



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

SOP No 07 / Version 1.2  
IEC - AIMSRS Chittoor, Review process of  
Research Protocol  
Effective date:10-03-2025

**Title: IEC - AIMSRS Chittoor, Review Process of Research Protocol**

**SOP Code: SOP 07 /v1.2**

**Effective Date: 10-03-2025**

**Prepared by:**

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

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

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

Dr Alfred Joseph Augustine Dean, AIMSRS Chittoor	Signature with date: <i>Alfred J Augustine 10/03/2025</i>
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**Details of superseded SOP No**

Subcommittee convenor name	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)
Not Applicable	Not Applicable	Not Applicable	Not Applicable

**Details of Current SOP No**

SOP subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr Sachidananda Adiga MN	Version 01	10-03-2025	Made changes as per the Biomedical Research guidelines needs in Review process of Research Protocols.(Excluding Clinical Trial)



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

SOP No 07 / Version 1.2  
IEC - AIMS R Chittoor, Review process of  
Research Protocol  
Effective date:10-03-2025

<b>SI No</b>	<b>Content</b>	<b>Page</b>
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Definitions	4
5	Detailed review process of research protocol	5
6	References	16
7	Annexures	17



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

SOP No 07 / Version 1.2

IEC - AIMSRS Chittoor, Review process of  
Research Protocol

Effective date:10-03-2025

<b>1. Purpose:</b> The purpose of this Standard Operating Procedure (SOP) is to describe the process of submission, categorization and review of research protocol by the IEC-AIMSRS Chittoor and provide detailed instructions for the preparation, review, approval and distribution of the proposals for review among the IEC-AIMSRS members.
<b>2. Scope:</b>
2.1. This SOP applies submission of research protocol by researchers, categorization, distributions to IEC members, process of review, submission of reviewed proposals back to IEC and its discussion during minutes of IEC -AIMSRS Chittoor.
<b>3. Responsibilities:</b>
<b>3.1. The IEC - AIMSRS Chittoor Member Secretary will:</b>
3.1.1. Screen for completeness of submission of research protocol in all aspects
3.1.2. Communicate with researcher if it is incomplete/ any further documents needed
3.1.3. Categorizes the research protocol into Exempted from review/ expedited reviewer full review or any other (amended/ expedited after initial full review etc based on request from PI and based on nature of study/ risk benefit ratio associated with the research for research participants
3.1.4. Decides to which IEC members should review the research protocol
3.1.5. Compiles the feedback received from the initial reviewer
3.1.6. Communicates the same to PI
3.1.7. Receives the satisfactory reply from PI
3.1.8. Submits the reply from the PI during the initial full review
3.1.9. Issues the Clearance certificates if the PI submits all the queries raised by the initial reviewer in a satisfactory manner.
3.1.10. Reminds PI regarding time-to-time submission of study report/ closure report/ any protocol deviation/ violation
<b>3.2. The IEC-AIMSRS Chittoor members:</b>
3.2.1. Receives the allotted research protocol from the IEC-AIMSRS Secretariat
3.2.2. Review the research protocol as per the pre-determined review form in-terms of scientific, ethical/ social/ cultural/ legal aspects
3.2.3. Cooperates with IEC -AIMSRS secretariat functioning of review in terms of timely submission of review report



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

SOP No 07 / Version 1.2

IEC - AIMSRS Chittoor, Review process of  
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<b>3.3.IEC- AIMSRS Chittoor Secretariat:</b>
3.3.1. Initially receives the required documents in hardcopy and softcopy format
3.3.2. Assigns protocol number to protocol serially as and when it is received
3.3.3. Sends the entire research protocol documents (softcopy) to the IEC member chosen by the member secretary.
3.3.4. Sends timely reminder to the IEC members regarding the deadline for submission of reviewed protocol
3.3.5. Coordinate with IEC members in case of any additional documents is required from the researchers
3.3.6. Compiles the review report sent from the IEC members and send it to member secretary for further action.
<b>4. Definitions:</b>
<b>4.1.Less than minimal risk:</b> Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
<b>4.2.Minimal Risk:</b> Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples.
<b>4.3.Minor increase over minimal risk:</b> Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. Routine research on children and adolescents, research on persons incapable of giving consent, delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials, use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing, trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.



