



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

SOP No 01 / Version 1.4
Constitution of IEC, Roles and Responsibilities
Effective Date: 10-03-2025

**Title: Constitution of IEC, Apollo Institute of Medical Sciences &
Research (AIMSR Chittoor), Roles and Responsibilities of members**
SOP Code: SOP No 01 /v1.4

Prepared by:

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Approved by:

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Notified by:

Dr Alfred Joseph Augustine Dean, AIMSR, Chittoor	Signature with date: <i>Alfred J. Augustine</i> 10/03/2025
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Details of Current SOP No: 01 / Version 1.4

SOP subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr Sachidananda Adiga MN	Version 1.4.	10-03-2025	Made the changes as per biomedical research needs in roles and responsibilities of IEC member (Excluding Sponsored Clinical Trial)



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1.Purpose:

1.1. The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR), which provide the framework for constitution, selection, roles and responsibilities of Institutional Ethics Committee, AIMSRS Chittoor, and its members.

2.Scope:

2.1 This SOP describes processes related to the constitution of IEC, AIMSRS Chittoor selection, roles and responsibilities of members (including terms of reference for appointment of members).

3.Responsibilities

3.1. The Dean, Apollo Institute of Medical Sciences and Research Chittoor will:

3.1.1. Approve the selection of Chairperson, Member-Secretary and other members of IEC - AIMSRS Chittoor as per national regulations and guidelines, gender balance and institutional representation.

3.1.2. Notify the constitution of IEC - AIMSRS Chittoor and ensure that the same is widely known to all through the AIMSRS website/ webpage.

3.1.3. Address and take appropriate steps regarding complaints from Grievance Redressal Committee.

3.2. The Chairperson will:

3.2.1. Approve and sign the TOR and appointment letters for all members of IEC, AIMSRS, Chittoor.

3.2.2. Accept and approve resignation of any member after exploring alternatives.

3.2.3. Ensure that the newly joined members receive the relevant training within a period of 30 days from the date of joining IEC, AIMSRS Chittoor or before the next scheduled full meeting of IEC, AIMSRS, Chittoor whichever is earlier.

3.2.4. Receive any complaints or grievances of any of the IEC, AIMSRS Chittoor members and take appropriate action, in consultation with the Member- Secretary.



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3.3. The Member-Secretary will:
3.3.1. Assist the Chairperson in selecting the members for appointment.
3.3.2. Prepare individualized terms of reference (appointment letters) for each of the roles of the various members of IEC, AIMS R Chittoor.
3.3.3. Ensure timely training of the newly joined members in research ethics, research ethics guidelines, regulations, Indian GCP guidelines and SOP training.
3.3.4. Ensure that all members sign copies of their terms of reference (appointment letters) and sign confidentiality agreement and declaration on conflict of interest.
3.3.5. Forward resignation letters and complaints of IEC, AIMS R Chittoor members to the Chairperson.
3.3.6. Communicate changes to the composition of IEC, AIMS R Chittoor to the concerned authorities as per the existing rules and regulations in force.
3.4. The IEC, AIMS R Chittoor Secretariat will:
3.4.1. Maintain the files on each of the members and ensure that CVs and training certificates are up to date.
3.5. The IEC, AIMS R Chittoor Members will:
3.5.1. Read, understand, follow and perform as per their specific role in the ethics Committee.
3.5.2. Sign the requisite forms before appointment; receive training as specified; and provide updated, signed CVs from time to time.
3.6. The Grievance Redressal Committee will:
3.6.1. Receive and hear the grievance of any researcher or other persons made against the functioning or decision-making of IEC, AIMS R Chittoor.
3.6.2. Convene a meeting, discuss the matter and report to the Dean, AIMS R, Chittoor.
3.7. Terms of References:
3.7.1. The TOR for the IEC and its members will be clearly specified by the institution in the EC SOPs



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3.7.2. IEC will have a written SOPs according to which the committee will function.

The IEC will refer to ICMR guidelines in preparing the SOPs for all biomedical and health research. The SOPs will be updated periodically to reflect changing requirements. A copy of the latest version of SOP will be made available to each member and they will be trained on the SOPs. The SOPs will be made available in the secretariat of IEC both as hard and soft copy



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3.7.3. Scope, tenure and renewal policy of the IEC will be stated in this SOP.

3.7.4. Members of the IEC should not have any known record of misconduct.

3.7.5. The IEC will for be registered with the relevant regulatory authorities, for example, IECs approving biomedical research under DHR.

3.8. Condition of Appointment of EC members:

3.8.1. Members will be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the IEC

3.8.2. Members are appointed to the IEC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

3.9. Terms of reference for EC members:

3.9.1. The head of the institution will appoint I IEC members, including the Chairperson

3.9.2. The appointment letter issued to all members will specify the TORs. The letter issued by the head of the institution will include role and responsibility of the member in the committee, Duration of appointment and conditions of appointment



3.9.3. Generally, the term of IEC membership is 5yrs, but may vary depending on the need of the IEC-AIMSR Chittoor. The duration could be extended as specified in the SOPs. A 50% percentage of IEC members could be changed on a regular basis.

3.9.4. IEC members may be given a reasonable honorarium for attendance at the meeting.

4.Detailed Instructions:

4.1 Constitution of IEC, AIMSR, Chittoor:

4.1.1. The Chairperson and Member-Secretary shall nominate potential members at the time of installation of the new committee or for residuary periods.

4.1.2. This will be approved and notified by the Dean AIMSR, Chittoor.

4.1.3. The tenure of the IEC, AIMSR Chittoor will be for a period specified in the registration letter of the DCGI.

4.1.4. After notification by the Dean AIMSR Chittoor, the Member-Secretary will inform the changes in the composition of IEC, AIMSR Chittoor to the concerned governmental authorities.

4.2. General composition of IEC, AIMSR Chittoor:

4.2.1. IEC, AIMSR Chittoor will be multidisciplinary in composition and include a combination of medical and non-medical, scientific and non-scientific persons with required qualifications as prescribed by current regulations/guidelines and also include lay person(s) to represent the different regional points of view.

