Institutional Ethics Committee
Apollo Institute of Medical Sciences Research Chittoor

Title: Protocols involving vulnerable populations: Review and Management.
SOP Code: SOP 04/v1.1
Effective Date: 10-03-2025

Title: Protocols involving vulnerable populations: Review and Management
SOP Code: SOP 04/v01.1
Effective Date: 10-03-2025

Prepared by:

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Notified by:

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Details of Current SOP No

SOP subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr Sachidananda Adiga MN	Version 01.1	10-03-2025	Made the changes as per Biomedical Research guidelines needs in vulnerable population research (Excluding sponsored clinical trial).

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2.Scope: This SOP covers the procedures applied to all research dealing with vulnerable participants submitted to the IEC - AIMSR Chittoor.
3.Definition:
3.1. Vulnerable subjects:
3.1.1. Vulnerable subjects are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens, social justice, lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so[1].
3.1.2. In addition - for the purpose of this SOP - vulnerable populations are defined as individuals whose willingness to volunteer in a research may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation; of socio - economic disadvantage such that their exploitation potential is greater than that of other people; of a retaliatory response from senior members of a hierarchy in case of refusal to participate. in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent[2].
3.1.3. For the purpose of this SOP, following are examples of vulnerable population including but not limited to:
3.1.3.1. Economically and socially disadvantaged or marginalized sections of society (Unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – LGBTIQA+, etc.)
3.1.3.2.Legally defined minors (up to 18 years);
3.1.3.3.Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare, or those who are victims of gender-based violence);
3.1.3.4. Tribals and other marginalized communities;
3.1.3.5.Refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations, people kept in detention, people experiencing communicable diseases of epidemic proportions.
3.1.3.6. People afflicted with mental illness, or cognitively impaired individuals, differently abled – mentally and physically challenged;

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3.1.3.7. Terminally ill or are in search of new interventions having exhausted all available therapies;
3.1.3.8. People with stigmatizing or rare diseases; or
3.1.3.9. Persons with diminished autonomy due to dependency or being within a hierarchical system (students - especially medical, pharmacy, dental, physiotherapy and nursing students especially subordinate in workplace such as hospital and laboratory personnel, defense services personnel, healthcare workers, institutionalized individuals, under trials and prisoners). Elderly people in the old age homes, children in orphanage will also come under this category.
4. **Mandate:** Gazette notification (GoI) G.S.R. 611 (E) dated 31st July 2015 has mandated audio-visual recording of informed consent process in case of vulnerable participants in research and only audio IC process in the case of research involving people living with HIV and patients of leprosy[3].
5.Responsibility:
5.1.IEC - AIMSR, Chittoor Chairperson will:
5.1.1. Ensure that all protocols involving vulnerable populations are reviewed and monitored appropriately
5.1.2. Ensure that all members present on the day of the meeting shall actively discuss the vulnerable research protocols.
5.2.IEC - AIMSR, Chittoor Member secretary will
5.2.1. Determine/identify protocols involving vulnerable population
5.2.3. Categorize protocols involving vulnerable populations as expedited review only if the risk is 'minimal' or 'less than minimal'
5.2.4. Oversee and confirm that each protocol involving vulnerable populations has the necessary checklist attached, duly filled and signed by the PI.
5.2.5. Ensure that the monitoring mechanism for protocols involving vulnerable population is planned at the time of approval and in place during the conduct of the research
5.3. IEC - AIMSR, Chittoor member will:
5.3.1. Review the checklist for risk: benefit assessment
5.3.2. Ensure adequate protection of vulnerable participants are strategized by the PI in the protocol

