


**Institutional Ethics Committee**  
**Apollo Institute of Medical Sciences and Research (AIMSR) Chittoor**

SOP No 02 / Version 01.1  
Conflict of Interest  
Effective date: 10-03-2025

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

**SOP Code: SOP No 02 /v 01.1**

**Prepared by:**

Dr Sachidananda Adiga M N Member, SOP Sub-committee	Signature with date:  10/03/2025
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**Verified by:**

Dr P Vijetha Member, SOP Sub-committee	Signature with date:  10/3/2025
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**Approved by:**

Dr Ravi Prabhu G Chairperson, IEC - AIMSR Chittoor	Signature with date:  10-03-2025
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**Notified by:**

Dr Alfred Joseph Augustine Dean, AIMSR Chittoor	Signature with date:  10/03/2025
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Apollo Institute of Medical Sciences and Research  
Murukambattu, Chittoor-517127 A.P.

**Details of Current SOP No**

SOP subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr Sachidananda Adiga MN	Version 01.1	10-03-2025	Made the changes as per biomedical research needs in the conflict of interest among IEC members. (Excluding Sponsored Clinical Trial )

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1. <b>Purpose:</b> The SOP has been drafted with the purpose of describing the process to identify and manage conflict of interest (CoI) among Institutional Ethics Committee (IEC) members, Apollo Institute of Medical Sciences and Research (AIMSR) Chittoor members, Secretarial staff, and Independent Consultants, Guests and Observers whenever applicable.
2. <b>Scope:</b> This SOP covers the policy related to identification, declaration and management of CoI and is applicable to all members and secretarial staff of IEC - AIMSR Chittoor and others (Independent Consultants, Guests and Observers).
3. <b>Definition &amp; Mandate:</b>
3.1. <b>Definition:</b> CoI is a set of conditions in which professional judgment concerning a primary interest like participant's welfare or the validity of research tends or appears to be unduly influenced by secondary interest - personal, academic, political or financial gain <sup>1</sup>
3.2. Types of CoI:
3.2.1. A personal (non-financial) CoI is said to exist when
3.2.1.1. There is a first-degree family relationship (spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse) between a IEC - AIMSR Chittoor member, secretarial staff, independent consultant, guest or observer and any person who is a stakeholder in the concerned research protocol (investigator, co-investigators, any other research team member, collaborator, consultant, any person from the sponsor or funding agency) submitted to IEC - AIMSR Chittoor for review
3.2.1.2. In addition, it will be deemed to exist in the case of any person (part of the research team) who resides with, or receives financial support from, or is in a close personal relationship with, a IEC - AIMSR Chittoor member
3.2.1.3. IEC - AIMSR Chittoor member himself/herself serves as a contributor to the research proposal in any role as described above.

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3.2.2. A financial CoI for IEC- AIMSRS Chittoor members exist if	
3.2.1.1.	The IEC - AIMSRS, Chittoor member or the spouse or dependent or immediate family member (as defined above) of a member receives – or has received – monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), or any of its sister concerns or subsidiaries, or from the principal investigator, or any of the research team members.
3.3. Mandate	
3.3.1.	The mandate for recording and reporting of CoI is provided by the Government of India and is binding on the ethics committee. “There should be no CoI. The members shall voluntarily withdraw from the Ethics committee meeting while making a decision on an application which evokes CoI which may be indicated in writing (in the prescribed format) to the Chairperson/ Member-Secretary prior to the review and to be recorded so in the minutes. All members shall sign a declaration on CoI”. <sup>2</sup>
3.3.2.	“A member must voluntarily withdraw from the Ethics Committee while making a decision on an application which evokes a CoI which should be indicated in writing to the Chairperson prior to the review and should be recorded so in the minutes. If one of the members has her/his own proposal for review, then the member should not participate when the project is discussed or a decision taken”. <sup>3</sup>
3.3.3.	“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 <sup>4</sup> .

