


<b>SOP 03</b>	 <p style="text-align: center;"><b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
<b>SOP code: SOP 03/ V4</b>	<i>Handling Conflict of Interest among Ethics Committee Members</i>	<b>Effective Date: 02.01.2024</b>

**Title: Handling Conflict of Interest among Ethics Committee Members**

**1. Purpose**

The purpose of this SOP is to describe the process to identify and manage conflict of interest among Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH - EC) members.

**2. Scope**


This SOP covers the policy related to identification, declaration and management of conflict of interest and is applicable to all EC members.

**3. Responsibility**


All EC members (regular and alternate) are responsible for understanding definition of conflict of interest (COI) and for self-identifying and disclosing these. The Chairman would need to ensure that COI are identified, declared and managed by all members during initial and continuing review of research studies.

**4. Detailed Instructions**

- Every newly recruited EC member will sign the Conflict of Interest agreement form at the time of appointment (AX 01/SOP 03/V4).
- Voluntary disclosure regarding COI by EC member - The EC member should determine whether he/she has a COI before reviewing research and declare all certain or potential conflicts of interest prior to engaging in any review process.
- EC members should not participate in discussing, or decision making on research proposals applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the EC.

<b>SOP 03</b>	 <b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital	
<b>SOP code: SOP 03/ V4</b>	<b><i>Handling Conflict of Interest among Ethics Committee Members</i></b>	<b>Effective Date: 02.01.2024</b>

- a) If an EC member has a COI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the EC Secretariat and return the documents.
  - b) If an EC member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the EC secretariat so that the review is re-assigned to other members.
  - c) If an EC member has a COI for review of research study at a meeting, he or she will inform the Chairman and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for EC meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed.
  - d) Recusal - EC member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a *recusal*, not an abstention or an absence.
  - e) If an EC member finds that he/she has a COI during the conduct of a research project approved by EC, he/she shall report the conflict to the EC at the next EC meeting.
- At the beginning of each meeting, the EC Chairman asks the members to disclose any COI concerning any of the items on the agenda. During the meeting, EC member having conflict discloses the existence of the conflict just before the review of the relevant item begins.
  - If the Chairman has a conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled. An acting Chair should be appointed for discussion on such a project.


SOP 03	 <p style="text-align: center;"><b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 03/ V4	<i>Handling Conflict of Interest among Ethics Committee Members</i>	<b>Effective Date: 02.01.2024</b>

- When determination regarding existence of COI is uncertain, more information is gathered from relevant sources and determination is done by EC member with the help of EC Chairman / Member Secretary
- The EC Chairman has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection.
- The EC shall not approve a research study proposal where a COI is not managed or eliminated
- Management of CO – In case of a COI ,
  - EC members will disclose the COI as discussed above
  - EC members will not serve as reviewers
  - EC members will not influence the discussion and decision making of the concerned study by staying away during the EC meeting.
- EC Member Secretary and the Secretariat will record the points related to disclosure and management of COI of EC members in the EC minutes.

### **Definitions and Mandate**

#### **Definitions**

- Conflict of interest is a set of conditions in which professional judgment concerning a primary interest like patient’s welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain. [[http://icmr.nic.in/ethical\\_guidelines.pdf](http://icmr.nic.in/ethical_guidelines.pdf) accessed on 23<sup>rd</sup> Nov 2015].
- Types of COI
  - A personal COI is said to exist when
    - There is immediate family relationship (spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent -who resides with an EC member or consultant or who receives 50% or more support from an EC member, regardless of age) or other close personal relationship (“step” relationships included) with the investigator, or with co-investigators.

SOP 03	 <p style="text-align: center;"><b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 03/ V4	<i>Handling Conflict of Interest among Ethics Committee Members</i>	<b>Effective Date: 02.01.2024</b>

- EC member or his/her immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff or financier.
- research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable)
- A professional COI means the EC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.
- A financial COI for EC members and immediate family exists when the EC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated)..


**Mandate**

- *G.S.R. 12(E). Registration of Ethics Committee. Ministry of Health and Family Welfare, Department of Health notification dated 8<sup>th</sup> February 2013*  
[http://www.cdsc.nic.in/writereaddata/G.S.R%2072\(E\)%20dated%2008.02.2013.pdf](http://www.cdsc.nic.in/writereaddata/G.S.R%2072(E)%20dated%2008.02.2013.pdf)  
*accessed on 23<sup>rd</sup> Oct 2018*

**2h.** There should be no conflict of interest. The members shall voluntarily withdraw from the Ethic committee meeting while making a decision on an application which evokes conflict of interest which may be indicated in writing to the chairman prior to the review and to be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

- <http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf>  
*accessed on 23<sup>rd</sup> Oct 2018.*

**2.4.2.6.** “A member must voluntarily withdraw from the EC while making a decision on an application which evokes a conflict of interest which should be indicated in writing to the Chairman prior to the review and should be recorded so in the minutes. If one of the

SOP 03	 <p style="text-align: center;"><b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 03/ V4	<i>Handling Conflict of Interest among Ethics Committee Members</i>	Effective Date: <b>02.01.2024</b>

members has her/his own proposal for review, then the member should not participate when the project is discussed”.

- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=56.107>  
accessed on 23<sup>rd</sup> Oct 2018.