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5.3.3. Deliberate on the issues of vulnerable participants, the risk: benefit assessment and the protection provided - during the IEC - AIMSR, meeting
5.4. IEC - AIMSR, Chittoor secretariat will:
5.4.1. Check whether every protocol involving vulnerable population includes the checklist for risk: benefit assessment and safeguards for the protection of vulnerable participants - duly filled and signed by the principal investigator
5.4.2. Ensure that the checklist for risk: benefit assessment and safeguards for the protection of vulnerable participants is sent to the reviewers during the review of protocols
5.4.3. Maintain a calendar for site monitoring (or audit) for protocols involving vulnerable populations, and remind the Member-Secretary of dates for due monitoring.
6.Detailed instruction
6.1.Completion of protocol submission:
6.1.1. The Member-Secretary should identify the protocols involving vulnerable populations (as listed in this SOP annexure-8-14).
6.1.2. The Secretarial staff must provide the appropriate checklists to the principal investigators, depending on the type of vulnerable populations involved in the research.
6.1.3. The Member-Secretary and/Secretarial staff must make sure that all checklists pertaining to the specific vulnerable population involved in the research are duly filled and signed by the principal investigator.
6.2.Categorization of the protocols: The member-Secretary should categorize the protocols as follows:
6.2.1. Protocols involving vulnerable populations, should be categorized as full review as per **SOP7A/v4.**
6.2.2. Protocols involving vulnerable populations, may be categorized as expedited review only if the risk is 'minimal' or 'less than minimal' and reviewed as per SOP7B/v4.
6.3. Selection of reviewers and review support:
6.3.1. The Member-Secretary should appoint two or more members of the IEC - AIMSR.
6.3.2 The Member-Secretary must provide appropriate reference material and /or help the reviewer locate the material relevant to review protocols involving vulnerable populations when specifically requested by a reviewer.

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6.3.3.A representative from the vulnerable population/caretaker may be consulted and invited to take part in the discussion during the full review meeting
6.4 Review of the protocols:
6.4.1. Members reviewing such protocols should be well versed with the potential harm or risk of such persons participating in the study.
6.4.2. Additionally, the reviewers should assess the following in the protocol and address all points in the checklists for different vulnerable populations (Annexures01-07)
6.5. Discussion in the full review meetings:
6.5.1. While discussing full review protocols involving vulnerable populations, IEC - AIMSR, Chittoor members should deliberate on the following issues, but not limited to these:
6.5.1.1. Is there adequate justification for involvement of vulnerable populations in the research?
6.5.1.2. Can the research be performed in any other non-vulnerable participants?
6.5.1.3. Are there additional safeguards for the protection of the vulnerable participants from harm?
6.5.1.4. Are there direct benefits to the population under study? Do the benefits justify the risks?
6.5.1.5. Are the participants selected equitably?
6.5.1.6. Have measures to protect the autonomy of the vulnerable population been described?
6.5.1.7. Has the informed consent been appropriately described?
6.5.1.8. Have issues about audio-visual recording of informed consent been adequately addressed?
6.5.2. The IEC - AIMSR, Chittoor members may consider a representative from the vulnerable population to attend the meeting, deliberate on the issues, but not take part in the decision making and voting.
6.5.3. The minutes will be prepared in detail as per **SOP05/v1**
6.6.Decision making:
6.6.1. Decision making for protocols will be done as per Ann 08/SOP 04/v1.1 for full review protocols and Ann 09/SOP 04/v1.1 for expedited review protocols
6.6.2. Post-approval plan should be incorporated in the final approval and should include the details and frequency of the following, whenever deemed essential:
6.6.2.1. Continuing review plan
6.6.2.2. Site monitoring plan