4.2.2. IEC, AIMSR Chittoor will be multi- sectoral in composition with differing backgrounds to promote complete and adequate review of research and representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of society

4.2.3. The IEC, AIMSR Chittoor will consist of at least 7 members and up to a maximum of 15 members.

4.2.4. IEC, AIMSR Chittoor members must have the expertise, time and commitment to perform all functions as detailed in this SOP.



4.3. Non- member representation in IEC, AIMS Chittoor.

4.3.1. IEC, AIMS Chittoor may invite member(s) of specific patient groups or special interest groups for EC meeting (based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research, etc.) or independent consultants in particular areas of research for eliciting their views.

4.3.2. Experts in certain areas of research may be appointed as independent consultants to review the protocol and related documents.

4.4. The Specific composition shall be at least as follows:

4.4.1. Chairperson (Non-affiliated to the institution)

4.4.2. Member Secretary (Affiliated to the institution)

4.4.3. One or more members from the basic medical sciences (at least one pharmacologist, especially if the EC is reviewing drug, device, vaccine or biological studies)

4.4.4. One or more clinicians from the various institutions of the university or outside

4.4.5. 1-2. Legal experts (non-affiliated)

4.4.6. 1-2 social scientists or representative of non-governmental agency/philosopher, ethicist or theologian.



4.4.7. One or more lay person from the community as per the National Ethical Guidelines (Non-affiliated, literate person from the community, who has not pursued any medical science or health -related career in the last five years, may be a representative of the community from which the participants are drawn, and is aware of the local language, cultural and moral values of the community. It is desirable if the layperson is involved in social and community welfare activities).

4.5. Criteria for the selection of members of IEC-AIMSR Chittoor

4.5.1. Chairperson/ Co- Chairperson (if any)

4.5.1.1. The chair-person/ Co- Chair person must be from outside the institute and preferably be from the healthcare sector.

4.5.1.2. He/she should be a person of good standing in society.

4.5.1.3. He/she should be probably having some experience as a prior EC member.

4.5.1.4. He/she is eligible for re-appointment as Chairperson/Co- Chairperson for any one additional term

4.5.2. Member Secretary/ Joint Secretary (If any)

4.5.2.1. Should be a full-time employee of AIMSR Chittoor

4.5.2.2. Should preferably be from a department doing biomedical research

4.5.2.3. Should have a state medical or other healthcare council recognized postgraduate degree or equivalent UGC recognized degree.

4.5.2.4. Should have qualifications, training and expertise in biomedical research and ethics.

4.5.2.5. Should have personal interest, capacity and good communication skills.

4.5.2.6. He/she is eligible for re-appointment as Member-Secretary/Joint Secretary for one term.

4.5.3. Members:

4.5.3.1. Selected in their personal capacity based on qualifications, experience, interest, ethical, scientific knowledge and/or expertise, without any known record of professional misconduct or criminal charges.

4.5.3.2. Scientists and clinicians should possess postgraduate qualifications.

4.5.3.3. Should be committed and willing to volunteer the necessary time and effort for the work of IEC, AIMSR Chittoor.

4.5.4: Quorum requirements for IEC meeting:

4.5.4.1. A minimum of five members present in the meeting room.

4.5.4.2. The quorum should include both medical, non-medical or technical or/and non-technical members.

4.5.4.3. Minimum one non-affiliated member should be part of the quorum.

4. 5.4.4. Preferably the lay person should be part of the quorum.



4.5.4.5. The quorum for reviewing should be in accordance with current DHR requirements.

4.5.4.6. No decision is valid without fulfilment of the quorum.

4.6. Hierarchy:

4.6.1. The Chairperson/Co-Chairperson will head the committee.

4.6.2. The Member Secretary/Joint Secretary will be the custodian of all the IEC, AIMS
Chittoor documents, the medium of communication and recorder of the expenses
Incurred.



4.6.3. All other IEC, AIMSRS Chittoor members will be regular committee members with equal Ranking
4.6.4. The Secretariat staff and support staff will ably assist the Secretariat
4.7. Membership agreement, confidentiality agreement and declaration of conflict of Interest
4.7.1. It is the responsibility of each IEC, AIMSRS, Chittoor member, at the time of joining the EC, to read and understand the terms of reference (appointment letter) given to him/her based on his/her role in the ethics committee (Ann02/SOP1/v1.4)
4.7.2. It is the responsibility of each IEC, AIMSRS, Chittoor member, at the time of joining, to read, accept and sign a membership agreement (Ann03/SOP01/v1.4), a confidentiality (Ann01/SOP02 /v01) and a declaration of conflict-of-interest agreement (Ann01/ SOP02/v01.1).
4.7.3. The Secretariat will keep the originals of the signed agreements (terms of reference, in the IEC, AIMSRS, Chittoor office in the individual member's files.
4.7.4. The Secretariat shall provide IEC, AIMSRS, Chittoor members photocopies of the agreement forms.
4.8. Tenure of membership:
4.8.1. The tenure of membership will be for a period of five years from the date of constitution, as stipulated in the DCGI's letter of recognition. This is liable to change from time to time.
4.9. Appointment of new members:
4.9.1. The Chairperson and Member-Secretary shall nominate members for appointment, based on the current regulatory and national guidelines, the workload on the committee and/or the vacancy position.
4.9.2. New members can be inducted in the following situations:
4.9.2.1. When a member completes his/her tenure
4.9.2.2. When a member resigns from the ethics committee before tenure completion (in which case the new member will be appointed for the residuary period)
4.9.2.3. When a member ceases to be a member for various reasons (in which case the new member will be appointed for the residuary period)
4.9.2.4. When the membership requirements need to be met (4.2 above)



