


SOP 02	 <p style="text-align: center;">Sri MANAKULA VINAYAGAR Medical college and Hospital</p>	
SOP code: SOP 02/ V4	<i>Constitution of SMVMCH Ethics Committee (EC), Selection, Roles and Responsibilities of Members of the EC</i>	Effective Date: 02.01.2024

Title: Constitution of SMVMCH Ethics Committee (EC), Selection, Roles and Responsibilities of Members of the EC

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR), which provides the framework for constitution, selection, roles and responsibilities of the Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC) and procedures for maintaining confidentiality of all activities and documents.

2. Scope

This SOP applies to the constitution of the EC, selection, roles and responsibilities of members of the EC and maintenance of confidentiality of all activities and documents.

3. Responsibility


The selection of Chairman, Member Secretary and EC members will be done by the Director. It is the responsibility of all the EC members and the Secretariat to read, understand, follow and respect this SOP.

4. Detailed Instructions

4.1 Composition of the Sri Manakula Vinayagar Medical College and Hospital Ethics Committee


The EC will be established by the Director. The Chairman and EC members can suggest names of potential members but the final decision will remain with the Director.

- Its hierarchical position in the organization and authority under which it is established will be clearly indicated (AX 02/SOP 02/V4)
- The EC will be multidisciplinary and multi-sectoral in composition.
- The EC will be composed of at least 7 members up to a maximum of 15 (as per current CDSCO requirements and 2017 ICMR guidelines). A minimum of 5 members should be present to meet the quorum requirements of which minimum one non affiliated member

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should be present, preferably, the lay person should be part of the quorum. The quorum for reviewing regulating clinical trials should be in accordance with current CDSCO requirements. No decision is valid without fulfillment of the quorum.

- The members will
 - ✓ include a combination of medical and non-medical, scientific and non-scientific persons including lay person to represent the different points of view.
 - ✓ have differing backgrounds to promote complete and adequate review of research.
 - ✓ Have the required qualifications as prescribed by applicable regulations and guidelines from time to time
 - ✓ Have the expertise, time and commitment to perform all functions
- The EC will have representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of the community / society.
- The committee should include at least one member whose primary area of expertise is in a non-scientific area, a clinician and at least one member who is independent of the institution/ research site.
- Preferably 50% of the members should be non-affiliated or from outside the institution.
- The EC may invite member(s) of specific patient groups or other special interest groups for an EC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement (AX 05/SOP 02/V4) and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Guest/ Observer' and will not have right to vote. (See SOP 05/V4)
- The Composition shall be as follows:
 - ✓ Chairman (non -affiliated to the institution)
 - ✓ Vice-Chairman (non-affiliated to the institution)
 - ✓ One Member Secretary (institutional)
 - ✓ One Assistant Member Secretary (institutional)

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- ✓ One or more persons from basic medical science. In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist - affiliated/Non affiliated
- ✓ One or more Clinician - affiliated/Non affiliated
- ✓ One legal expert – affiliated/Non affiliated
- ✓ One social scientist/philosopher, ethicist or theologian - affiliated/Non affiliated
- ✓ One or more lay person - non affiliated

4.2 Criteria for selection of members of EC

Chairman

- From outside the institution.
- A well respected person from any background with prior experience of having served/serving in an EC.

Vice-Chairman (if applicable)


- From outside the institution.
- A well respected person from any background with prior experience of having served/serving in an EC.

Member-Secretary and Assistant Member-Secretary

- Will be a staff member of the institution.
- Preferably be a medical professional with state medical council recognized postgraduate degree.
- Should have domain speciality experience, clinical research and ethics knowledge, personal interest and capacity, good communication skills.

Members

- Members will be selected in their personal capacities based on their qualification, experience in domain field, interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the EC. They should not have any known record of professional misconduct.
- Medical scientists and clinicians should have post graduate qualifications.

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- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests (See SOP 03/V4).

