

SOP No 05/ Version 01.1

IEC - AIMSR Chittoor Minutes of the meeting

Effective date: 10-03-2025

Title: IEC - AIMSR Chittoor Minutes of the meeting

SOP Code: SOP 05/v01.1 Effective Date: 10-03-2025

Prepared by:

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Notified by:

Dr Alfred Joseph Augustine Dean AIMSR Chittoor	Signature with date:  Apollo A
	Murukambattu, Chittool-31/12/ A.i.

**Details of Current SOP No** 

SOP subcommittee	Version	Effective	Describe the main change(s)
convenor name		date	
Dr Sachidananda Adiga	Version 01.1	10-03-2025	Made the changes as per Biomedical
MN			Research guidelines needs in IEC -
			AIMSR Chittoor Minutes of the
			meeting (excluding sponsored clinical
			trial)



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process and pro	purpose of this Standard Operating Procedure (SOP) is to describe the ovide detailed instructions for the preparation, review, approval and the agenda and minutes of the meetings IEC - AIMSR Chittoor (regular ary).
2. Scope:	
	ies to processes concerning the preparation and distribution of the agenda ninutes of the meetings, IEC - AIMSR Chittoor (online, offline or hybrid).
2.2. This SOP addit IEC at AIMSR	ionally covers the protocols for conducting extraordinary meetings of the Chittoor
3. Responsibilitie	s:
3.1. The IEC - AIN	ASR Chittoor Chairperson will
3.1.1. Approve th	e date, time and venue of the ordinary meeting, IEC - AIMSR Chittoor
3.1.2. Review and	d approve the agenda of the meetings, IEC - AIMSR Chittoor
3.1.3. Call the me	eeting to order
3.1.4. Ensure that	quorum is maintained
3.1.5. Ensure that	conflict of interest is appropriately managed
3.1.6. Permit mer	nbers to attend the meeting online, if they have so requested
3.1.7. Encourage	all members to actively participate in the deliberations and discussions
3.1.8. Ensure that	no external influence is affecting the deliberations
3.1.9. Ensure that	the members vote after the deliberations
3.1.10. Exercise c	asting vote as and when necessary.
3.1.11. Provide pe	mission for including any other matter not listed in the agenda
3.1.12. Review and	d approve the minutes of the meetings IEC - AIMSR Chittoor



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	late. 10-03-2023
3.2. <b>Th</b>	e IEC - AIMSR Chittoor Member-Secretary will
3.2.1.	Plan the dates, time and oversee the arrangements for the venue for the ordinary meetings of IEC - AIMSR Chittoor
3.2.2.	Prepare the agenda
3.2.3.	Record the minutes of the meeting
3.2.4.	Get the minutes of the meeting approved by the Chairperson and IEC - AIMSR Chittoor members
3.3. <b>Th</b>	e IEC - AIMSR Chittoor secretarial staff will
3.3.1.	Assist the Member-Secretary in preparing the agenda for the meeting
3.3.2.	Table all other full review protocols for the forthcoming meeting, if the complete protocol package is received at least 14 calendar days before the date of the meeting
3.3.3.	Circulate the agenda of the meeting after Chairperson's approval
3.3.4.	Prepare the online link in case any member has requested an online attendance
3.3.5.	Prepare the attendance forms, voting forms and decision forms for each full review protocol
3.3.6.	Make all the arrangements for the meeting at the venue including protocol-related files refreshments, computers, vehicle for external members and sitting fees for the external members.
3.3.7.	Assist the Member-Secretary in recording the minutes of the meeting
3.3.8.	Circulate the minutes of the meeting after Chairperson's approval
3.4. Th	e IEC - AIMSR Chittoor members will:
3.4.1.	Read the agenda of the meeting.
3.4.2.	Read and approve the minutes of the meetings.
4. De	finitions:
4.1. Ag me tak	enda of the IEC – AIMSR, Chittoor meetings: Refers to the systematic list of eting activities, prepared ahead of the meeting, in the order in which they are to be en up for discussion in the meeting IEC - AIMSR Chittoor, starting from greeting I calling the meeting to order to adjournment of the meeting.