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

SOP No 07 / Version 1.2

IEC - AIMSRS Chittoor, Review process of  
Research Protocol

Effective date:10-03-2025

4.4. <b>More than minimal risk:</b> Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures.
4.5. <b>Protocol Deviation:</b> This refers to any change in the initial submitted/approved protocol with respect to study design/ methodology/sample size/ change in the guide/ study duration or anything like title etc.
4.6. <b>The informed consent document (ICD):</b> Include patient /participant information sheet (PIS) and informed consent form (ICF)
<b>5. Detailed Review Process of Research Protocol:</b>
<b>Submission of Research Proposal:</b>
5.1. Researchers will submit research proposals as soft and hard copies to the Secretariat for review in the prescribed format and required documents as per IEC-AIMSRS Chittoor
5.2. The Checklist of documents to be submitted to IEC-AIMSRS Chittoor should include:
5.2.1. Cover letter to the Member Secretary
5.2.2. Application form for initial review as specified by the IEC-AIMSRS Chittoor
5.2.3. The correct version of the informed consent document (ICD) in English and the local language(s). Translation and back translation certificates
5.2.4. Case record form/questionnaire
5.2.5. Recruitment procedures: advertisement, notices (if applicable)
5.2.6. Patient instruction card, diary, etc. (if applicable)
5.2.7. Investigator's brochure (as applicable for academic trial)
5.2.8. Details of funding agency/sponsor and fund allocation (if applicable)
5.2.9. Brief curriculum vitae of all the study researchers



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

SOP No 07 / Version 1.2

IEC - AIMSRS Chittoor, Review process of  
Research Protocol

Effective date:10-03-2025

5.2.10. A statement on COI, if any
5.2.11. GCP training certificate (preferably within 5 years) of investigators trials)
5.2.12. Any other research ethics/other training evidence, if applicable as per EC SOP
5.2.13. List of ongoing research studies undertaken by the principal investigator (if applicable)
5.2.14. Undertaking with signatures of investigators
5.2.15. Regulatory permissions (as applicable)
5.2.16. Relevant administrative approvals (such as HMSC approval for international studies)
5.2.17. Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
5.2.18. MoU in case of studies involving collaboration with other institutions (if applicable)
5.2.19. Clearance letter from Institutional Scientific Committee- AIMSRS Chittoor/ respective institutes of TAU whenever applicable.
5.2.20. Any additional document(s), as required by IEC-AIMSRS Chittoor (such as other EC clearances for multicentric studies)
5.2.21. A detailed protocol
<b>6. Contents of Protocol: The protocol should include the following:</b>
6.1. The front page carrying the title of the protocol with signatures of the investigators;
6.2. Brief summary/ lay summary;
6.3. Background with rationale of why a human study is needed to answer the research question;





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

SOP No 07 / Version 1.2

IEC - AIMSRS Chittoor, Review process of  
Research Protocol

Effective date:10-03-2025

6.4. Justification of inclusion/exclusion of vulnerable populations
6.5. Clear research objectives and end points (if applicable)
6.6. Eligibility Criteria and participant recruitment procedures
6.7. Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;
6.8. Duration of the study;
6.9. Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, justification for the same.
6.10. Procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. AV recording if applicable; informed consent for stored samples;
6.11. Plan for statistical analysis of the study;
6.12. Plans for publication of results – Positive or negative – while maintaining confidentiality of personal information/ identity.
6.13. Plan to maintain the privacy and confidentiality of the study participants;
6.14. For research involving more than minimal risk, an account of management of risk or injury;
6.15. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period (if applicable)
6.16. Provision of ancillary care for unrelated illness during the duration of research;
6.17. An account of storage and maintenance of all data collected during the trial; and