4.10. Conditions to be fulfilled by a member at the time of appointment
4.10.1 Provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
4.10.2. The members is either be trained in human research protection and/or GCP at the time of induction into the IEC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
4.10.3. Be willing to undergo training or update their skills/knowledge during their tenure as an IEC member.
4.10.4. Be aware of relevant guidelines and regulations;
4.10.5. Read, understand, accept and follow the COI policy of the IEC and declare it, if applicable, at the appropriate time;
4.10.6. Sign a confidentiality and conflict of interest agreement/s;
4.10.7. Be willing to place her/his full name, profession and affiliation to the IEC in the domain.
4.10.8. Be committed and understanding to the need for research and for imparting protection to research participants in research.
4.11. Composition of EC:
4.11.1.1. IECs will be multi-disciplinary and multi-sectoral.
4.11.1.2. There will be adequate representation of age and gender.
4.11.1.3. Preferably 50% of the members will be non-affiliated or from outside the institution.
4.11.1.4 The number of members in an IEC will preferably be between seven and 15 and a minimum of five members should be present to meet the quorum requirements.
4.11.1.5 The IEC will have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.
4.12. Composition, affiliations, qualifications, member specific roles and responsibilities of an EC
4.12.1.1: Chairperson/Vice Chairperson: Should be a Non-affiliated



4.12.1.2. Should be a well-respected person from any background with prior experience of having served/ serving in an IEC
4.12.1.3. Conduct IEC meetings and be accountable for independent and efficient functioning of the committee
4.12.1.4. Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberation.
4.12.1.5. Ratify minutes of the previous meetings
4.12.1.6. In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting.
4.12.1.7. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
4.12.1.8. Seek COI declaration from members and ensure quorum and fair decision making
4.12.1.9. Handle complaints against researchers, EC members, conflict of interest issues and requests for use of IEC data,
4.12.2. Member Secretary/ Alternate Member Secretary (optional)
4.12.2.1. Should be a staff member of the institution, should have knowledge and experience in clinical research and ethics, be motivated and have good communication skill.
4.12.2.2. Should be able to devote adequate time to this activity which should be protected by the institution
4.12.2.3. Organizes an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
4.12.2.4. Schedules IEC meetings, prepare the agenda and minutes
4.12.2.5. Organizes IEC documentation, communication and archiving
4.12. 2.6. Ensures training of IEC secretariat and EC members
4.12.2.7. Ensures SOPs are updated as and when required
4.12.2.8. Ensures adherence of IEC functioning to the SOPs
4.12.2.9. Responds to audits and inspections
4.12.2.10. Ensures completeness of documentation at the time of receipt and timely inclusion in agenda for IEC review.
4.12. 2.11. Assess the need for expedited review/ exemption from review or full review.



4.12. 2.12. Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
4.12. 2.13. Ensures quorum during the meeting and record discussions and decisions.
4.12.3: Qualification, eligibility and responsibility of Basic scientist
4.12.3.1. Basic Medical Scientist(s) Affiliated/ non-affiliated can be non-medical or medical person with qualifications in basic medical sciences
4.12. 3.2. In case of EC reviewing academic clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist
4.12.3.3. Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, protocol deviation, progress and completion report
4.12.3.4. For academic clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
4.12.2.4 Clinician(s) Affiliated/ non-affiliated member qualification and responsibility
4.12. 4.1. Should be individual/s recognized medical qualification, expertise and Training
4.12.4.2. Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
4.12.4.3. Ongoing review of the protocol (protocol deviation or violation, progress and completion report)
4.12.4.4. Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.
4.12.4.5. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
4.12.2.5. Qualification and responsibility of legal expert (Affiliated/ non-affiliated)
4.12.5.1. Should have a basic degree in Law from a recognized university, with experience and desirable training in medical Ethical review of the proposal, ICD along with law.
4.12.5.2. Ethical review of the proposal, ICD along with translations, MoU.
4.12.5.3. Review of 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.
4.12.5.4. Interpret and inform EC members about new regulations if any



4.12.2.6. Qualification and responsibility of social scientist/ philosopher/ethicist/theologian
4.12.2.6.1. Affiliated/ non-affiliated
4.12.2.6.2. Qualifications - Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities
4.12.2.6.3. • Ethical review of the proposal, ICD along with the translations.
4.12.2.6.4. Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any
4.12.2.6.5. Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
4.12.2.7. Qualification and responsibility of Lay person:
4.12.2.7.1. Lay person(s) must be Non-affiliated
4.12.2.7.2. Must be a literate person from the public or community
4.12.2.7.3. Has not pursued a medical science/ health related career in the last 5 years
4.12.2.7.4. May be a representative of the community from which the participants are to be drawn
4.12.2.7.5. Is aware of the local language, cultural and moral values of the community
4.12.2.8. Specific roles of IEC - AIMS Chittoor members:
There will be two types of members in IEC - AIMS Chittoor.
4.12.2.8.1. Scientific
4.12.2.8.2. Non-scientific
4.12.2.8.1 Scientific members will consist of:
4.12.2.8.1.1. Medical: The roles of the medical members will be to do a medical, scientific and ethical review of the health research protocol-related documents assigned to them. They will fulfill quorum requirements and take part in the decision-making. As and when nominated they will perform the role of member of Site Monitoring Visit (SMV) or any other subcommittee of IEC.
4.12.2.8.1.2. Non-medical: The roles of the non- medical members will be to do a scientific and ethical review of the observational, epidemiological and social science research protocol-related documents assigned to them. From this category, the Social Scientist alone will fulfill quorum requirements and take part in the decision-making. As and when nominated they will perform the role of member of SMV or any other subcommittee of IEC - AIMS Chittoor.



4.12.2.8.2. Non-scientific members:

Legal expert: The legal expert will review the legal documents as described in ToR (Ann02/SOP1.4/v3)

4.13. Roles and responsibilities of the IEC

4.13.1. The basic responsibility of an IEC is to ensure protection of the dignity, rights, safety and well-being of the research participants.