4.3 Agreement regarding Maintenance of Confidentiality

- It is the responsibility of each EC member, reviewing research project or attending EC meetings, to read, understand, accept and sign the agreement contained in the confidentiality Form (AX 03A/SOP 02/V4).
- The staff of the secretariat will sign confidentiality agreement which should be filed with the EC.(AX 03B/SOP 02/V4)
- The Secretariat will obtain the signature of the EC Chairman on the Confidentiality form.
- The secretariat will provide EC member a photocopy of the Confidentiality Form for their records (duly signed and dated by them and EC Chairman) and acknowledge the receipt of agreement with their signature.
- The Secretariat will keep the original copies of the signed Agreements in the EC office in the file entitled ‘Confidentiality Agreement file’ for members and photocopies of the agreement in the individual member’s files.


4.4 Tenure of Membership

- The tenure of EC members will be for a period of 3 years from the date of appointment. A particular member cannot hold membership for more than two continuous tenures.

4.5 Appointment of New Members

- a) The EC members will be appointed by the Director.
- b) New members will be appointed under the following circumstances:
 1. When a regular member completes his/ her tenure.
 2. If a regular member resigns before the tenure is completed.
 3. If a regular member ceases to be a member for any reason including death or disqualification.
 4. To fulfill the membership requirements as stated in this SOP

New members will be identified by the Chairman according to the membership requirement (i.e. as per the composition specified in Section 4.1 of this SOP) ensure that the potential member fulfils the conditions of appointment. The names of new

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members to be appointed may be suggested by the EC members and the Chairman to the Director. The final decision regarding appointment of members will be taken by the Director.


4.6 Conditions to be fulfilled by a member after appointment

Members to be appointed on the EC will need to fulfill the following conditions:

- Members must submit
 - ✓ a recent signed CV
 - ✓ training certificates in Ethics and/ or GCP.
- Members must be willing to
 - ✓ publicize his/her full name, profession and affiliation.
 - ✓ sign the Confidentiality Agreement (as per Annexure 3A/SOP 02/V4) and regarding meeting, deliberations, applications, information on research participation and related matters.
 - ✓ read, understand, accept and follow the Conflict of interest policy and sign the Conflict of interest agreement/form (See SOP 03/V4).


4.7 Resignation and Disqualification of Members.

- Resignation: An EC member may resign from membership by submitting a letter of resignation to the Chairman. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairman.
- Disqualification for conduct unsuitable of an EC member: A member may be disqualified from continuance should EC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been inappropriate of an EC member.
 - (i) The process will be initiated if EC Chairman or Member-secretary receives a communication in writing (provided by EC member or a member of the public) alleging misconduct by a member.
 - (ii) The Chairman will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairman, the matter is of grave significance where integrity of EC could be questioned, the Chairman may suspend

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the membership of the concerned EC member till final decision is taken by EC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an EC member and will not perform any duties of EC member.

- (iii) The Chairman may call for a meeting of the EC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the EC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.
- (iv) The member would stand disqualified, if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting). The Chairman will convey the disqualification to the concerned member through a written communication.
- Disqualification for not attending EC meetings: A member may be disqualified from EC membership if the member fails to attend more than 3 regular consecutive EC meetings without prior intimation. The process conducted will be as follows:
 - (i) The Member Secretary will inform Chairman (if required), in writing, if a member has not attended more than three consecutive regular meetings of the EC without prior intimation to the EC.
 - (ii) The Chairman will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular EC meeting.
 - (iii) A written communication will be sent to the concerned EC member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned EC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairman
 - (iv) The matter will be discussed and reviewed at the EC meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.

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- The Chairman or Member-Secretary will inform the EC members about the cessation of membership by a confidential written communication to the concerned and other members of EC will be informed during the upcoming meeting of EC.

4.8 Reconstitution of Ethics Committee

- At least 20% of the EC members will be changed every 3 years.
- Any change in EC membership will be communicated to the DCGI within 14 working days.

4.9 Training of the EC Members in Research Ethics

- 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 introductory training in Research Ethics, GCP and SOPs to the new member.
- A newly inducted member should submit certificate of training.
- All members including Chairman and Member Secretary will be encouraged to receive continued training by participating in a workshop, conference and/ or re-training program related to research ethics, as a delegate, faculty, facilitator, etc.
- The EC will conduct workshops on ethics in clinical research, GCP and SOPs from time to time to impart training and update the EC Members and Institutional faculty members.