a m	nutes of the meetings IEC - AIMSR Chittoor: Refers to the detailed notes taken by nember of IEC - AIMSR Chittoor during a meeting as the meeting proceeds, in ler to capture accurate and clear record of the proceedings of the meetings in order ensure transparent functioning of IEC - AIMSR Chittoor
5. De	tailed instructions for IEC - AIMSR Chittoor meeting:
5.1. <b>C</b> a	lendar of meetings:
5.1.1.	IEC - AIMSR Chittoor will prepare a calendar of meetings for the year in advance.
5.1.2.	The calendar of meetings will be prepared by the Member-Secretary and approved by the Chairperson and circulated among all the members of the IEC - AIMSR Chittoor
5.1.3.	The calendar of meetings will be displayed on the AIMSR website and the notice board of IEC - AIMSR Chittoor office for easy access by the researchers planning their protocol submissions.
5.1.4.	Meetings will be scheduled at least once a month on a day preferably on a fixed weekday as per the general convenience of the members
5.1.5.	If any rescheduling of the meeting day and time is required for any reason, the Member-Secretary will take approval from the Chairperson and inform the IEC -AIMSR Chittoor members by email/telephone at least 4 calendar days in advance, unless justified by unavoidable/extraordinary situations.
5.1.6.	The IEC - AIMSR Chittoor will hold regular meetings at least once in three months. If IEC - AIMSR Chittoor requires to conduct additional meetings in view of more protocols, the Chairperson and Member-Secretary will decide the date and conduct the meeting in the same manner as the regular meeting.
5.2. Pr	eparation of the IEC - AIMSR Chittoor meeting agenda:
5.2.1.	The member secretary will prepare the agenda of IEC - AIMSR, Chittoor meeting
5.2.2.	The agenda is prepared at least 7 calendar days before the scheduled meeting
5.2.3.	The agenda is sent to the Chairperson at least 7 calendar days before the meeting.
5.2.4.	The Chairperson will review the agenda and approve it
5.2.5.	Once approved, the agenda is circulated to all the IEC - AIMSR Chittoor members at least 5 calendar days before the scheduled meeting.



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5.2.6.	The secretarial staff will keep all the concerned documents ready to be kept for the meeting.
5.2.7.	The secretarial staff will organize and sequence the protocols in the agenda according to their submission.
5.2.8.	For all protocols requiring a full review, if the complete protocol package is received and verified at least 14 calendar days before the next meeting, the Secretariat will include the protocol details in the agenda. If not, the Secretariat will hold the protocol for discussion at the subsequent meeting."
5.2.9.	Resubmitted protocols received at least 7 calendar days before the IEC - AIMSR Chittoor meeting are included in the agenda
5.2.10.	Amended protocols received at least 7 calendar days before the IEC - AIMSR, meeting is included in the agenda
5.2.11.	All other listings on the agenda (ratifications, reports, are included for the meeting when received at least 7 calendar days before the meeting when the agenda is prepared and circulated
5.2.12.	Any addition to the agenda within 7 calendar days of the meeting, after circulating the agenda to the IEC - AIMSR Chittoor members will be done after approval by the IEC - AIMSR Chittoor Chairperson and many include reports concerning the safety of the participants or other extraordinary issues.
5.2.13.	IEC - AIMSR Chittoor members will approve the agenda, at the start of the meeting
5.3. Fo	rmat for preparation of the agenda
5.3.1.	The agenda will be prepared by the secretariat in the format provided in Ann01/SOP05/v1.1.
5.3.2.	The agenda will be confirmed by the Member-Secretary and approved by the Chairperson before sending out to the members.
5.4. At	the meeting:
5.4.1	The secretarial staff will make sure that the meeting venue, equipment and facilities are available for the meeting day. In case there is a change in the venue, the secretariat will inform the members as soon as possible.



