

Institutional Ethics Committee
Apollo Institute of Medical Sciences Research Chittoor

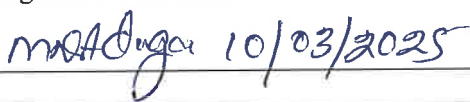
SOP No 03 / Version 1.1
IEC - AIMSRS Chittoor **Training of EC members**
Effective date: 10-03-2025

Title: IEC - AIMSRS, Chittoor Members: Training of members

SOP Code: SOP 03/v1.1

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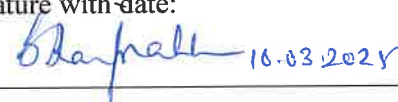
Prepared by:

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

Dr K Ashok Kumar Reddy Member, SOP Sub-committee	Signature with date:  10/03/2025
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Approved by:

Dr Ravi Prabhu G Chairperson, IEC, AIMSRS, Chittoor	Signature with date:  10.03.2025
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Notified by:

Dr Augustine Joseph Augustine Dean AIMSRS Chittoor	Signature with date:  10/03/2025 DEAN Apollo Institute of Medical Sciences and Research Murukambattu, Chittoor-517127 A.P.
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Details of Current SOP No

SOP subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr Sachidananda Adiga MN	Version 1.1	10-03-2025	Made Changes as per biomedical Research guidelines needs in Training of EC Members. (Excluding Clinical Trials)

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IEC - AIMSRS Chittoor **Training of Members**

Effective date:10-03-2025

1.Purpose: The purpose of this SOP is to describe the training, assessment and feedback of IEC - AIMSRS, Chittoor, members and the secretarial staff
2.Scope: SOP applies to initial and continuing training and assessment of IEC - AIMSRS, Chittoor members and secretarial staff in research ethics including but not limited to research ethics, research methodology, ethics committee functioning, ethical review process, SOPs, guidelines, standards, regulations and emerging fields in research and ethics. The SOP also applies to obtaining feedback from IEC - AIMSRS members.
3. Responsibilities
3.1. IEC - AIMSRS, Chittoor Chairperson will:
3.1.1. Ensure that there is a system in place to perform adequate initial and continuing training of the IEC - AIMSRS, Chittoor members and the secretarial staff as per the scope of this SOP.
3.1.2. Approve the calendar prepared by the Member-Secretary, for the training and assessment sessions
3.1.3. Evaluate the training and assessment program to identify areas of weaknesses and recommend corrective measures.
3.1.4. Take note of the feedback from the IEC, AIMSRS Chittoor and ensure action wherever deemed necessary
3.2. IEC - AIMSRS Chittoor Member -Secretary will:
3.2.1. Arrange for initial training of the new members
3.2.2. Prepare the calendar (schedule) for continuing training, get it approved by the Chairperson and arrange for the conduct of these training programs
3.2.3. Prepare the assessment schedule for the members, get it approved by the Chairperson and make arrangements for the conduct of these exercises.
3.2.4. Issue annual certification for all the members and the secretarial support staff
3.2.5. Provide feedback forms, for the IEC - AIMSRS, Chittoor, members to use and take corrective measures based on such feedback
3.3. IEC - AIMSRS, Chittoor members (including Chairperson and Member-Secretary) will:
3.3.1. Take note of and abide by the calendar for training and assessment sessions for members of IEC - AIMSRS, Chittoor
3.3.2. Undertake the initial and continuing training sessions organized for the IEC - AIMSRS, Chittoor members