4.10 Hierarchy

- There will be one Chairman, one Vice-Chairman, one Member Secretary and one Assistant Member Secretary.
- The Chairman and Vice-Chairman will head the committee.
- The Member Secretary and the Assistant Member Secretary will be the guardian of all documents and funds in the possession of the committee.
- Other EC members will be regular committee members with equal ranking.

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4.11a Functions of Chairman


- The Chairman will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals.
- The Chairman will be accountable for independent and efficient functioning of the committee
- The Chairman will conduct EC meetings and ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations
- The Chairman will preside over all elections as well as administrative and financial matters pertinent to the committee's functions.
- The Chairman will represent the EC at various meetings and forums.
- The Chairman will sign documents and communications related to EC functioning.
- The Chairman will Seek COI declaration from members and ensure quorum and fair decision making.
- The Chairman will handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
- In case of anticipated absence of both Chairman and Vice-Chairman at a planned meeting, the Chairman will nominate a committee member as Acting Chairman or the members present may elect the Acting Chairman. The Acting Chairman should be non-affiliated and will have all the powers of the Chairman for that meeting.

4.11b Functions of Co- Chairman

- To act as Chair in the absence of Chairman and to perform all functions of Chairman.

4.12 Functions of the Member secretary

- Receive research proposals
- Organize an effective and efficient tracking procedure for each proposal received.
- Prepare, maintain and distribute study files.
- Schedule and organize EC meetings
- Prepare and maintain meeting agenda and minutes.

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- Maintain EC documentation and to archive them.
- Sign documents and communications related to EC functioning.
- Communicate with the EC members and applicants/ investigators.
- Notify the Principal Investigator regarding EC decisions related to the submitted research proposal.
- Ensure training of EC members on SOP, regulatory requirements, bioethics and GCP
- Organize the preparations, review, revision and distribution of SOPs and guidelines.
- Provide necessary administrative support for EC related activities to the Chairman.
- Provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- A reasonable fee for review may also be charged by the EC to cover the expenses related to optimal functioning in accordance to the institutional policies.
- Delegate various responsibilities to appropriate and authorized individuals
- Ensure adherence of EC functioning as per SOPs
- Prepare for accreditations and inspections
- Prepare compliance report
- Ensure availability of funds for smooth functioning of EC.

4.13 Functions of the Assistant Member Secretary

The Assistant Member Secretary will perform the same functions of Member Secretary in his/her absence.

4.14 Functions of EC members

- Attend EC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- Review, discuss and consider research Proposals submitted for evaluation.
- Monitor Serious Adverse Event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate.

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- Do onsite visits whenever needed
- Evaluate final reports and outcomes.
- Maintain confidentiality of the documents and deliberations of EC meetings.
- Declare any conflict of interest in writing to the Chairman, if any, at each meeting.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the EC secretariat
- Provide an updated CV when requested for by the EC secretariat
- Carry out the work delegated by Chairman, Vice-Chairman, Member-secretary and Assistant Member-secretary
- Assist Chairman, Vice-Chairman, Member-secretary and Assistant Member-secretary in carrying out EC work as per SOPs
- Be updated on relevant laws and regulations

4.15 Functions of EC members – member specific role of Basic medical scientist

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

4.16 Functions of EC members – member specific role of Clinician

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

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4.17 Functions of EC members – member specific role of legal expert

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher’s undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any

4.18 Functions of EC members – member specific role of Social scientist


- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

4.19 Functions of EC members – member specific role of Lay person

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant’s perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any

4.20 Functions of Secretariat

- The Secretariat will be composed of the scientific officer/s, the administrative Officer/s and other administrative supporting staff.
- The Secretariat will support the Member Secretary and Assistant Member Secretary in all their functions
- All the staff of the Secretariat will sign confidentiality agreement which should be filed with the EC.(AX 03-B/SOP 02/V4)
- The working rules for the Secretariat are stated in (AX 01/SOP 02/V4)

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4.21 Types of projects reviewed by EC

The EC will review scientific and ethical aspects of all types of research studies involving human participants; sponsored by pharmaceutical companies, sponsored by Government of India / NGOs, studies in collaborations with international organizations/universities, all dissertation projects of (postgraduate students : MD, MS & PhD) research projects of undergraduate students carried out under guidance of teachers (e.g. Indian Council for Medical research studentship or any other) and investigator initiated research studies which are self-funded / funded by institutional funding bodies.