4.13.2. The IEC will ensure ethical conduct of research by the investigator team

4.13.3. The IEC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes

4.13.4. The IEC will perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.

4.13.5. The IEC will ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs

4.13.6. The IEC will assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.

4.13.7. Responsibilities of members will be clearly defined. The SOPs should be given to EC members at the time of their appointment.

4.13.8. The Secretariat will support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.

4.13.9. The IEC will ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.

4.13.10. The IEC reviews progress reports, final reports and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable

4.13.11. The IEC will recommend appropriate compensation for research related injury, wherever required.

4.13.12. The IEC will carry out monitoring visits at study sites as and when needed.

4.13.13. The IEC will participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations



4.13.14. The IEC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted.
4.14. Resignation of Members:
4.14.1.A member may resign from IEC - AIMS R Chittoor membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson, and approved by the Registrar.
4.15. Disqualification of members:
4.15.1. For not attending IEC - AIMS R Chittoor meetings:
4.15.1.1.A member may be disqualified from IEC - AIMS R Chittoor membership if they fail to attend more than 3 regular consecutive meetings without prior intimation. The process conducted will be as follows:
4.15. 1.2. The Member Secretary will inform the Chairperson, if a member has not attended more than three consecutive regular meetings of the IEC - AIMS R Chittoor without prior intimation.
4.15.1.3. Chairperson will initiate the process of review of membership of such a member by including the matter in agenda of the next regular meeting.
4.15.1.4.A written communication will be sent to the concerned 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. Alternatively, the concerned IEC- AIMS R, Chittoor member will be allowed to state his/her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson.
4.15.1.5. The matter will be discussed and reviewed at the IEC - AIMS R 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.
4.15.1.6. The Chairperson or Member-Secretary will inform the IEC - AIMS R Members /COO/Dean by a confidential written communication.



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4.16. For inappropriate conduct:
4.16.1. A member may be disqualified from continuance should IEC - AIMSRS Chittoor determine, by a >50% majority specifically called for the purpose that the member's conduct has been inappropriate.
4.16.2. The Chairperson will satisfy himself/ herself that a <i>prima facie</i> case exists before initiating action.
4.16.3. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IEC - AIMSRS Chittoor could be questioned, the Chairperson may, with approval from the Office of the COO, provisionally suspend the membership of the concerned member till the final decision is taken.
4.16.4. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of a IEC - AIMSRS Chittoor member.
4.16.5. The member would stand disqualified, if the other members present at the meeting approve of disqualification by voting (voting by >50% of members present in the meeting and voting).
4.16.6. The Chairperson will convey the disqualification to the concerned member through a written communication.
4.17. Research Ethics Training:
4.17.1. An individual selected as a new member of IEC - AIMSRS Chittoor (Except member secretary) will be required to attend at least one meeting as an 'Observer' before being inducted as a member. In addition, he/she will be assigned a mentor.
4.17.2. Member Secretary/Joint Secretary or a IEC - AIMSRS Chittoor member or an external experienced faculty will provide introductory training in Research Ethics, GCP, National ethical guidelines & SOPs to the new member.



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| 4.17.3. A newly inducted member should submit a certificate of training, within 60 days of joining IEC - AIMS Research Chittoor. or before the next scheduled full meeting of IEC- AIMS Research, Chittoor. All members will be encouraged to receive continued training by participating in workshops, conferences or re-training programs related to research ethics, as delegate, faculty, facilitator, etc |
| 4.17.4. IEC - AIMS Research Chittoor. will conduct in-house training sessions on research ethics, GCP and SOPs from time to time to impart continued training to IEC - AIMS Research Chittoor, members. |
| 4.17.5. IEC - AIMS Research Chittoor may nominate and/or request the university to sponsor a member or prospective members for attending conference, continuing education session workshop and/or training program etc. |
| 4.18. Functions: |
| 4.18.1. Chairperson (and Co-Chairperson): |
| 4.18.1.1. The Chairperson will be responsible for conducting meetings, leading all discussions and deliberations pertinent to review of research proposals and ensuring equitable distribution of the discussion by all the members. |
| 4.18.1.2. In the event of tied vote on a protocol, in addition to his/her initial vote, the Chairperson has a casting vote. |
| 4.18.1.3. At the start of every IEC - AIMS Research Chittoor meeting the Chairperson will ensure quorum and ask members for conflict of interest. |
| 4.18.1.4. The Chairperson will approve the dates for the meeting, the agenda and the minutes before these are circulated. |
| 4.18.1.5. The Chairperson will preside over all administrative and financial matters pertinent to the committee's functions. The Chairperson will represent the IEC- AIMS Research, Chittoor at various meetings and forums, or if unable to, will request the Co-Chairperson/Member-Secretary/Joint Secretary to do so. |
| 4.18.1.6. The Chairperson will approve the Member-Secretary's signing of all documents and communications related to IEC - AIMS Research Chittoor functioning. |
| 4.18.1.7. The Chairperson will approve the formation of any sub-committee from among the members of the IEC - AIMS Research Chittoor, and will ask the Member-Secretary to communicate the same. |



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4.18.1.8. In the absence of the Chairperson, the Co-Chairperson will have all the powers and responsibilities of the Chairperson.
4.18.1.9. In the event both Chairperson and Co-Chairperson are absent on the day of the meeting, the Chairperson will nominate an external member as acting Chairperson or the members present may elect an alternative Chairperson, from among the external members present for the meeting. The acting Chairperson will have all the powers of the Chairperson for that meeting only.
4.18.2. Member-Secretary:
4.18.2.1. Member-Secretary shall receive research proposals, categorize them based on risk (full/expedited/exemption), identify reviewers/ discussants, and ensure that the protocols are sent out within the timelines.
4.18.2.2. Organize efficient tracking procedure for each proposal received and arrange for the same to be displayed in the Secretariat.
4.18.2.3. Identify and allocate research proposal files to the corresponding members based on their field of expertise. In case there are more than one member from a given field the Member-Secretary shall ensure that the distribution of proposals is fair and equitable.
4.18.2.4. In consultation with and approval from the Chairperson, schedule and organize IEC- AIMSRS, Chittoor, meetings and ensure that these dates are publicized.
4.18.2.5. Prepare and maintain meeting agenda and minutes. These shall be approved by the Chairperson before circulating among the members.
4.18.2.6. Draft the minutes of the meeting and after approval from the Chairperson, circulate within the stipulated time. A copy of the core minutes (without PI identifiers will be marked to the Dean and C.O.O. AIMSRS, Chittoor.
4.18.2.7. Maintain IEC- AIMSRS, Chittoor, documentation on correspondence and communication and archive them.
4.18.2.8. Member-Secretary shall have the responsibility of communicating with the IEC- AIMSRS, Chittoor members, applicants/ investigators/ AIMSRS Office.
4.18.2.9. Member-Secretary shall notify the Principal Investigator regarding IEC - AIMSRS 's decisions related to the submitted research proposal.