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

SOP No 07 / Version 1.2  
IEC - AIMSRS Chittoor, Review process of  
Research Protocol  
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6.18.	Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.
6.19.	Ethical considerations and safeguards for protection of participants.
<b>7. Types of review process:</b>	
<b>7.1.Exemption from review:</b>	
<b>Proposals with less than minimal risk where there are no linked identifiers, for example;</b>	
<ul style="list-style-type: none"><li>• Research conducted on data available in the public domain for systematic reviews or meta-analysis;</li><li>• Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;</li><li>• Quality control and quality assurance audits in the institution;</li><li>• Comparison of instructional techniques, curricula, or classroom management methods;</li><li>• Consumer acceptance studies related to taste and food quality; and</li><li>• Public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).</li></ul>	
<b>7.2.Expedited review:</b>	
<b>Proposals that pose no more than minimal risk may undergo expedited review, for example;</b>	
<ul style="list-style-type: none"><li>• Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;</li><li>• Research involving clinical documentation materials that are non-identifiable (data, documents, records);</li><li>• Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);</li><li>• Revised proposals previously approved through expedited review, full review or continuing review of approved proposals;</li></ul>	





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- Minor deviations from originally approved research causing no risk or minimal risk;
- Progress/annual reports where there is no additional risk, for example activity limited to data analysis.
- For multicentre research where a designated main IEC- AIMSRS Chittoor among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
- Research during emergencies and disasters

**7.3. Full committee review:**

- All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are;
- Research involving vulnerable populations, even if the risk is minimal;
- Research with minor increase over minimal risk
- Studies involving deception of participants
- Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;
- Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;
- Major deviations and violations in the protocol;
- Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit-risk assessment;
- Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;
- Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.



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

SOP No 07 / Version 1.2

IEC - AIMSRS Chittoor, Review process of

Research Protocol

Effective date:10-03-2025

7.4. Other research review process guidelines:
7.4.1. The Member Secretary shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review, and full committee review.
7.4.2. A researcher cannot decide that her/his protocol falls in the exempted, expedited or full review category. All research proposals must be submitted to the IEC- AIMSRS Chittoor. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the IEC- AIMSRS Chittoor with appropriate justification for the protocol to be considered as exempt, expedited or if waiver of consent is requested.
7.4.3. Expedited review can be conducted by Member Secretary and one or two designated members or as specified in SOPs.
7.4.4. Approval granted through expedited review must be ratified at the next full committee meeting if applicable.
7.4.5. IEC- AIMSRS Chittoor members will be given enough time (at least 1 week) to review the protocol and related documents, except in the case of expedited review
7.4.6. The IEC- AIMSRS Chittoor may have a system of appointing primary and secondary reviewers. The Member Secretary will identify the primary and secondary reviewers for reviewing the scientific content and the ethical aspects in the protocols well as the informed consent document, depending upon their individual expertise.
7.4.7. The Member Secretary may identify subject experts to review the protocol as per need. These experts may be invited to the EC meeting or join via video/tele conference but will not participate in final decision making.
7.4.8. The IEC- AIMSRS Chittoor will meet regularly, adopt best practices, try to reduce turnaround time or have procedures in place for early decision making so that research is not delayed.
<b>8. Aspects to be reviewed during review process</b>
8.1. Social Values: The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society. All stakeholders, including sponsors, researchers and IEC- AIMSRS Chittoor will ensure that the planned research has social value.



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

SOP No 07 / Version 1.2

IEC - AIMS R Chittoor, Review process of  
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**8.2. Scientific design and conduct of the study:** Valid scientific methods are essential to make the research ethically viable as poor science can expose research participants or communities to risks without any possibility of benefit. Even though IEC- AIMS R Chittoor may obtain documentation from a prior scientific review, they should also determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy. The IEC- AIMS R Chittoor can raise scientific concerns (even if the study has prior approval of a scientific committee) if it may affect quality of research and or safety of research participants

**8.3. Benefit-risk assessment:**

- The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research.
- Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level. It is necessary to first look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole.
- The IEC-AIMS R will review plans for risk management, including withdrawal criteria with rescue medication or procedures.
- The IEC- AIMS R Chittoor will give advice regarding minimization of risk/ discomfort wherever applicable.