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3.3.3. Take part in the assessment sessions conducted for the IEC - AIMSRS Chittoor members
3.3.4. Take part in the feedback sessions and provide feedback for identifying areas of weakness that require corrective action
3.4. IEC -AIMSRS Chittoor Secretarial staff will:
3.4.1. Assist the Member-Secretary to develop a calendar for training and assessment programs for the year and remind the Member-Secretary from time to time to conduct these exercises.
3.4.2. Communicate the training and assessment schedule to the IEC - AIMSRS Chittoor members and make necessary logistic arrangement
3.4.3. Maintain the record (including annual certificate) of training of members and the secretarial staff
3.4.4. Maintain the feedback provided by the members in a separate file
3.4.5. Take part in the assessment sessions organized by the IEC - AIMSRS Chittoor
4. Detailed instructions:
4.1. Topics for training of IEC - AIMSRS Chittoor members (including but not limited to):
4.1.1. Basics of research methodology and research ethics
4.1.2. Relevant and currently applicable ethical and regulatory guidelines applicable to research on human participant.
4.1.3. Structure and content of the SOPs of IEC - AIMSRS Chittoor
4.1.4. Review process of protocols and protocol-related documents and use of reviewer's checklists and other templates
4.1.5. Roles of IEC - AIMSRS Chittoor members as appointed in the IEC - AIMSRS Chittoor (layperson, lawyer, basic scientist, clinician, social scientist, member-secretary, chairperson)
4.1.6. Responsibilities of IEC - AIMSRS Chittoor members in the designated roles reviewers, site monitors and sub-committee members
4.1.7. Recent developments in health care, research and ethics

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4.2. Topics for training of the Secretarial staff (in addition to 4.1):
4.2.1. Communication skills: written, electronic and verbal
4.2.2. Use of templates, preparation of agenda, minutes and reports
4.2.3. Confidentiality
4.2.4. Maintenance of IEC - AIMSRS, Chittoor database and its security
4.2.5. Maintenance of files
4.2.6. Audits
4.3. Initial training of new IEC - AIMSRS, Chittoor members:
4.3.1. Every time a new member is inducted into IEC - AIMSRS, Chittoor, the Member-Secretary should organize an initial training for the new member before taking part in the first meeting as a member.
4.3.2. The topics covered should include IEC - AIMSRS, Chittoor scope and functioning, IEC-AIMSRS, Chittoor SOPs, the applicable ethical and regulatory guidelines, roles and responsibilities of the new members and the review process
4.3.3. The new member is required to attend at least one meeting as an 'Observer' before being inducted as a member of the IEC - AIMSRS, Chittoor to understand the conduct and proceedings of the IEC - AIMSRS, Chittoor meetings except the member secretary who has already had sufficient experience in IEC functioning.
4.4. Continuing training of the IEC - AIMSRS, Chittoor members:
4.4.1. The Member-Secretary will prepare the calendar of continuing training schedule and get it approved
4.4.2. Continuing training of IEC - AIMSRS, Chittoor members will be conducted as per the training schedule
4.4.3. Training on essential national guidelines like ICMR and Good Clinical Practice will be conducted at least once in 3 years and whenever the guidelines are revised by the regulatory authorities
4.4.4. All the IEC - AIMSRS, Chittoor members must be encouraged to actively take part in the continuing training organized by the IEC - AIMSRS, Chittoor
4.4.5. The resource persons will be selected based on the topic from within the IEC - AIMSRS, Chittoor or an external resource person may be called, whenever required

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4.4.6.	The resource persons will be required to circulate handouts or reading material to the IEC - AIMSRS, Chittoor members, wherever applicable.
4.4.7.	Annual training certification will be provided to the IEC - AIMSRS, Chittoor members and secretarial staff
4.4.8.	The IEC - AIMSRS, Chittoor members will be encouraged to participate in workshops, conferences or other training programs conducted within or outside the University, in areas of research ethics as delegates or resource persons or facilitators.
4.5. Assessment of IEC - AIMSRS, Chittoor members	
4.5.1.	At the end of every second training program, assessment of IEC - AIMSRS, Chittoor members will be conducted using evaluation forms prepared by the resource person/Member-Secretary
4.5.2.	Training will be reinforced if performance is found inadequate (scores <50%)
4.6. Feedback from the Members of IEC - AIMSRS, Chittoor:	
4.6.1.	IEC - AIMSRS, Chittoor members will provide their feedback on IEC - AIMSRS, Chittoor functioning once a year or when deemed necessary on a regular basis (Ann06/SOP03/v1.1)
4.6.2.	The feedback will be assessed by the Member-Secretary and the Chairperson and necessary action initiated
4.6.3.	The feedback forms and assessment will be maintained in the Secretariat.
4.6.4.	The feedback from members requiring action will be tabled in the next immediate meeting of the IEC - AIMSRS, Chittoor
4.7. Training of the Secretarial staff:	
4.7.1.	The IEC - AIMSRS, Chittoor Member-Secretary or other member designated by the Member-Secretary, will train the Secretarial staff on the importance, structure and content of the IEC - AIMSRS, Chittoor SOPs.
4.7.2.	The secretarial staff will have one initial training and this will be supplemented with continuing training sessions
4.8. Maintenance of training records and feedback forms:	
4.8.1.	The secretarial staff will maintain a training file of the IEC - AIMSRS, Chittoor which will include - calendar of training and assessment schedules, details of the training and assessment sessions conducted, self-assessment forms duly filled and feedback forms.