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6.6.2.3. Audit plan of the protocol documents
6.6.3. IEC - AIMSR approval should state that if in future the vulnerability status of the participants change, for e.g. unconscious patient gaining consciousness or a schizophrenic patient regains insight or for any other reason , the participant will be re-consented, wherever deemed necessary
6.7 Post-approval:
6.6.3. The continuing review, audit and site monitoring plans should be conducted as per the decision at the time of approval of the protocols.
6.7.2. Continuing review should be conducted as per SOP
6.7.3. Audit and Site monitoring should be conducted as per SOP.
References:
7.1. ICMRs National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017
7.2. Indian GCP Guidelines, 2001
8.Annexures
8.1. Ann 01/SOP 04/v1.1: Checklist for research involving children <18 years
8.2. Ann02/SOP 04/v1.1: Checklist for research involving pregnant women & fetuses
8.3. Ann03/SOP 04/v1.1: Checklist for studies involving neonates
8.4. Ann04/SOP 04/v1.1: Checklist for research involving cognitively impaired adults
8.5. Ann05/SOP04/v1.1 - Checklist for research involving students, employees or Residents
8.6 Ann06/SOP04/v1.1 - Checklist for involving marginalized populations. Tribal population
8.7 Ann07/SOP04/v1.1 -Checklist for involving populations for genetic research
8.8. Ann 08/SOP 04/v1.1- Reviewer assessment form for Initial full review protocols
8.9. Ann 09/ SOP 04/v1.1- Reviewer assessment form for expedited review protocols
8.10. Ann 10/SOP 04/v1.1-Guidelines for Informed Consent Process

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Ann 01/SOP 04/v1.1
Checklist: Research Involving Children <18 years

Note to PI: Children (minors) have reduced capacity to understand and give informed consent. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees in reviewing this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

S. No	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	IEC - AIMSR, Chittoor Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: **Academic clinical trial/ Observational study**	
6	Nature of intervention: Specify	
	Checklist item	**PI Response Please include these descriptions in relevant sections of the protocol**
1.	**Does the research pose greater than minimal risk to children? Yes/No**	
	a. If yes: Are there convincing scientific and ethical justifications to carry out the research as designed?	Yes/No Included in protocol: Yes/No Comment:
	b. If yes: Are adequate safeguards in place to minimize these risks?	Yes/No Included in protocol: Yes/No Comment:
	c. Is there an alternate study design that can achieve the same objectives without involving such vulnerable participants?	Yes/No Included in protocol: Yes/No Comment:

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2.	**Does the study involve healthy children? Yes/No**	
	a. If yes, is the inclusion of healthy children justified?	Yes/No Included in protocol: Yes/No Comment:
	b. If yes, have scientifically appropriate preclinical studies, including studies on animals, and clinical studies, including studies on children and/or adults, been conducted and do these provide data for assessing potential risks to children/minors?	Yes/No/Not applicable Included in protocol: Yes/No Comment:
	c. If your response is No to b, in the absence of animal studies or studies on adults, is it justified to conduct this study?	Yes/No/Not applicable Included in protocol: Yes/No Comment:
	d. Will older children be enrolled before younger ones?	Yes/No Comment
3.	**Is consent of both parents necessary? Yes/no**	
	a. Are the conditions acceptable?	Yes/No Included in protocol: Yes/No Comment:
4.	**Is an attempt made to ensure voluntary informed consent of the parent and assent from the child?**	
	a. Will efforts be made to ensure that parents' consent to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?	Yes/No Included in protocol: Yes/No Comment:
	b. Are provisions made to obtain the written assent of children over 12 years, and oral assent of children between 7 and 12 years, and where appropriate, honor their dissent?	Yes/No Included in protocol: Yes/No Comment:
5.	**Are specific safeguards available to protect the children included in research?**	
	a. Are provisions made to protect participants' privacy and the confidentiality of information gathered in the course of the research?	Yes/No Included in protocol: Yes/No Comment:
	b. Are there special problems that call for the presence of an external monitor during consent	Yes/No Included in protocol: Yes/No

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	procedures?	Comment:
	c. Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?	Yes/No Included in protocol: Yes/No Comment:
6.	**Does the research involve possibility of findings which may have implications for other family members? (for eg. genetic risk, HIV infection, Hepatitis C)**	
	a. Are there adequate mechanisms in place to deal with other members of the family, should there be a risk to such bystanders?	Yes/No Included in protocol: Yes/No Comment:
	b. Are parents required to be present during the conduct of the research?	Yes/No Included in protocol: Yes/No Comment:
7.	**Risk and benefit assessment**	.
	a. What are the anticipated risks to the children from research participation?	
	b. Risk assessment	Minimal risk More than minimal risk
	c.What are the anticipated risks to the children from research participation?	
	d.Benefits assessment	Direct benefit Indirect benefit
	e. Risk: benefit ratio:	Favorable Not favorable
8	Signature of the principal investigator with date *(PI to confirm that all the relevant descriptions are included in the protocol)*	
9	**IEC - AIMSR, Chittoor use only**	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.