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<b>4. Responsibility:</b>
<p><b>4.1. The Chairperson will:</b></p> <p>4.1.1. Ensure that the CoI policy of the IEC -AIMSR Chittoor is followed at all times</p> <p>4.1.2. Ensure that the IEC - AIMSR Chittoor members declare any CoI at the time of review, during deliberation of the concerned protocol, during decision-making and during the post-approval activities.</p>
<p><b>4.2. The Secretariat will</b></p> <p>4.2.1. File the CoI forms in the respective protocol files</p> <p>4.2.2. Report the CoI for the relevant protocol in the minutes of the meeting</p>
<p><b>4.3. The the IEC - AIMSR Chittoor Member(s) will:</b></p> <p>4.3.1. Understand the definition of CoI, identify it's presence and declare it</p> <p>4.3.2. Manage the CoI by declaring it, and not taking part in the review, deliberation, decision making and post-approval activities of the protocols</p>
<p><b>4.4. The Independent Consultant/Guest/Observer will:</b></p> <p>4.4.1. Understand the definition of CoI, identify and declare it</p> <p>4.4.2. Declare the CoI and not take part in the review and deliberation of the protocol</p>

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<b>5. Detailed Instructions:</b>
<b>5.1. IEC - AIMSRS Chittoor Members:</b>
<b>5.1.1. Declaration at the time of joining IEC AIMSRS Chittoor:</b>
All IEC - AIMSRS Chittoor members (including the Chairperson and Member-Secretary) and the staff of the IEC - AIMSRS Chittoor secretariat shall sign a declaration at the time of joining the ethics committee – that they will disclose CoI as and when the same arises, for their entire tenure as ethics committee members, and beyond, if necessary.
<b>5.1.2. Voluntary disclosure regarding CoI by IEC -AIMSRS Chittoor member</b>
5.1.2.1. The - AIMSRS Chittoor member should determine whether he/she has a CoI before reviewing a protocol and declare all actual or potential (financial or non-financial) conflicts of interest prior to engaging in any review process.
5.1.2.2. The IEC - AIMSRS Chittoor member should determine whether he/she has a CoI for any protocol that is kept for discussion in the IEC - AIMSRS Chittoor meeting before the meeting begins
5.1.2.3. The IEC - AIMSRS Chittoor member should determine whether he/she has a CoI for any protocol that he/she has been assigned to review, or in any other activity related to such protocols.
<b>5.1.3. Managing the CoI:</b>
5.1.3.1. If the Member-Secretary has a CoI, then he/she will hand over the responsibility of the protocols to the Joint-Secretary (if any) or another member and will not take part in the categorization, review or decision making or signing of the approval letters or any post-approval activities.
<b>5.1.3.2.</b> IEC - AIMSRS Chittoor members should not participate in discussion, or decision-making on research proposals reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by IEC - AIMSRS Chittoor.

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5.1.3.4. If a member has a CoI for a full-review study for which he/she has been assigned as primary reviewer/lead discussant, he/she will inform Secretariat in writing so that the review is reassigned to another member.
5.1.3.5. If a IEC - AIMSRS Chittoor member has a CoI for review of research study at a meeting, he or she will inform the Chairperson, at the beginning of the meeting when the Chairperson is asking for declaration of CoI and leave the meeting room at the time when the discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research protocol, if needed. This is applicable also for IEC - AIMSRS Chittoor meetings at which discussion on serious adverse events, deviations/violations, amendments/continuing review reports related to studies are done.
5.1.3.6. If a IEC - AIMSRS Chittoor member finds that he/she has a CoI during the conduct of a research project approved by IEC - AIMSRS Chittoor, he/she shall report the conflict to the IEC - AIMSRS Chittoor at the next IEC - AIMSRS Chittoor meeting.
5.1.3.7. At the beginning of each meeting, the IEC - AIMSRS Chittoor Chairperson will ask the members to disclose any CoI concerning any of the items on the agenda. During the meeting, the IEC - AIMSRS Chittoor member having conflict discloses the existence of the conflict just before the review of the relevant item begins.
5.1.3.8. If the Chairperson has a CoI for a particular project, this should be so declared and handled like any other member's conflict is handled. The acting Chairperson should be appointed for discussion on such a project proposal
5.1.3.9. IEC - AIMSRS Chittoor approval of a research proposal shall be deemed invalid, where a CoI is not managed or eliminated, or subsequently discovered so.
5.1.3.10. If more than 2-3 members of IEC - AIMSRS Chittoor have CoI for the same protocol, the protocol may be considered for review by IEC - AIMSRS Chittoor after discussion with the Chairperson, IEC - AIMSRS Chittoor.