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4.8.2. The secretarial staff will maintain copies of the training schedules, records and annual certification of all training sessions conducted for the IEC - AIMSRS, Chittoor members in the individual members' file. These documents will be shredded as per the shredding protocol after a period of 5 years.

4.8.3. The secretarial staff will also maintain the certificates of workshops and conferences in research ethics attended by the individual IEC - AIMSRS, Chittoor members. In addition, if any member is invited as a resource person in a research or research ethics program, the secretarial staff will maintain records of these as well.

4.8.4. The copies of the certificates will be filed in the individual members' files.

5. References:

5.1. ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Subjects, 2017

5.2. Indian GCP Guidelines, 2001

6. Annexures

6.1. Ann01/SOP 03/v1.1: Template for calendar of training schedule

6.2. Ann02/SOP 03/v1.1: Feedback form of IEC - AIMSRS members on IEC - AIMSRS functioning

6.3. Ann03/SOP 03/v1.1: Annual training certification

Ann01/SOP 03/v1.1:

Template for calendar of training, assessment and feedback schedule for members.

Template for calendar of training, assessment and feedback schedule for members			
Training Schedule			
Session	Date	Topic	Resource Person
Jan-March			
April-Jun			
July-Sept			
Oct-Dec			
Training Assessment			
Jan-June		July-Dec	
Feedback schedule (Annual)			
Month		Date	

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Ann02/SOP 03/v1.1:
 Feedback of the IEC - AIMSRS, members on the IEC - AIMSRS, Chittoor functioning

No	Item	Yes/ No	Remarks
1	The time allotted for review of expedited protocols is adequate		
2	The time allotted for review of full-review protocols is adequate		
3	The checklist provided for review of protocols is appropriate		
4	The SOPs, guidelines and regulations are provided by IEC - AIMSRS, Chittoor for reference		
5	Confidentiality of the documents is adequately maintained		
6	Training programs are conducted regularly		
7	Training programs conducted by IEC - AIMSRS, Chittoor are useful		
8	The members are free to express their vote of dissent during the decision making		
9	The meetings of the IEC - AIMSRS, Chittoor are conducted as per SOP (time, quorum, discussion, decision making)		
10	The IEC - AIMSRS, Chittoor manages conflict of interest as per the SOP		
11	The duration of the meetings is adequate for the number of protocols discussed		
12	The functioning and decision making of the IEC - AIMSRS, Chittoor is independent		
13	The agenda of the meeting and meeting notes are circulated well ahead of the meeting		
14	The SOPs, guidelines and regulations are provided by IEC - AIMSRS, Chittoor for reference		

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15	The minutes of the meeting are circulated within 7 calendar days of the meeting for approval of the IEC - AIMSRS, Chittoor members		
16	The review process includes both scientific and ethical issues in the protocols		
17	Every member is able to freely contribute to discussion and deliberation of protocols in the meeting		
18	The SOPs are clear and practical		
19	The venue and arrangement of the meetings is adequate		
20	What according to you is the strength of the IEC - AIMSRS, Chittoor?		
21	What according to you needs improvement?		
	Signature of the IEC - AIMSRS, member with date		
	Assessment of feedback by Member-Secretary and Chairperson	Action needed (if any):	
	Signature of the Member-Secretary with date		
	Signature of the Chairperson with date		

Ann03/SOP03/v1.1: Annual training certification

IEC - AIMSRS, Chittoor

This is to certify that (Name and designation in IEC - AIMSRS, Chittoor), has successfully undergone the following training in IEC - AIMSRS during the year conducted by IEC - AIMSRS, Chittoor.