** Consent of both parents (and assent) may be needed as applicable.

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Checklist: Requirements for Research Involving Pregnant Women & Fetuses

Note to PI: Pregnant women and their unborn or just born fetuses are considered as vulnerable participants in research and therefore subject to increased harm. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations.

Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees in reviewing this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

A	**Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)**	
1	IEC - AIMSR, Chittoor Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: **Academic clinical trial/ Observational study**	
6	Nature of intervention: Specify	
A.	**If the research involves pregnant women and/or their fetuses, please fill this form and submit along with the research protocol:** **Please include these descriptions in relevant sections of the protocol**	
1	For research on pregnant women, have scientifically appropriate pre- clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, been conducted and do these provide data for assessing potential risks to pregnant women and fetuses?	Yes/ No/ Not applicable Comment:

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2	Is the risk to the pregnant woman or the fetus "not greater than minimal", or, any risk to the woman or the fetus, which is greater than minimal, is caused solely by the research intervention/procedure and this holds out the prospect of direct benefit for the woman or the fetus?	Yes/ No/ Not applicable Comment:
3	Is any risk that is likely to occur, the least possible for achieving the objectives of this study?	Yes/ No/ Not applicable Comment:
A.	**Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)**	
1	For research on pregnant women, have scientifically appropriate pre- clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, been conducted and do these provide data for assessing potential risks to pregnant women and fetuses?	Yes/ No/ Not applicable Comment:
2	Is the risk to the pregnant woman or the fetus "not greater than minimal", or, any risk to the woman or the fetus, which is greater than minimal, is caused solely by the research intervention/procedure and this holds out the prospect of direct benefit for the woman or the fetus? In future is there any adverse effect on baby due to this research?	Yes/ No/ Not applicable Comment:
3	Is any risk that is likely to occur, the least possible for achieving the objectives of this study?	Yes/ No/ Not applicable Comment:

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Ann 03/SOP 04/v1.1 Checklist for studies involving neonates Please fill this section of the checklist if the research involves neonates:		
	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	IEC - AIMSR, Chittoor Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: Academic clinical trial/ Observational study	
6	Nature of intervention: Specify	
	Checklist item: If the research involves neonates, please fill this form and submit along with the research protocol: Please include these descriptions in relevant sections of the protocol	
a.	Can this research be performed in any other non-vulnerable participants?	
b.	Is there adequate justification for involvement of neonates in the research?	
c.	Are scientifically appropriate, pre - clinical and clinical studies, conducted and provide data for assessing potential risks to neonates?	

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d.	Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate?	
e.	Will any inducements, monetary or otherwise, be offered to terminate the pregnancy before enrolling the neonate?	
7	Do individuals engaged in the research have a part in any decisions as to the timing, method or procedures used to terminate pregnancy?	Yes/ No/ Not applicable Comment:
8	Do individuals engaged in the research have a part in determining the viability of a fetus?	Yes/ No/ Not applicable Comment:
9	**Signature of the principal investigator with date** *(PI to confirm that all the relevant descriptions are included in the protocol)*	
10.	**For IEC - AIMSR, Chittoor use only** **Note:** If the response to item no. 1 is **YES** and item no. 2-7 is **NO**, the research should not be approved	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

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Checklist: Research Involving Cognitively Impaired Adults

Note to PI: Cognitively impaired adults have reduced capacity to understand and give informed consent. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