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<b>5.1.4. Uncertain CoI:</b>
5.1.4.1. When determination regarding the existence of CoI is uncertain, more information is gathered from relevant sources and a final determination is done by IEC - AIMSRS, Chittoor member with the help of IEC - AIMSRS Chittoor Chairperson/Member Secretary
5.1.4.2. The IEC - AIMSRS Chittoor Chairperson has the final authority to determine whether a CoI has been managed or eliminated appropriately, and may permit the said member to continue attending the meeting, if the CoI is perceived as negligible or uncertain. The Chairperson's decision is final and binding
<b>5.2. Independent consultants (IC):</b>
<b>5.2.1. Declaration at the time joining IEC - AIMSRS Chittoor as IC:</b>
5.2.1.1. An IC shall sign a declaration at the time of joining the panel of ICs for the IEC - AIMSRS Chittoor that he/she will disclose the CoI as and when the same arises, for their entire tenure as ethics committee members.
<b>5.2.2. Managing CoI:</b>
5.2.2.1. An IC will declare CoI for a protocol when it is sent for review within the stipulated time.
5.2.2.2. All other conditions mentioned for members will apply to ICs.
<b>5.3. Guest observer:</b>
<b>5.3.1. Declaration at the time requesting the IEC - AIMSRS Chittoor to visit as guest observer:</b>
5.3.1.1. A guest observer will declare CoI for any protocol that is included in the IEC - AIMSRS Chittoor meeting.
5.3.1.2. The Guest observer will refrain from attending that meeting.
5.3.1.3. All other conditions mentioned for members will apply to guest observers



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<b>5.4. Recusal:</b>
5.4.1. An IEC - AIMSRS Chittoor member who declares CoI and leaves the meeting does not count towards the quorum for the vote.
5.4.2. The member's absence under these circumstances is called a <i>recusal</i> , not an abstention or an absence
5.4.3. After said member recuses himself/herself, the quorum may be reassessed, and recorded as such, in the minutes.
<b>5.5. Recording of the CoI:</b>
5.5.1. IEC - AIMSRS Chittoor Member-Secretary and the Secretariat will record the points related to disclosure and management of CoI of IEC - AIMSRS members/ Independent consultants in the IEC - AIMSRS Chittoor minutes.
5.5.2. IEC - AIMSRS Chittoor Member-Secretary and the Secretariat will record the points related to disclosure and management of CoI of IEC - AIMSRS Chittoor members in the approval letter.
<b>6. References:</b>
6.1. <sup>1</sup> Thompson DF. <i>Understanding Conflict of Interest</i> . N Engl J Med. 1993 Aug 19; 329: 573-76
6.2. <sup>2</sup> <a href="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</a> accessed 28 Apr 2023
6.3. <sup>3</sup> <a href="https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf">https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf</a> accessed on 28 Apr 2023
6.4. <sup>4</sup> <a href="https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.107">https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.107</a> accessed on 28 Apr 2023

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**7. Annexures:**

**7.1. Ann01/SOP2/v1.1: CoI Form/Declaration for Members/ Independent consultants**

**Ann01/SOP2/v1.1**

**Conflict of Interest (CoI) Form/ Declaration for IEC - AIMS Chittoor Members/  
Independent consultants**

To

The Chairperson,  
IEC - AIMS Chittoor

Sir/ Madam,

I am aware of the policy of the IEC - AIMS Chittoor regarding conflict of interest and that no member/reviewer may participate in the review, comment or participate in decision-making of any activity in which he/she has actual/potential CoI except to provide information as requested by the IEC - AIMS Chittoor. I declare financial/non-financial CoI (strike out whichever is not applicable) in relation to the following protocol

Protocol Number:	
Protocol Title:	
Principal Investigator:	
Funding agency:	

I declare CoI for the following reason (s): Tick whichever applicable

I am a member of the research team	
My immediate family member is a part of the research team	
I have a direct/indirect financial interest	

To manage the CoI (Tick after agreeing to the following points), I declare that:

I will return the protocol document package	
I will refrain from the review process	
I will not be present in the IEC - AIMS Chittoor meeting room during the discussion and decision-making on this protocol	
I will not participate in any post-approval activities like ongoing review/ site monitoring/ audit and others pertaining to this protocol.	