**8.4. Selection of the study population and recruitment of research participants:**

- Recruitment should be voluntary and non-coercive.
- Participants should be fairly selected as per inclusion and exclusion criteria. However, selection of participants should be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit.
- Participants should be able to opt out at any time without their routine care being affected.
- No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits.
- Vulnerable groups may be recruited after proper justification is provided.



SOP No 07 / Version 1.2

IEC - AIMSRS Chittoor, Review process of  
Research Protocol

Effective date:10-03-2025

**8.5.Payment for participation:**

- Plans for payment for participation, reimbursement of incurred costs, such as travel or lost wages, incidental expenses and other inconveniences should be reviewed.
- There is a need to determine that payments are not so large as to encourage prospective participants to participate in the research without due consideration of the risks or against their better judgement.
- No undue inducement must be offered.

**8.6.Protection of research participants' privacy and confidentiality:**

- IEC-AIMSRS Chittoor will examine the processes that are put in place to safeguard participants' privacy and confidentiality.
- Research records to be filed separately than routine clinical records such as in a hospital setting.

**8.7.Community considerations:**

- The IEC- AIMSRS will ensure that due respect is given to the community, their interests are protected and the research addresses the community's needs.
- The proposed research should not lead to any stigma or discrimination. Harm, if any, should be minimized.
- Plans for communication of results to the community at the end of the study should be carefully reviewed.
- It is important to examine how the benefits of the research will be disseminated to the community

**8.8.Qualifications of researchers and adequacy assessment of study sites:**

The IEC- AIMSRS Chittoor should look at the suitability of qualifications and experience of the PI to conduct the proposed research along with adequacy of site facilities for participants



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

SOP No 07 / Version 1.2

IEC - AIMSRS Chittoor, Review process of  
Research Protocol

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<b>8.9. Disclosure or declaration of potential COI:</b>	
<ul style="list-style-type: none"> <li>The IEC will review any declaration of COI by a researcher and suggest ways to manage these.</li> <li>The IEC will manage COI within the IEC- AIMSRS Chittoor and members with COI should leave the room at the time of decision making in a particular study.</li> </ul>	
8.10.	<p>Plans for medical management and compensation for study related injury:</p> <ul style="list-style-type: none"> <li>The proposed plan for tackling any medical injuries or emergencies should be reviewed.</li> <li>Source and means for compensation for study related injury should be ascertained.</li> </ul>
8.11.	<p><b>Review of the informed consent process:</b></p> <p>The informed consent process must be reviewed keeping in mind the following:</p> <ul style="list-style-type: none"> <li>The process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations;</li> <li>The adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their LARs;</li> <li>contents of the patient/participation information sheet including the local language translations.</li> <li>Back translations of the informed consent document in English, wherever required; • provision for audio-visual recording of consent process, if applicable, as per relevant regulations; and</li> <li>If consent waiver or verbal/oral consent request has been asked for, this should be reviewed by assessing whether the protocol meets the criteria</li> </ul>
<b>9. Types of decisions on the research protocol:</b>	
IEC-AIMSRS can give one of the following decisions:	
9.1. Approved – with or without suggestions or comments	
9.2. Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review.	