5.4.2.	If the meeting is being conducted online, or if some of the members are attending the meeting online, the secretarial staff share a secure meeting link with the members.
5.4.3.	For online or hybrid meetings, the secretariat will create a Google form to mark the attendance which will be shared with the online members at the beginning of the meeting.
5.5. Qu	orum for the meeting:
5.5.1,	The main business of the meeting will be conducted only after the quorum is ensured by the Chairperson, as per the ICMR National Ethics Guidelines, 2017 (for all other types of trials)
5.5.2.	The following seven categories of members will constitute the quorum (above and beyond the five mentioned in both, the rules and the guidelines):
5.5.2.1.	One basic medical scientist (preferably a pharmacologist)
5.5.2.2.	One social worker (or a social scientist, theologist, ethicist, member or representative of a non-governmental voluntary agency or a similar person)
5.5.2.3.	A clinician
5.5.2.4.	A lay person
5.5.2.5.	A legal expert
5.5.2.6.	Chairperson or acting Chairperson in the absence of Chairperson
5.5.2.7.	Member Secretary/Joint Secretary or any other designated internal member in the absence of Member Secretary/Joint Secretary
5.5.3.	The quorum will be maintained in line with the current regulatory guidelines and national ethical guidelines, in force, from time to time.
5.5.4.	If the quorum is not present, the meeting will be adjourned by 15 minutes, until the quorum requirement is met.
5.5.5.	If the quorum requirement is still not met, the meeting will be rescheduled within the next 7 calendar days, or the next suitable date as decided by the Chairperson



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	5.5.6.	During the deliberation of a protocol, if a member declares conflict of interest and recuses himself, the quorum must be reassessed and must be ensured.
	5.6. <b>M</b> o	embers' attendance:
	5.6.1.	The secretarial staff will take signatures from all the members present in the meeting on the attendance sheet. The online members will fill the attendance on the precirculated Google form
	5.6.2.	The guest/observer will also sign the attendance sheet for the IEC - AIMSR Chittoor meeting and the same will be included in the minutes of the meetings.
	5.7. <b>C</b> o	onflict of interest:
	5.7.1.	The Chairperson will ensure that members who have any conflict of interest for one or more protocols will declare the same before beginning the meeting
	5.7.2.	For each full review protocol, all members will declare whether or not they have any conflict of interest on the CoI form.
	5.7.3.	The CoI forms are filed in the respective protocol file
	5.7.4.	If a member declares CoI for a protocol, the member will step out of the meeting room when the concerned protocol comes up for deliberation.
	5.8. Pr	oceedings of the meeting:
	5.8.1.	The Chairperson will initiate the meeting
	5.8.2.	Member-Secretary will proceed in the order as per the agenda of the meeting.
	5.8.3.	Each point on the agenda will be discussed in order by the members after the primary reviewer provides a plain-language summary of each protocol.
	5.8.4.	The Chairperson will encourage all members to contribute to the scientific discussion and ethical deliberations.
	5.8.5.	The secretariat will provide concerned files, as and when necessary.
	5.8.6.	If the investigator/independent consultant/community representative/guest observer has been invited to the IEC - AIMSR Chittoor meeting for giving clarifications, they are allowed to offer their opinions within a set time-frame but will not be engaged in the deliberation or decision-making process.)



5.9. <b>De</b>	cision making:
5.9.1.	The Chairperson will initiate the voting process
5.9.2.	The final decisions on initial full review protocols, re-submission for full review and amendments for full review will be done on Google forms, as per the specific SOPs.
5.9.3.	The final decision will be based on majority voting which is defined as >50% of the members present.
5.9.4.	In the event of a tie on the decision, the Chairperson will cast an extra vote (known as casting vote)
5.9.5.	The following persons will not take part in the voting:
5.9.5.1.	An independent consultant
5.9.5.2.	A guest/observer/special invitee (including principal investigator)
5.9.5.3.	Members who have declared a conflict of interest will neither vote, nor will be present during the scientific discussion and ethical deliberation.
5.9.6.	The final decision of ratification of already approved protocols will be done after brief discussion and deliberation
5.10.	Recording the minutes of the meeting:
5.10.1.	The secretariat will assist the Member-Secretary in recording the minutes of each matter discussed during the meeting in a concise, clear and appropriate language.
5.10.2.	The recording of the minutes will be done on the template for minutes of the meeting real time and displayed on screen for the benefit of members, IEC - AIMSR Chittoor.
5.10.3.	After each protocol or issue is discussed and voted, the resolutions and minutes recorded will be read out to ensure correctness of content
5.11. <b>Draft</b>	ing of the minutes:
5.11. The f	ollowing points will be included in the beginning of the minutes of the meeting
	ation, date, time and duration of the meeting
	eting number
	nes of the IEC - AIMSR Chittoor members and guests attending the meeting, whether
	person or online, and the members absent.