4.22 Quorum Requirements

- The full board meeting will be held as scheduled provided there is quorum.
- For the EC meeting, a quorum will consist of at least 5 members for regulatory clinical trials with the following representation: one basic medical scientist (preferably one pharmacologist), one clinician, one legal expert, one social scientist/representatives of non-governmental voluntary agency/Philosopher/ethicist/theologian or a similar person, one Lay person from the community, **apart from** Member Secretary and Chairman as mandated by NDCT rules 2019.
- Without satisfying this condition, any decision taken by the committee shall remain null and void.
- In absence of the Chairman, Vice-Chairman will chair the meeting.


4.23 Honorarium to the Members

Reimbursement of travelling expense, accommodation (if required) and honorarium of Rs. 2000 per day will be given to the non – affiliated/external EC members, for attending the EC meetings.

4.24 Preparing an annual activity report of the EC for submission to the Head of the Institute

The Member Secretary will make a yearly activity report for submission to the Head of the Institute which will include the following elements:

- a. Number and dates of the EC meetings of full board

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- b. Number of SAE subcommittee and any other subcommittee, as applicable)
Number and type of proposals (Pharma/ Government sponsored/ Dissertations/ investigator initiated) reviewed in a year, status of each study proposal whether completed / ongoing / terminated
- c. Number of approvals for full board review/ expedited review with decisions
- d. Brief details about workshops, training programmes and other activities undertaken by the EC and those attended by EC members
- e. Any other matter

5. Reference to other applicable SOPs

SOP 03/V4 - Conflict of Interest Policy for Institutional Ethics Committee

SOP 08/V4 - Agenda Preparation, Meeting Procedures and Recording of Minutes


6. Annexures

Annexure 1 *AX 01/SOP 02/V4 - EC Administrative Staff: Working rules*

Annexure 2 *AX 02/SOP 02/V4 - Organizational Chart of the Institution*

Annexure 3A *AX 03 A/SOP 02/V4 - Confidentiality Agreement Form for EC members*

Annexure 3B *AX 03B/SOP 02/V4 – Confidentiality Agreement Form for Staff of the Secretariat*

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Annexure 1: AX 01/SOP 02/V4

The EC Administrative Staff: Working Rules


- There will be administrative officer / assistant /s and attendant/s /helper/s who will help the EC Chairman and Member-Secretary in executing functions of the EC. Additional staff may be appointed and duties assigned; as and when deemed necessary by the EC. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications, office timing, salary structure and number of leaves may be recommended by EC members and discussed during regular EC meeting and will be recorded in minutes.
- The administrative staff will report to the Chairman and/or Member Secretary.
- The administrative staff will be appointed by the Head of the institute by conducting formal interviews.

Duties of Administrative officer/ assistant

- Correspondence with EC members and external experts
- Correspondence with the investigators
- Preparing agenda and minutes of the EC meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files, SOPs, all correspondences
- Maintaining electronic database of the EC records