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4.18.2.10. The Member-Secretary shall arrange for the training of the personnel and the IEC- AIMSRS members, in the areas of research ethics and SOPs. While preparing the calendar list of meeting dates the Member-Secretary shall also prepare a tentative list of training sessions for the year.
4.18.2.11. Organize the preparations, review, revision and distribution of SOPs and guidelines.
4.18.2.12. Provide necessary administrative support for IEC - AIMSRS Chittoor related activities to the Chairperson and the various subcommittees of IEC- AIMSRS.
4.18.2.13. Provide updates on relevant and contemporary issues to ethics in health research as well as relevant government circulars/guidelines to the committee members.
4.18.2.14. Receive ethics committee review processing fees and a copy of the official receipt from the College accounts office.
4.18.2.15. Delegate various responsibilities to appropriate and authorized individuals and ensure adherence to SOPs.
4.18.2.16. Prepare for audits and inspections.
4.18.2.17. Prepare and make available for scrutiny by auditors/inspectors' annual reports/annual financial statements of the IEC - AIMSRS Chittoor.
4.18.2.18. Prepare and make available for scrutiny to IEC - AIMSRS Chittoor members a collective assessment of IEC - AIMSRS Chittoor activities including review time and completion, conduct of meetings post-approval activities and training activities.
4.18.2.19. Be the custodian for all documents, materials and equipment of IEC - AIMSRS , Chittoor.
4.18.2.20. The Joint-Secretary (if any) will have all the powers and responsibilities of the Member-Secretary, in the absence of the Member-Secretary.
4.18.2.21. Nominate an internal member as acting Secretary in case Member- Secretary and Joint-Secretary are both absent on the meeting day. The acting Secretary will have all the powers of the Member-Secretary for that meeting only



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4.18.3. IEC - AIMS Chittoor members:
4.18.3.1. IEC - AIMS Chittoor members must receive, read and familiarize themselves with a copy of the SOPs relating to the functioning of the IEC - AIMS Chittoor.
4.18.3.2. They must sign the appointment letter (terms of reference) stating that they will abide by the rules/regulations of the university and IEC – AIMS Chittoor.
4.18.3.3. IEC - AIMS Chittoor members shall attend IEC - AIMS Chittoor meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at. In case of inability, the member must submit a leave note in writing and the absence of the member should be recorded in the minutes.
4.18.3.4. Actively engage in review, discussion and considerations of the ethical issues in research proposals submitted for evaluation.
4.18.3.5. Members must sign the confidentiality agreement and abide by it throughout the term of membership and beyond if need be.
4.18.3.6. Review the progress reports and monitor ongoing studies as appropriate, and recommended by the Chairperson.
4.18.3.7. Participate in any role in the IEC - AIMS Chittoor subcommittees, whenever Requested
4.18.3.8. Approve the agenda and minutes of the IEC - AIMS Chittoor meetings.
4.18.3.9. Declare any conflict of interest in writing to the Chairperson, if any, at each meeting. In case they fail to do so in writing, they can announce the same at the start of the meeting when the Chairperson asks for it.
4.18.3.10. Participate in continuing education and training activities in biomedical ethics and biomedical research and submit the certificates for records to the Secretariat and attend and submit the certificate of initial training within 60 days from the date of joining IEC - AIMS Chittoor or before the next scheduled full meeting of IEC- AIMS Chittoor
4.18.3.11. Provide updated CV when requested by the IEC - AIMS Chittoor secretariat
4.18.3.12. Carry out work delegated by Chairperson, Member-Secretary and assist in the smooth functioning of the IEC - AIMS Chittoor



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4.18.4. Secretariat:

4.18.4.1. The Secretariat will be composed of administrative support staff. (One 2nd division assistants). Hereinafter, for the purpose of all the SOP chapters in this version of the manual, the term Secretariat will mean the support staff – not including the office assistant – assigned to the IEC - AIMS R Chittoor

4.18.4.2. The Secretariat will maintain the database of protocols in one or more Excel spreadsheets and update these regularly.

4.18.4.3. The Secretariat will ensure that the desktop computers are stored securely and the password to access these are updated frequently.

4.18.4.4. The Secretariat will maintain the logs of all the activities of the IEC - AIMS R Chittoor including the shredding, despatch and end-user assistance.

4.18.4.5. Secretariat will support the Member Secretary in all their functions

4.18.4.6. All the staff of the Secretariat will sign the confidentiality agreement which should be filed with IEC - AIMS R Chittoor. (Ann01/SOP02/v1)

4.19. Scope/ Types of projects reviewed by IEC - AIMS R Chittoor:

4.19.1. The type of studies reviewed by IEC - AIMS R Chittoor will be determined by the AIMS R, Chittoor, through a notification IEC - AIMS R Chittoor review scientific and ethical aspects of all types of research studies involving human participants:

4.19.1.2. PhD Studies

4.19.1.3. Research studies which are funded by institutional funding bodies or any other funding Agency

4.19.1.4. Research studies submitted by faculty members, research scholars, doctoral, post-graduate and under-graduate students

4.19.1.4. Academic research study including academic clinical trial initiated by academicians.

4.19.1.5. The research activities of researchers within AIMS R campus or from outside the institution, registered for PhD work under The Apollo University (TAU) or outside where the guide/doctoral committee member belongs to AIMS R/ TAU, and research activity is carried out in AIMS R-Chittoor campus with prior approval from head of institution of both researcher and guide/ DAC/RAC committee.