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5.11.4. Name of the individual serving as Chairperson/Co-Chairperson/ Acting Chairperson for the
meeting
5.11.5. Determination of a duly constituted quorum by the Chairperson
5.11.6. Declaration of conflict of interest by any member(s)
5.12. The following points will be included in all full review protocols (initial, resubmissions and
amendments
5.12.1. Protocol number
5.12.2. Protocol title with version and date
5.12.3. Investigator's name and department
5.12.4. Sponsor's name
5.12.5. Names of the primary reviewers and secondary reviewers who presented their findings
5.12.6. Discussion by the IEC - AIMSR Chittoor members, point by point (preferably under the headings of Scientific issues, Ethical issues, PIS/ICF,
5.12.7. Final decision of the IEC - AIMSR Chittoor (in the form of resolutions)
5.12.8. Number of dissent votes
5.12.9. Additional decision on follow up action and dates, if required
5.12.10. Communication to the PI
5.13. Requirements for studies listed for ratification (initial expedited and exemption from review, amendment-expedited, study completion, continuing review, extension of studies and shredding of protocols)
5.13.1. Protocol number
5.13.2. Protocol title with version and date
5.13.3. Investigator's name and department
5.13.4. Final decision taken during expedited review
5.13.5. IEC - AIMSR Chittoor decision on ratification
5.13.6. Number of dissent votes
5.13.7. Additional decision on follow up action and dates, if required



5.14. Requirements for decision on reports (site monitoring report, audit report/ protocol deviations/violations, suspension or termination report)
5.14.1. Protocol number
5.14.2. Protocol title with version and date
5.14.3. Investigator's name and department
5.14.4. Summary of the report
5.14.5. Decision and recommendation at the initial level
5.14.6. Final IEC - AIMSR Chittoor decision on the report
5.14.7. All other matter including training program, communications, assessment.
5.15. Approval of the minutes of the meeting
5.15.1. The Member-Secretary will check the correctness and completeness of the minutes drafted
5.15.2. The Member-Secretary will send the draft to the Chairperson within 5 calendar days of the meeting by email
5.15.3. The Chairperson will review and approve the minutes of the meeting within 6 calendar days of the meeting
5.15.4. The secretariat will circulate the approved minutes of meeting to all the members of IEC - AIMSR Chittoor within 7 calendar days of the meeting by email
5.15.5. The IEC - AIMSR Chittoor members who were present at the meeting will also approve the minutes by email within a period of 2 calendar days or else their approval is presumed.
5.15.6. The final approval of the minutes is done in the subsequent IEC - AIMSR Chittoor meeting when the IEC - AIMSR Chittoor Member-Secretary will read out the minutes of the previous meeting and get it approved by all members.
5.15.7. The secretariat will send out the matter for communication with the various PIs as soon as possible, after the minutes are approved.



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#### 5.16. Core minutes of the meeting:

- 5.16.1. The Member-Secretary will make a redacted copy of the minutes of the meeting (known as core minutes) consisting of the salient features of the protocol and final decision without the details of the researcher's name, affiliation, discussion in the meeting, and names of the primary reviewers.
- 5.16.2. The Member-Secretary will forward a copy of the core minutes of the meeting to the Dean and Chief Operating Officer AIMSR Chittoor for information within 10 calendar days.
- 5.16.3. The secretarial staff will maintain a copy of the core minutes of the meeting in the IEC AIMSR Chittoor office.
- 5.16.4. In case the audit, regulatory bodies or other bodies require copies of the IEC AIMSR Chittoor meeting, the Member-Secretary will forward the core minutes of the meeting in order to maintain confidentiality. If requested the full copy of the minutes may be forwarded