**56.107** “No Institutional review board (IRB) may have a member participate in the IRB's initial or continuing review of any project in which the member *has* a conflicting interest, except to provide information requested by the IRB. [45 CFR 46.107(e) and 21 CFR 56.107(e), Sec. 56.107 EC membership”.

#### 5. Reference to other applicable SOPs - Nil

#### 6. Annexure

Annexure 1 *AX 01/SOP 03/V4*– Conflict of Interest Form/ Declaration for SMVMCH -  
EC Members at time of appointment


Annexure 2 *AX 01/SOP 03/V4* – Conflict of Interest Form/ Declaration for SMVMCH -  
EC Members during EC meeting

#### *Annexure 1: AX 01/SOP 03/V4*

#### **Conflict of Interest Agreement Form for Ethics committee members at time of appointment**

It is recognized that the potential for conflict of interest will always exist and resolution of the same is of paramount importance. It is the responsibility of SMVMCH EC members to voluntarily disclose any potential conflict of interest to the Chairperson. It is the responsibility SMVMCH EC Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human participants.

It is the policy of the SMVMCH Ethics Committee that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the SMVMCH Ethics Committee for Clinical Studies.

<b>SOP 03</b>	 <b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital	
<b>SOP code: SOP 03/ V4</b>	<i>Handling Conflict of Interest among Ethics Committee Members</i>	<b>Effective Date: 02.01.2024</b>

The Undersigned will immediately disclose to the Chairperson of the SMVMCH Ethics Committee any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

At the start of the EC meeting, the member should identify the proposal for which he/she has conflict of interest and document it in the Conflict of Interest Form/ Declaration for SMVMCH - EC Members during EC meeting (*AX 01/SOP 03/V4*)

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment

**Agreement on Conflict of Interest**

*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 Ethics Committee. A copy will be given to you for your records.*

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.


I, ....., have read and accept the aforementioned terms and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals.

\_\_\_\_\_  
Undersigned Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Chairperson's signature

\_\_\_\_\_  
Date

SOP 03	 <p style="text-align: center;"><b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 03/ V4	<i>Handling Conflict of Interest among Ethics Committee Members</i>	<b>Effective Date: 02.01.2024</b>

*Annexure 2: AX 01/SOP 03/V4*

Conflict of Interest Form/ Declaration for SMVMCH-EC Members during EC meeting

I am aware of the policy of the SMVMCH-EC regarding conflict of interest and that no reviewer may participate in the review, comment or participate in decision making of any activity in which he/she has actual/potential conflict of interest except to provide information as requested by the SMVMCH-EC.


I will refrain from the review process and /or discussion at the SMVMCH-EC meeting / and also will not take part in ongoing and periodic review and monitoring of this study.

I declare relation to the proposal entitled

S. No	SMVMCH-EC No of Research Proposal	Name of the EC Member	Conflict of Interest	Signature
1.				
2.				
3.				
4.				

Signature of Chairman


Date

<b>SOP 03</b>	 <b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital	
<b>SOP code: SOP 03/ V4</b>	<i>Handling Conflict of Interest among Ethics Committee Members</i>	<b>Effective Date: 02.01.2024</b>

### 7. Flow Chart


No.	Activity	Responsibility
1	Determination of Conflict of Interest (COI)	EC Member
2	Disclosure and management of COI	EC Member
3	Ensuring declaration and management of COI during review process	EC Chairman
4	Recording of COI in minutes of EC meeting	EC Member Secretary/ Secretariat


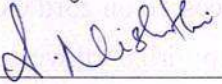
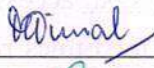



SOP 03	 <p style="text-align: center;"><b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital</p>	
SOP code: SOP 03/ V4	<i>Handling Conflict of Interest among Ethics Committee Members</i>	Effective Date: 02.01.2024

### 8. References:

1. Part 56 -institutional review boards,Subpart B--Organization and Personnel, Sec. 56.107 IRB membership, 45 CFR 46.107(e) and 21 CFR 56.107(e)<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=56.107> accessed on 23rd Oct 2018.
2. <http://irb.northwestern.edu/sites/default/files/documents/hrp-050-sop-conflicting-interests-members.pdf> accessed on 23rd Oct 2018.
3. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 23rd Oct 2018). Available from: <http://www.ferci.org/sops/>
4. 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>.
5. G.S.R. 12(E). Registration of Ethics Committee. Ministry of Health and Family Welfare, Department of Health notification dated 8<sup>th</sup> February 2013 [http://www.cdsc0.nic.in/writereaddata/G.S.R%2072\(E\)%20dated%2008.02.2013.pdf](http://www.cdsc0.nic.in/writereaddata/G.S.R%2072(E)%20dated%2008.02.2013.pdf) accessed on 23<sup>rd</sup> Oct 2018
6. <http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf> accessed on 23<sup>rd</sup> Oct 2018.
7. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=56.107> accessed on 23<sup>rd</sup> Oct 2018.
8. 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 03	 <b>Sri MANAKULA VINAYAGAR</b> Medical college and Hospital	SOP 03
SOP code: SOP 03/ V4	<i>Handling Conflict of Interest among Ethics Committee Members</i>	<b>Effective Date:</b> 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	