4.19.1.6. Research review Fee: There is no sitting fee charged for the researcher/ institute. However, for researchers from outside AIMS R/TAU will be levied Rs 15000/ which has to be deposited to AIMS R-Chittoor account along with submission of research documents.



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4.20 Honorarium to the members:
4.20.1. Internal members shall do all the duties as provided in the SOP with or without any remuneration, as decided by the AIMSRS, Chittoor, from time to time.
4.20.2. External members of the IEC - AIMSRS Chittoor will be provided local transport and an honorarium as per existing rules/norms, from time to time.
4.20.3. The Secretariat will inform the Finance Officer the list of the external members who attended the meeting after every meeting.
4.20.4. Finance Officer shall transfer the amount to account number of the external members or provide a cheque after the meeting is co included if applicable.
4.20.5. The Secretariat will take signatures of external members on the receipt vouchers and file them.
4.21. Preparing an annual activity report of the IEC - AIMSRS Chittoor
4.21.1. It is the responsibility of the Member-Secretary to make the annual report.
4.21.2. Once approved by the Chairperson, it shall be circulated among members.
4.21.3. A copy will be sent to the Dean, COO, AIMSRS, and one copy maintained in the Secretariat.
4.21.4. This report should contain all the details of the activities of the IEC - AIMSRS Chittoor in the calendar year and should at least include information on
4.21.4.1. Membership details including changes in the membership
4.21.4.2. Number and dates of the IEC - AIMSRS Chittoor meetings
4.21.4.3. Number of subcommittees
4.21.4.4. Numbers and types of proposals reviewed in a year, status of each study proposal whether completed /ongoing / terminated.
4.21.4.5. Number of approvals for full/expedited/exempted reviews with decisions
4.21.4.6. Brief details about workshops, training programmes and other activities undertaken by IEC - AIMSRS Chittoor and those attended by members



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4.22. Grievances against the IEC - AIMSRS Chittoor.
4.22.1. If any of the stakeholders including researchers, sponsors, participants or any other individual has a complaint or grievance against the IEC - AIMSRS Chittoor, functioning, they may approach the Grievance Redressal Committee, with a complaint submitted in writing.
4.22.2. The IEC - AIMSRS Chittoor, Grievance Redressal Committee constituted by the Dean, AIMSRS, Chittoor, will look into the grievances and submit a report to the Dean, AIMSRS, Chittoor recommending appropriate action
4.23. Appellate authority of the Dean, AIMSRS, Chittoor:
4.23.1. Anyone having a grievance against the recommendation of the Grievance Redressal Committee he/she can appeal against such a decision in writing to the Dean, AIMSRS, Chittoor, with a copy marked to the IEC - AIMSRS Chittoor, Secretariat.
4.23.2. The Dean, AIMSRS Chittoor can consider the matter by hearing both sides and taking a decision, keeping in mind the laws, regulations and guidelines in current use in the country. The Dean, AIMSRS Chittoor decision will be final.
4.24. IEC - AIMSRS Chittoor Secretarial staff:
4.24.1. There will be a secretary /assistant(s) who will help the IEC - AIMSRS Chittoor, Chairperson and Member-Secretary in executing functions of the IEC - AIMSRS Chittoor.
4.24.2. The administrative staff will be appointed as per the AIMSRS, Chittoor rules/regulations prevailing from time to time.
4.24.4. The need for appointment of administrative staff, job profile and qualifications, office timing, salary structure and number of leaves may be decided by the Chief Operating Officer/Dean AIMSRS, Chittoor from time to time.
4.24.5. Administrative staff will report to the Chairperson and/or Member-Secretary.



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4.25. Duties of the Secretariat: On behalf of and under the instructions of the Member- Secretary and the IEC - AIMSRS Chittoor:
4.25.1. Carry out the correspondence with IEC - AIMSRS Chittoor Chairperson, members, external experts and AIMSRS Chittoor officials.
4.25.2 Communicate with the newly appointed members, the terms of reference, agreement letters, etc
4.25.3. Communicate with the Principal Investigators.
4.25.4. Assist the Member-Secretary in preparing the agenda, agenda notes and minutes of the IEC - AIMSRS Chittoor meetings.
4.25.5. Maintain filing, classifying & archiving of all protocol documents.
4.25.6. Maintain the filing and archiving of the SOPs (all versions), member files.
4.25.7. Maintain copies of relevant guidelines, regulations and government circulars related to ethical review of biomedical research.
4.25.8. Maintain, update, backup and protect the electronic database of IEC - AIMSRS Chittoor Records.
4.25.9. Respond to general enquiries, attend to telephone calls and emails.
4.25.10. Send email reminders to members who default on review deadline.
4.25.11. Send email reminders to the Principal Investigators for resubmission / continuing reports/ completion reports.
4.25.12. Coordinate functions of subcommittees, audits and site monitoring.
4.25.13. Assist in the audit/ inspection of the ethics committee.
4.25.14. Coordinate training program of the EC members.
4.25.15. Perform any other duties assigned by Chairperson, related to working of IEC -AIMSRS.
4.25.16. Dispatching study documents to IEC - AIMSRS Chittoor members and ICs.
4.25.16. Dispatch of post and couriers of the IEC - AIMSRS Chittoor.
4.25.17. Dispatch & receive documents from and dispatching letters to concerned parties.