#### 5.17. Filing of documents:

- 5.17.1. The secretariat of IEC AIMSR Chittoor will securely store documents and place them in their designated files. Numbering can be 5.17.1 and so on
- 5.17.2. Approved agenda in the Agenda File
- 5.17.3. Approved signed minutes in the Minutes File
- 5.17.4. Approved, signed core minutes in the Core Minutes File
- 5.17.5. Attendance sheet and leave of absence letters in the Attendance File
- 5.17.6. Conflict of interest for each protocol in the respective Protocol File
- 5.17.7. Extract of the minutes of the meeting in the respective Protocol File
- 5.17.8. Copy of the signed and received approval letter in the respective Protocol File
- 5.17.9. Assessment forms, decision forms, and all protocol-related communications in the respective Protocol files



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#### 6. References:

ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

#### 7. Annexures:

Ann 01/SOP5/v1.1: Format for the agenda of the IEC - AIMSR Chittoor meeting Ann 02/SOP05/v1.1: Members' attendance in IEC - AIMSR Chittoor meeting

Ann 03 /SOP05/v1.1: Template for Minutes of Meeting



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Ann 01/SOP05/v1.1: Format for the agenda of the IEC - AIMSR Chittoor meeting

Meeting details: Meeting number, date, time, venue, Name of the Chairperson

Welcome by Member-Secretary

Member's leave of absence information/letter, if any

Ensuring quorum by the Chairperson

Declaring conflicts of interest, if any, for any protocol tabled in the agenda by the IEC - AIMSR

Chittoor members

Approval of the tabled agenda

Reading and approving the minutes of the previous meeting

Action taken report (if any)

Initial Full Review protocols (Protocol details to include protocol number, investigator's name, type of study, sponsor details)

Re-submission for full review

Amended protocols for full review

Continuing review of protocols

Number of protocols granted extension of EC approvals

Study completion reports

Protocol deviations/ violation reports

List of protocols which were issued ethical clearance after expedited review for ratification

Initial expedited review protocols

Re-submissions for expedited reviews

Amended protocols

Waiver of consent

Protocols exempted from review

Termination/suspension of studies

Site monitoring reports

List of protocol documents for shredding

Any issues raised by the members regarding IEC - AIMSR Chittoor functioning like IEC - AIMSR

Chittoor policies/training of members/ revising SOPs /etc

Training session of the Members: topic and speaker

Communications with regulatory authorities/ management or others

Any other matter

Signature: Chairperson/Member Secretary



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#### Ann02/SOP05/v1.1: Members' attendance in IEC- AIMSR Chittoor meeting

Sl No.	Name	Role	Internal/External	Signature
1				
2				
3				
4				

Signature of the Chairperson/Member Secretary with date

Ann03/SOP05/v1.1: Template for the Minutes of the meeting	
IEC - AIMSR Chittoor Minutes of the Meeti	ing

Themeeting of the IEC - AIMSR Chittoor_was held on						
atAM in the The following members were present:		resent:	chaired the meeting.			
Sl No	Name	Role	External /Internal	Male/I		

Sl No	Name	Role	External /Internal   Male/Fema	

The following members were granted of absence

SI No	Name	Role	External /Internal	Male/Female

The following items as per the agenda were discussed:

- 1. Member-Secretary welcomed the members and handed over the proceedings to Chairperson.
- 2. Members were informed about the leave of absence of members.
- 3. The Chairperson confirmed that the quorum was present and declared the meeting open.
- 4. The Chairperson clarified whether any member had conflict of interest.
- 5. The Chairperson called upon the Member-Secretary to start the business on the agenda.
- 6. The agenda for the meeting which was circulated prior to the meeting was approved
- 7. The minutes of the meeting IEC -AIMSR Chittoor which were circulated earlier were displayed and approved



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8. Action taken report:

No	Meeting	Agenda	Resolution	Action taken	Approved/Ratified

### 9. Initial full review protocols (n=)

S No	Protocol No	Details
1.		Title: Name of the PI & Department: Type of study: Sponsor: Names of the primary reviewers: Discussion: Conflict of interest: Resolution: Type of modifications/ Type of re-submission/ Choice of re-submission reviewers/ Continuing review (or audit)/ Site monitoring visit Chairperson's casting vote/ Dissent vote: Matter for communication to the PI:

