment Form for EC Chairman*

1. Current tenure-
2. Terms served -
3. Training received -
4. Type of training received -
5. No. of meetings held in current year -
6. No of meetings attended-
7. Whether quorum requirement fulfilment ensured as per schedule Y in EC meetings
8. Whether considerations related to conflict of interest considered
9. Any significant contribution to the field of research ethics
10. Any other comments

SOP 21	 <p style="text-align: center;">Sri <b>MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 21/ V4	<i>Training and Assessment of Ethics Committee Members &amp; Assessment of IEC Functioning</i>	Effective Date: <b>02.01.2024</b>

*Annexure 3: AX 02/SOP 21/V4  
Self-Assessment Form for IEC Functioning*

1. Adequate time is allotted to review the expedited protocols. Yes/No
2. The time allotted for review of full-review protocols is adequate. Yes/No
3. The checklist provided for review of protocols is appropriate. Yes/No
4. Reminders are sent by the secretarial staff if timeline for review is missed. Yes/No
5. The SOPs, guidelines and regulations are provided by IEC for reference. Yes/No
6. Confidentiality of the documents is adequately maintained. Yes/No
7. Training programs are conducted regularly. Yes/No
8. Training programs conducted by IEC are useful. Yes/No
9. In decision making on proposals; members are free to express their dissent. Yes/No
10. IEC meetings are conducted as per SOP (time, quorum, discussion, decision making).  
Yes/No
11. The IEC manages conflict of interest as per the SOP. Yes/No
12. The EC meeting duration is adequate for reviewing the submitted protocols. Yes/No
13. The functioning and decision making of the IEC is independent. Yes/No
14. The meeting- agenda and notes are circulated well ahead of the meeting. Yes/No
15. The meeting minutes are circulated within 1 week for EC members approval. Yes/No
16. The review process includes both scientific and ethical issues in the protocols. Yes/No
17. Every member is able to freely contribute to discussion and deliberation of protocols in the meeting. Yes/No
18. The SOPs are clear and practical. Yes/No
19. The venue and arrangement of the meetings is adequate. Yes/No
20. What according to you is the strength of the IEC?
21. What according to you needs improvement?

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SOP code: SOP 21/ V4	<i>Training and Assessment of Ethics Committee Members &amp; Assessment of IEC Functioning</i>	Effective Date: <b>02.01.2024</b>

*Annexure 4: AX 04/SOP 21/V4*

*Annual report for IEC Functioning*

No: outward/SMVMCH-ECO/AR/ / XXXX

Date: XX.XX.XXXX

**EC Meeting conducted:**

Total number of meetings conducted in the year XXXX:

EC Meeting dates:

**Proposal Reviewed:**

Total number of proposals reviewed:

Total number of proposals approved without modifications:

Total number of proposals approved with modifications:

Total number of proposals rejected:

Total number of faculty proposals reviewed:

Total number of PG student's proposals reviewed:

Total number of UG student's proposals reviewed:

**Trainings Conducted:**

No. of training program:

Date of training program:

Mode of training program:


Speakers for the program:

No. of EC members attended:

**Any other Information (If required):**

**MEMBER SECRETARY**

Signature & date with Stamp

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## 7. Flow Chart

S. No	Activity	Responsibility
1	Ensuring Training of EC Members	EC Member Secretary/Chairman
2	Training of Secretariat	EC Member Secretary/Members
3	Assessment of performance of members	EC Chairman
4	Assessment of EC of performance of Chairman	EC Chairman (self evaluation)

## 8. 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/](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](http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf)
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: [https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/NewDrugs\\_CTRules\\_2019.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf)



SOP 21	 <p style="text-align: center;"><b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 21/ V4	<i>Training and Assessment of Ethics Committee Members &amp; Assessment of IEC Functioning</i>	Effective Date: 02.01.2024

	Name	Designation	Signature
Prepared	Dr. Girija. S	Member	
	Dr. Nishanthi. A	Member	
Reviewed	Dr. Vimal. M	Member Secretary	
Approved	Dr. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	