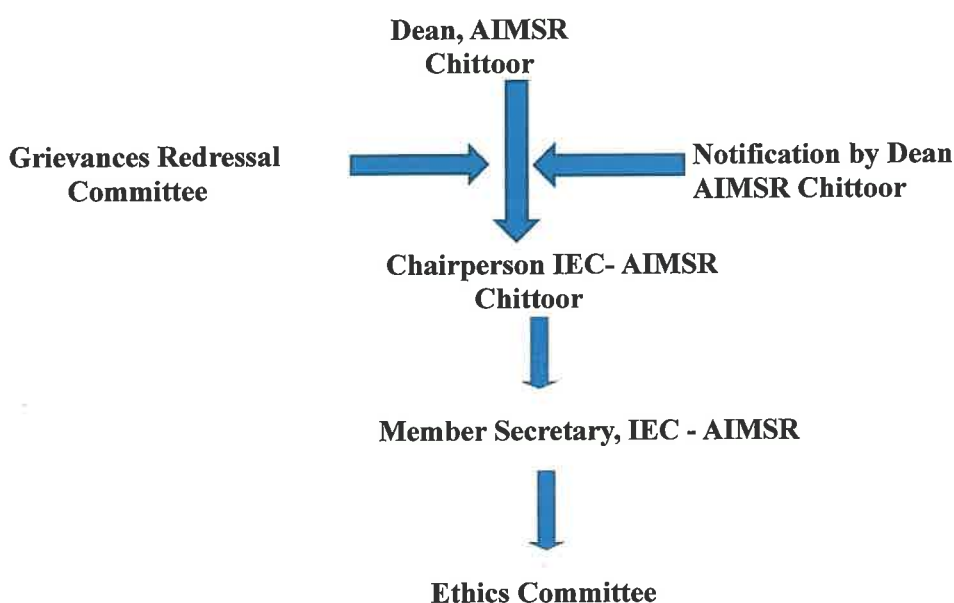
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5. References:
5.1. Conflict of interest policy for IEC - AIMSChittoor (SOP02/v1)
5.2. Agenda preparation/Meeting procedures/Recording of Minutes (SOP05/v1)
National Ethical Guidelines for Biomedical and Health Research Involving Human Participants: 2017; Section 4: Ethical Review Procedure: Pg No 25-48.
6. Annexures:
Ann01/SOP01/v1.4: Organizational Chart of the IEC - AIMSChittoor.
Ann02/SOP01/v1.4: Terms of reference for the members
Ann03/SOP02/v1.4: Membership Agreement Form for IEC - AIMSChittoor members

6.1. Ann01/SOP01/v1.4

**Organizational Chart of the
IEC - AIMSChittoor and its functioning**



Lay Person
Legal Expert
Theologian
Social Scientists
Clinician
Basic Scientists
Nurse-Clinician
Pharmacologist



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6.2. Ann02/SOP01/v1.4: Terms of reference for the members

Members	<ul style="list-style-type: none">• Appointment to IEC - AIMS R Chittoor with designation• Term of office• Train in SOPs, Research Ethics, GCP• Submit updated Curriculum Vitae and training certificates.• Conduct scientific and ethical review of protocols, adhere to timelines Adhere to SOPs.• Follow the current applicable guidelines Attend meetings regularly.• Contribute actively to the deliberations and discussions in the meetings Participate in the subcommittees, whenever required.• Participate in the post-approval activities, whenever required Abide by the confidentiality agreement.• Abide by the conflict-of-interest declaration agreement Maintain good conduct and integrity as a member.• Name and affiliation will be publicly linked to IEC - AIMS R Chittoor (as on the IEC - AIMS R letter head, website etc).• Resignation/Failing to attend three consecutive meeting without prior intimation eligible for disqualified from IEC - AIMS R Chittoor• If you have any grievance about the functioning of the IEC - AIMS R Chittoor, you may submit the same in writing.
External Member	<ul style="list-style-type: none">• Remuneration (sitting fee) on a per diem basis, as decided by the college. Encourage and guide IEC - AIMS R Chittoor to take an independent and free decision.• Provide details of bank account and PAN for the purpose of remuneration and reimbursement of travel expenses.
Internal Member	<ul style="list-style-type: none">• Assist the IEC - AIMS R Chittoor in its smooth functioning.
Chairperson	<ul style="list-style-type: none">• Head the IEC - AIMS R Chittoor.• Lead the discussions and deliberation during the meetings Preside over the administrative matters of the IEC- AIMS R Chittoor Ensure adherence to current SOPs and guidelines.• Ensure a timely ethical review process.



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Member Secretary	<ul style="list-style-type: none">• Receive, categorize, allocate the protocols Sign the approval of the protocols.• Prepare and maintain the agenda and minutes of the meeting Plan and conduct training activities.• Schedule and conduct post-approval activities.• Prepare and respond to audits and inspections of the IEC- AIMS R Chittoor.• Maintain the archival of files.• Coordinate with members the activities of the IEC- AIMS R Chittoor.
Legal person	<ul style="list-style-type: none">• Review of protocol with emphasis on legal issues, compensation, agreements, MoUs, Insurance, Indemnity, permissions and other documents in the protocol.
Social scientist/ theologist	<ul style="list-style-type: none">• Review of protocol with emphasis on ethical, social, cultural & religious issues.
Lay person	<ul style="list-style-type: none">• Review of protocol with emphasis on informed consent document- language, content and translation with local communities in mind.
Clinician	<ul style="list-style-type: none">• Review of protocol with emphasis on ethical and clinical aspects, complications, management of complications issues in the protocol.
Basic Scientist	<ul style="list-style-type: none">• Ethical review of protocol (emphasis on basic scientific issues, genomic/laboratory research, etc).



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Ann03/SOP01/v1.4

Membership Agreement Form for IEC - AIMSRS Chittoor members

I, Dr/Mr./Ms. _____

(*Member's name, his/her position in IEC - AIMSRS Chittoor, affiliation*) herein referred to as the "undersigned" have been appointed as a member of IEC - AIMSRS Chittoor and have been asked to carry out ethical review of research studies involving human participants in order to ensure that such studies are conducted in a humane and ethical manner, adhering to the highest standards of care as per the international national and local regulations/guidelines and institutional policies. I understand that my appointment as member of IEC - AIMSRS Chittoor is based on individual merits and not as an advocate or representative of a territory, or community, nor as a delegate of any organization. I am aware that IEC - AIMSRS 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 participants and that as a member of IEC - AIMSRS Chittoor, I will meet the standards of ethical behavior to carry out its mandate.