Duties of the attendant/s /helper/s

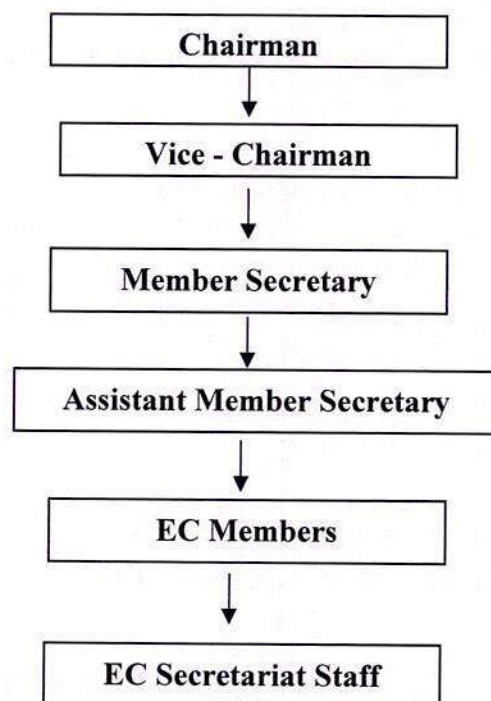
- Assisting the secretariat in arranging the EC meetings
- Dispatching sets of study documents to EC members and external experts
- Receiving the study related documents from and dispatching the EC letters to the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Assisting the Secretariat during the meetings


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Annexure 2: AX 02/SOP 02/V4

Organizational flow chart of SMVMCH-EC

After the Director of SMVMCH constitutes the EC and after registration with DCGI, the newly registered body will function in the following hierarchical order.



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Annexure 3A: AX 03A /SOP 02/V4

Confidentiality Agreement Form for SMVMCH-EC Members

In recognition of the fact, that I, _____

(Member's name, and his/her affiliation) herein referred to as the "undersigned", have been appointed as a member of the SMVMCH-EC and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member of the EC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an EC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;


Whereas, the EC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;

The undersigned, as a member of the EC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the EC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the EC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore,

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the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Undersigned Signature _____
Date

Agreement on Confidentiality

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the SMVMCH-EC. A copy will be given to you for your records.

In the course of my activities as a member of the EC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairman upon termination of my functions as a Committee member.


I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

Signature _____
Date

Chairman's Signature _____
Date

I acknowledge that I have received a copy of this Agreement signed by the EC Chairman and me.

Signature _____
Date

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Annexure 3B: AX 03-B/SOP 02/V4

Confidentiality Agreement Form for Staff of the Secretariat

In recognition of the fact, that I,

(*Member's name, and his/her affiliation*) herein referred to as the "undersigned", have been appointed as a member of the SMVMCH-EC and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member of the EC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an EC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the EC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;


The undersigned, as a member of the EC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the EC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written

Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the EC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

SOP 02	 <p style="text-align: center;">Sri MANAKULA VINAYAGAR Medical college and Hospital</p>	
SOP code: SOP 02/ V4	<i>Constitution of SMVMCH Ethics Committee (EC), Selection, Roles and Responsibilities of Members of the EC</i>	Effective Date: 02.01.2024

Undersigned Signature

Date

Agreement on Confidentiality

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the EC. A copy will be given to you for your records.

In the course of my activities as a member of the EC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairman upon termination of my functions as a Committee member.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.


Signature

Date

Chairman's Signature

Date

I acknowledge that I have received a copy of this Agreement signed by the EC Chairman and me.


SOP 02	 Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 02/ V4	<i>Constitution of SMVMCH Ethics Committee (EC), Selection, Roles and Responsibilities of Members of the EC</i>	Effective Date: 02.01.2024


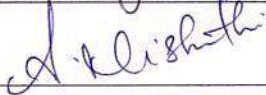
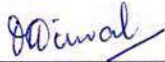

7. Flow Chart

No.	Activity	Responsibility
1	Composition of the Ethics Committee	Director as per DCGI guidelines
2	Selection and appointment of Chairman	Director as per DCGI guidelines
3	Appointment of new members	Director as per DCGI guidelines
4	Conditions of appointment	All EC Members
5.	Initiation of the process of appointment	Secretariat
6.	Tenure of Membership	Chairman, EC Members and Secretariat
7.	Resignation and disqualification of Members	EC Members and Secretariat
8.	Quorum requirements	EC Members and 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. 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
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

SOP 02	<p style="text-align: center;">  Sri MANAKULA VINAYAGAR Medical college and Hospital </p>	
SOP code: SOP 02/ V4	Constitution of SMVMCH Ethics Committee (EC), Selection, Roles and Responsibilities of Members of the EC	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. Thiagarajan. T	Chairman	
Issued	Dr. R. N. Kagne	Dean	