### 10. Re-submission protocols for full review: (n=)

S No	Protocol No	Details
s.1.s		Title: Name of the PI and Department: Type of study: Sponsor: Name of the Primary Reviewer: Conflict of interest: Discussion: Resolution: Type of modifications/ Type of re-submission/ Choice of resubmission reviewers/ Continuing review (or audit)/ Site monitoring visit Dissent vote: Matter for communication to the PI:



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#### 11. Protocol amendments (for full review) (n=)

Protocol No	Details
	Title: Name of the PI: Type of study: Sponsor: Name of the Reviewer: Nature of amendment: Discussion: Resolution: Dissent vote: Matter for communication to the PI:

### 12. Periodic review and continuing review:

 Protocol No	Details
	Title: Name of the PI:
	Type of study: Sponsor: Name of the Pavianer.
Name of the Reviewer: Decision of the reviewer:	
	Discussion: Resolution:
	Dissent vote:  Matter for communication to the PI:

### 13. Number of protocols granted extension of EC approvals: For ratification (n=)

S. No.	Protocol No	Title of the protocol	PΙ	Type of study	Date and validity of issue	Ratification

#### 14. Completion reports (for ratification):

S. No	Protocol No	Title of the protocol	ΡΙ	Type of study	Date and validity of issue	Ratification



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	15.	Protocol D	eviations / Violations –	(n=	)					
		Protocol No	Details							
	Title: Name of the PI: Type of study: Name of the Reviewer: Nature of protocol deviation: Recommendation of the reviewer/Member-Secretary: Discussion: Resolution: Dissent vote: Matter for communication to the PI:									
	A. Expedited Review approved for ratification (n=):									
S	. No.	Protocol No	Title of the protocol	PI	Type of study	Date of issue & validity	Ratification			

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Date of issue & validity	Ratification

### B. Initial full review protocol resubmitted for expedited review and approved:

S. No.	Protocol No.	Title of the protocol	PI	Initial reviewers	Type of study	Date of issue & validity	Ratification

### C. Amended protocols approved (for ratification): (n=)

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Nature of amendment	Date of issue	Ratification

#### 16. Waiver of Consent forms approved (n=):

S. No.	Protocol No.	Title of the protocol	PI	Type of study	Ratification

#### 17. Exemption from ethical review (n=):

S. No.	Protocol No.	Title of the protocol	ΡI	Department	Date of Approval	Ratification



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18.	Termination/sus	pension (n=):
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S. No.	Protocol No.	Title of the protocol	PI	Type of study	Reason for termination

#### 19. Auditing reports – For review (n=):

Protocol N	o Details
	Title: Name of the PI: Name of the Auditor: Brief summary of the Audit: Decision of the Auditors: Discussion: Resolution: Dissent vote: Matter for communication to the PI:

### 20. Auditing reports – For review (n=):

Pro	otocol No	Details
		Title: Name of the PI: Name of the Auditor: Brief summary of the Audit: Decision of the Auditors: Discussion: Resolution: Dissent vote: Matter for communication to the PI:

### 21. List of protocol documents for shredding (n=):

No.	Protocol No.	Title of the protocol	Completion report ratified meeting	Completion date	Ratification

#### 22. Training Session:

S. No	Training session topic	Resource person	Remarks



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### 23. Correspondence from regulatory authorities, university and other communications: (n=)

S. No	Communication details	Remarks

#### 24. Any other matter with the permission of the chair:

Prepared by: Signature of the secretariat staff with date and place

Checked by: Signature of the Member Secretary with date and place

Approved by: Signature of the Chairperson with date and place

Prepared by:		
Dr Sachidananda Adiga MN	Signature with date:	
Member, SOP Sub-committee	moddiga 10/03/2025	
Verified by:	- 1 V	
Dr Jayapriya T	Signature with date:	
Member, SOP Sub-committee	Signature with date:	
Approved by:		
Dr Ravi Prabhu G	Signature with date:	
Chairperson, IEC, AIMSR Chittoor	6 danhell 10.03. 2021	
Notified by:		
Dr Alfred Joseph Augustine	Signature with date:	
Dean AIMSR Chittoor	alfred 1 Chywm 10/03/2025	
	Apollo institute of Medical Sciences than asset of Murukambattu Chittoor-517127 A.P	