I agree to sign the confidentiality agreement and abide by it. I agree to the Conflict-of-interest declaration policy of IEC - AIMSRS Chittoor and abide by it. I have been given the current SOP manual (Soft copy). I agree to take part in the training programs organized by the IEC- AIMSRS Chittoor for the members. I agree to take part in the review process and adhere to the timelines.

Signature of the member with date

Chairperson's Signature with date

[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat, IEC - AIMSRS, Chittoor. A copy will be given to the Undersigned.]

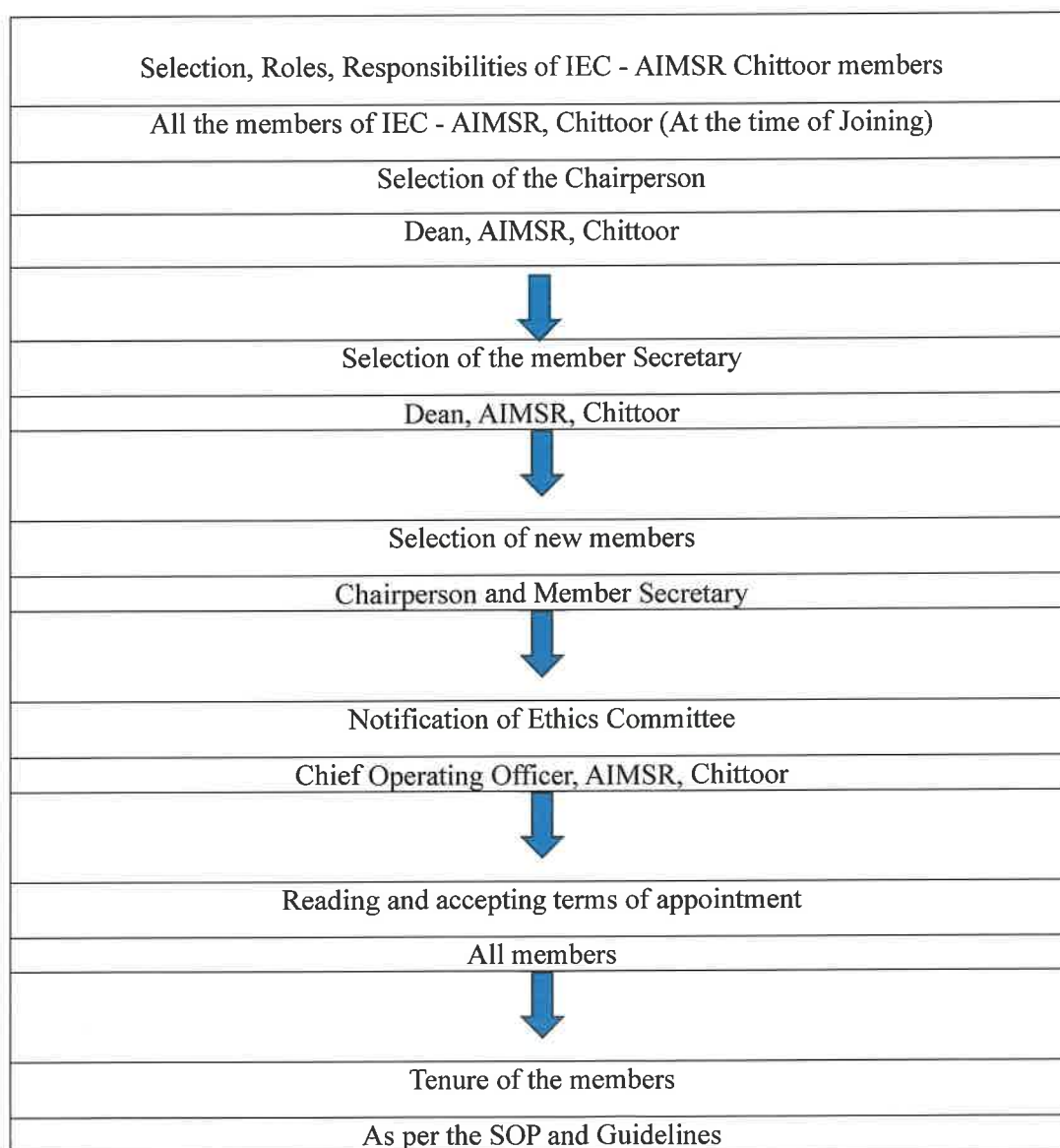
I acknowledge that I have received a copy of the signed Membership Agreement Signature with



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7. Flow-Chart





8. Glossary:

GCP: Good Clinical Practice

ICH-GCP: International Committee for Harmonization - Good Clinical

Practice ICMR: Indian Council of Medical Research

SOP: Standard Operating, Procedure, ToR: Terms of Reference


**Title: Constitution of IEC, Apollo Institute of Medical Sciences &
Research (AIMSR Chittoor), Roles and Responsibilities of members**

SOP Code: SOP No 01 /v1.4

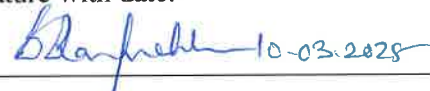
Prepared by:

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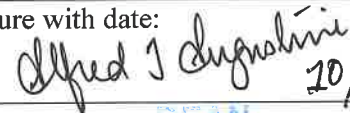
Verified by:

Dr Jayapriya T Member, SOP Sub-committee	Signature with date:  11/03/2025
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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:  20/03/2025
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DEAN

Apollo Institute of Medical Sciences and Research
Murukambattu, Chittoor-517127 A.P.