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SOP No 07 / Version 1.2

IEC - AIMSRS Chittoor, Review process of

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9.3. Revision with major modifications for resubmission – this will be placed before the full committee for reconsideration for approval in the subsequent meeting once the PI submits the modified version with changes made in the protocol as suggested by IEC-AIMSRS Chittoor.
9.4. Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of permission.
<b>10. Validity period of decision on research protocol:</b>
10.1. Approval may be granted for the entire duration of the proposed research or can be subject to annual review depending on the type of study. The IEC- AIMSRS Chittoor should review the annual report (counted from the day of approval or date of actual start of the study) for continuation as per SOP
10.2. Depending on the risk involved, the progress of the protocol may be monitored annually or at shorter intervals (quarterly, half yearly) as per IEC- AIMSRS Chittoor decision. Approval may be continued if progress is satisfactory.
10.3. IEC-AIMSRS may decide to reverse its positive decision on a study if it receives information that may adversely affect the benefit-risk assessment.
10.4. The Member Secretary (assisted by the Secretariat) will record the discussions and prepare the minutes which should be circulated to all the members for comments before final approval by the Chairperson/Vice-Chairperson/designated member of the committee.
10.5. The decision of the IEC- AIMSRS Chittoor will be communicated to the researcher along with suggestions,
10.6. The researcher will have an opportunity to reply/clarify to IEC- AIMSRS Chittoor comments or to discuss or present her/his stand.
10.7. The researcher can also approach the head of the institute who serves as an appellate for EC matters IEC- AIMSRS Chittoor





SOP No 07 / Version 1.2

IEC - AIMSRS Chittoor, Review process of  
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10.8.	The head of the institute as appellate has the power to dissolve the IEC-AIMSRS or reappoint an IEC- AIMSRS Chittoor.
<b>11. Continuing review</b>	
11.1.	Ongoing research will be reviewed at regular intervals, at least once a year, (or more often, if deemed necessary depending on the level of risk) or as may be specified in the SOP of the IEC- AIMSRS Chittoor and at the time of according approval, and as indicated in the communication letter.
11.2.	The IEC- AIMSRS Chittoor will continually evaluate progress of ongoing proposals along with protocol deviations/violations and non-compliance, any new information pertaining to the research and assess final reports of all research activities.
11.3.	For protocol deviations/violations, the IEC- AIMSRS Chittoor will examine the corrective actions. If the violations are serious the IEC-AIMSRS may halt the study. The IEC- AIMSRS Chittoor may report to the institutional head/government authorities where there is continuing non-compliance to ethical standards.



**Institutional Ethics Committee  
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<b>12. Site monitoring</b>	
12.1.	IEC- AIMSRS Chittoor will follow mechanisms described in a SOP to monitor the approved study site until completion of the research to check for compliance or improve the function.
12.2.	Monitoring can be routine or “for cause” and must be decided at a full committee meeting. For research that involves higher risk or vulnerable participants or if there is any other reason for concern, the IEC- AIMSRS Chittoor at the time of initial review or continuing review can suggest that routine monitoring may be conducted at more frequent intervals.
12.3.	<b>Reasons for conducting Site Monitoring</b>
	The following situations may justify “reasons for” monitoring:
	High number of protocol violations/ deviations;
	Large number of proposals carried out at the study site or by the same researcher;
	High recruitment rates
	Complaints received from participants
	Any adverse media report;
	Adverse information received from any other source;
	Misconduct by the researcher
	Non-compliance with EC directions;

**Reference:**

1. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants: 2017; Section 4: Ethical Review Procedure: Pg No 25-48.



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### Annexures:

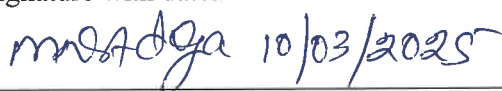
1. Application form for Initial Review Process	6. Protocol Deviation/ Violation Reporting Form
2. Application Form for Expedited Review	7. Application Form for Human Genetics Testing Research
3. Application Form for Exemption Review Form	8. Application Form for Socio-Behavioral and Public Health Research
4. Application Form for Exemption Review Form	9. Study completion/Final report format
5. Application/Notification for Amendments	10. Format for Curriculum Vitae for Investigators

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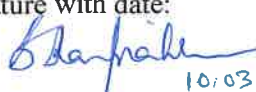
**Prepared by:**

Dr Sachidananda Adiga MN Member, SOP Sub-committee	Signature with date:  10/03/2025
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Dr Vijetha P Member, SOP Sub-committee	Signature with date:  10/03/2025
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Dr Ravi Prabhu G Chairperson, IEC, AIMS Research Chittoor	Signature with date:  10.03.2025
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**Notified by:**

Dr Alfred Joseph Augustine Dean, AIMS Research Chittoor	Signature with date:  10/03/2025
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