Sl.No.	Date	Topic

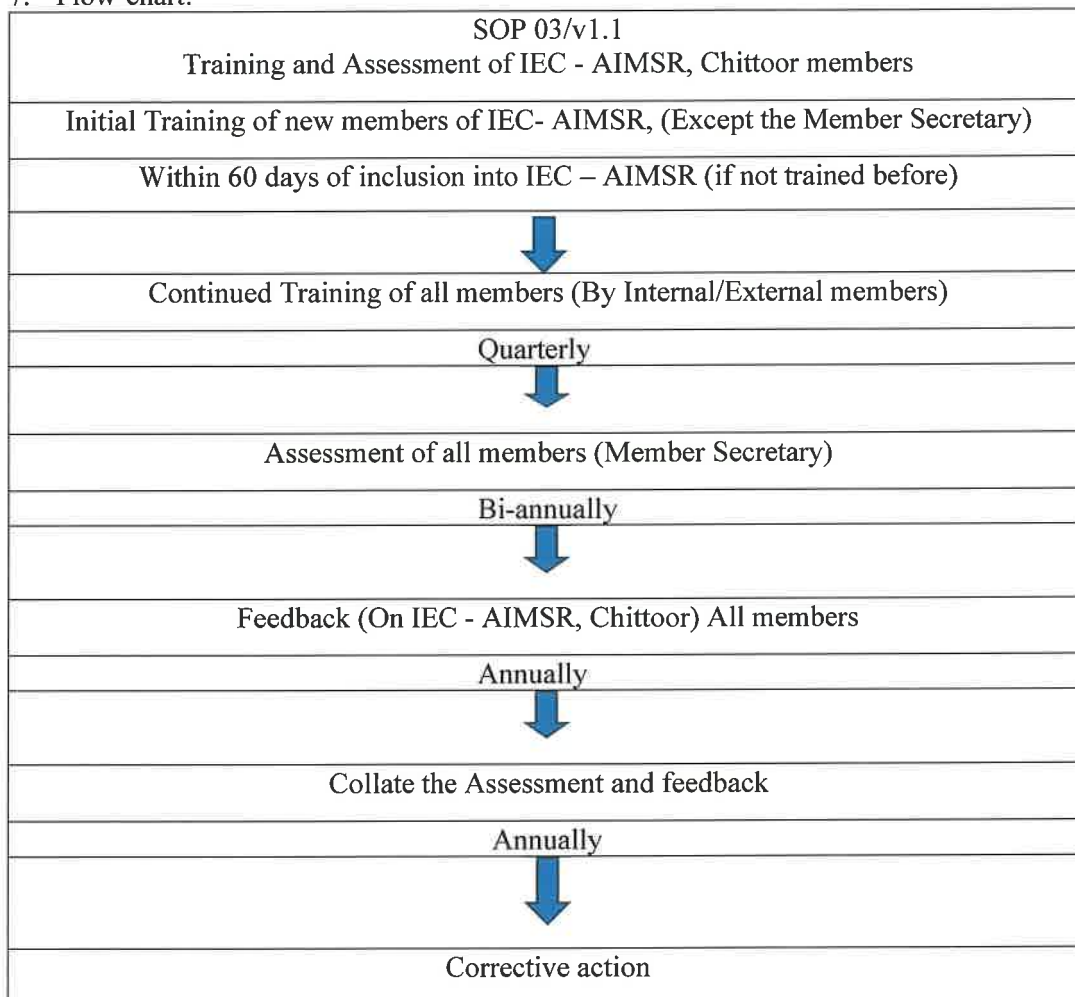
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7. Flow-chart:



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8. Glossary:

GCP: Good Clinical Practice
ICMR: Indian Council of Medical Research
NDCTR: New Drugs and Clinical Trials Rules

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Prepared by:

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

Dr K Ashok Kumar Reddy Member, SOP Sub-committee	Signature with date: <i>Dr K Ashok Kumar Reddy 10/03/2025</i>
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Approved by:

Dr Ravi Prabhu G Chairperson, IEC, AIMSRS, Chittoor	Signature with date: <i>Dr Ravi Prabhu G 10-03-2025</i>
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Notified by:

Dr Augustine Joseph Augustine Dean AIMSRS Chittoor	Signature with date: <i>Dr Augustine Joseph Augustine 10/03/2025</i> DEAN
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