


SOP 05	 Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 05/ V3	Procedures for allowing Guest/ Observer to visit Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC) or attend EC meeting	Effective Date: 31.12.2021

Title: Procedures for allowing Guest/ Observer to visit Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC) or attend EC meeting

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to be followed by Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC) and the Guest/ Observer whenever he/she visits the EC Office or attends an EC full board meeting. The SOP is needed to ensure adequate protection of confidentiality of information related to research studies.

2. Scope

This SOP covers the procedures for allowing guest / observer to visit the EC Office and observe a meeting in progress.


3. Responsibility

- It is responsibility of Member Secretary in consultation with Chairman to decide whether a guest / observer may be allowed to visit the EC Office or attend an EC meeting.
- It is the responsibility of the guest/observers intending to attend an EC meeting to read, understand, accept and sign the agreement contained in the Confidentiality form prior to visiting EC/ attending an EC meeting.
- The Secretariat will ensure that the Confidentiality Form is duly signed and dated by the guest or observer for EC / EC meeting and will file it in EC records.

4. Detailed instructions

4.1 Receiving request from guest/observer to visit EC or attend EC meeting

- On receiving a written or verbal request from a guest regarding visiting the EC Office or to observe an EC meeting, the EC member/Member Secretary/ Secretariat will obtain permission from Chairman.

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- The date and time of the visit to EC or for EC meeting will be informed to the guest/ observer preferably in writing/email.
- The request letter/email will be filed in EC records by the secretariat.

4.2 Filling up of Confidentiality Agreement Form


- Confidentiality Agreement Form (AX 01/SOP 05/V3) will be provided to the guest attendee/ observer on the day of visit/ at the time of meeting.
- The guest/ observer will read the form carefully before visit / or before commencement of the meeting and follow it.
- He/she will fill up the details in the form.

4.3 Ask questions, if any

- If there are any doubts, the guest/observer will seek clarifications or additional information from the Secretariat. The Member Secretary will provide explanations, additional information and / or clarifications.

4.4 Signing of Confidentiality Agreement Form

- The guest /observer will sign and date the document before a member of the Secretariat.
- He/she will return the signed form to the Secretariat.
- The Secretariat will obtain the signature of the EC Chairman on the Confidentiality / Agreement Form.
- The secretariat will provide guest or observer for EC a photocopy of the Confidentiality Agreement Form for their records (duly signed and dated by them and EC Chairman) and acknowledge the receipt of agreement by their signature.
- The Secretariat will keep the original copy of the signed Agreements at the EC office in the files entitled 'Confidentiality Agreement file for guests/observers, Independent Consultants (IC)'.
- The Secretariat will store the file in a secure cabinet with limited and named access.

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4.5 Keep the Agreement in mind

- The guests /observer must implement the clauses of the signed Confidentiality Agreement Form.

5. Reference to other applicable SOPs - Nil

6. Annexures

Annexure 1 AX 01/SOP 05/V3 Confidentiality Agreement for Guest/Observer to Sri Manakula Vinayagar Medical College and Hospital Ethics committee (SMVMCH-EC) Meeting

Annexure 1: AX 01/SOP 05/V3

Confidentiality Agreement Form

For Guest / Observer Attendees to Sri Manakula Vinayagar Medical College and Hospital Ethics committee (SMVMCH-EC) Meeting


I, _____ (name), understand that I am being allowed to visit EC office facility / attend the EC meeting on _____ at _____ am as a Guest. The venue of the EC meeting will be _____. I may become aware of some confidential information during my visit to EC / during the course of the EC meeting. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

Signature of the Guest with Date

Chairman of EC with Date

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the EC -Chairman and me.

Signature of the Guest with Date


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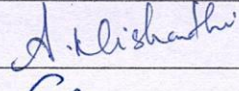
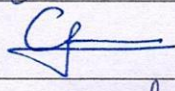
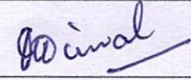
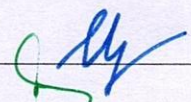
7. Flow chart

No.	Activity	Responsibility
1.	Receiving request from guest/ observer	EC Secretariat/ Member/ Member Secretary
2.	Allowing a guest/ observer	Chairman
3.	Informing guest/ observer about visit/ meeting date and time	EC Secretariat
4.	Read the text carefully and thoroughly, sign the confidentiality agreement	Guest/observer
5.	Filing of signed confidentiality form in EC records	EC Secretariat

8. 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](http://www.ferci.org/sops)
2. Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017. (cited 23rd October 2018) available from: <http://www.icmr.nic.in>.
3. 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
4. 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

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