Date:

Signature and name of the IEC - AIMS Chittoor member/ Independent consultant

Signature of the Chairperson/Member-Secretary with date

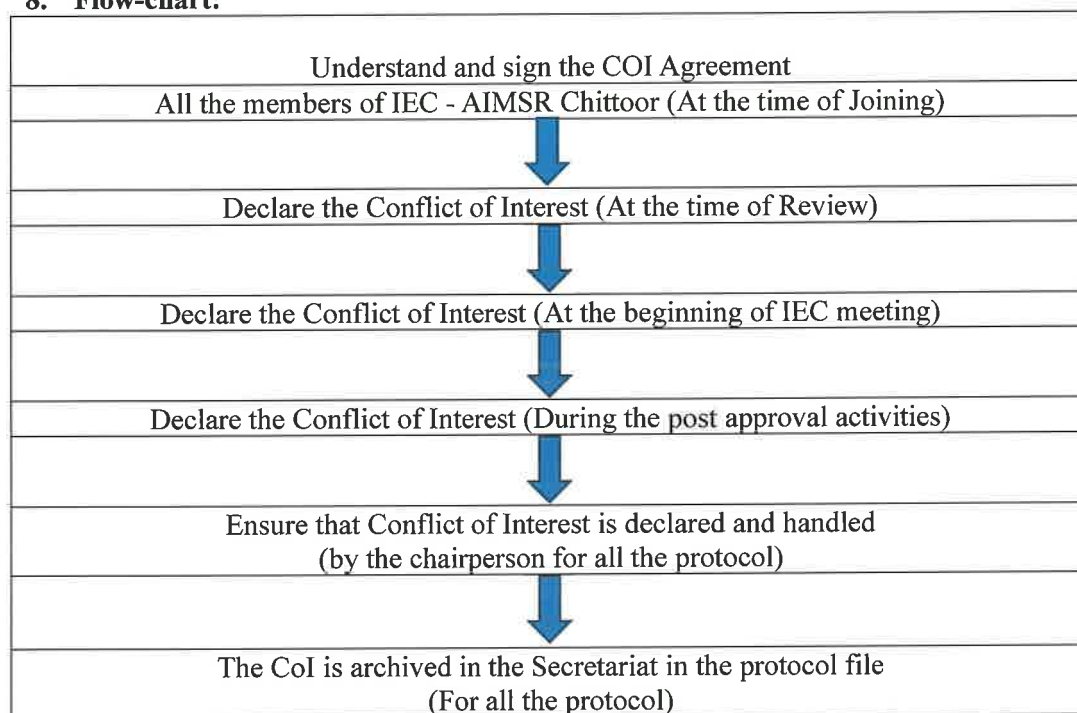
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**8. Flow-chart:**



**9. Glossary:**

CDSCO: Central Drugs Standard Control

Organization CoI: Conflict of Interest

CFR: Code of Federal Regulations

ICMR: Indian Council of Medical Research

2019 SOP: Standard Operating Procedure

IC: Independent Consultant

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**Prepared by:**

Dr Sachidananda Adiga M N Member, SOP Sub-committee	Signature with date: <i>msadiga 10/03/2025</i>
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**Verified by:**

Dr P Vijetha Member, SOP Sub-committee	Signature with date: <i>pvijetha 10/3/2025</i>
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**Approved by:**

Dr Ravi Prabhu G Chairperson, IEC - AIMS Chittoor	Signature with date: <i>Ravi Prabhu G 10.03.2025</i>
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**Notified by:**

Dr Alfred Joseph Augustine Dean, AIMS Chittoor	Signature with date: <i>Alfred J Augustine 10/03/2025</i> <b>DEAN</b>
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