	Checklist item for the PI to fill before submission (information provided

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	here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	IEC - AIMSR, Chittoor Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: A**cademic clinical trial/ Observational study**	
6	Nature of intervention: Specify	
	Research Involving Cognitively Impaired Adults All items should be answered and the substantiation for the same should be evident in the protocol (methodology) as well as in the participant information sheet and informed consent form)	
1	Is recruitment of cognitively impaired participants justified considering the rationale and objectives of the study?	Yes/No Comment:
2	Is there an anticipated direct benefit to the participant?	Yes/No Describe the benefit:
	a. If there is anticipated benefit, is the risk justified by the anticipated benefit?	Yes/No Comment:
	b. If there is anticipated benefit, is the relation of the anticipated benefit to the risk at least as favorable to the participants as that presented by available alternative approaches?	Yes/No
	c. If there is no anticipated benefit, are the foreseeable risks to the participants low?	Yes/No
	d. If there is no anticipated benefit, is the negative impact on the participant's well-being minimized and low?	
	e. If there is no anticipated benefit, will the participants be closely monitored?	
3	Will the participants be withdrawn if they appear to be unduly distressed?	Yes/No Comment:

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4	Is the proposed plan for the assessment of the capacity to consent adequate?	Yes/No Comment:
5	Will consent be taken from participants capable of being consulted?	Yes/No Comment:
6	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?	Yes/No Comment:
7	**Signature of the principal investigator with date** *(PI to confirm that all the relevant descriptions are included in the protocol)*	
	For IEC-AIMSR, Chittoor use only	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

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Checklist-Research Involving Students, Employees or Residents

Note to PI: Research participants drawn from institutions with hierarchical cultures, have reduced capacity to understand and give informed consent. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	IEC - AIMSR, Chittoor Protocol No.	
2	Title:	

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3	Name of the PI	
4	Department	
5	Type of study: Academic clinical trial/ Observational study	
6	Nature of intervention: Specify	
	Research Involving dependent participants (employees, students, residents) *All items should be answered and the substantiation for the same should be evident in the protocol (methodology) as well as in the participant information sheet and informed consent form)*	
1	Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not?	Yes/No Comment:
2	Have the risks to participants been minimized and are such strategies described in the protocol?	Yes/No Comment:
3	Have participants been assured that participation is voluntary (no signs of coercion)?	Yes/No Comment:
4	Have participants been assured that privacy and confidentiality will be protected?	Yes/No Comment:
5	Is the research team member taking consent directly related to the welfare of the participants?	Yes/No Comment:
	Signature of the principal investigator with date *(PI to confirm that all the relevant descriptions are included in the protocol)*	
	For IEC - AIMSR, Chittoor use only	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

Annexure 06 /SOP04/ v1.1

Checklist: Research Involving Marginalized Sections of Society

Info to PI: Persons from marginalized sections of society (such as tribal populations, homeless persons, LGBTIQA+ community) have reduced ability to exercise their rights and give voluntary informed consent. Such participants have decreased

autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	IEC - AIMSR, Chittoor Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: Social science study/observational study	
6	Is recruitment of cognitively impaired participants justified considering the rationale and objectives of the study?	Yes/No Comment:
7	Is the risk justified by the anticipated benefit?	Yes/No Comment:
8	Is the relation of the anticipated benefit to the risk at least as favorable to the participants as that presented by available alternative approaches?	Yes/No Comment:
9	Will the participants be withdrawn if they appear to be unduly distressed?	Yes/No Comment:
10	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?	Yes/No Comment:
11	Is the negative impact on the participant's well-being minimized and low?	Yes/No Comment:

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12	Will adequate privacy be provided to the participants so as to not increase the risk of social stigma and discrimination?	Yes/No Comment:
13	Will the results of the study be shared with the participants?	Yes/No Comment:
14	Will anonymity be maintained at the time of presentation/publication	Yes/No Comment:
15	Will audio-visual recording of informed consent process be done?	Yes/No Comment:
	Signature of the principal investigator with date (PI to confirm that all the relevant descriptions are included in the protocol)	
	For IEC-AIMSR, Chittoor use only	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

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Checklist: Considerations for Genetic Research

Note to PI: Genetic research is still poorly understood and there is much to be learned by the scientific community, for a fuller and more comprehensive understanding of the genetic functions of the human body. Potential participants may have difficulty in understanding the research details and thus give informed consent on less-than-optimal understanding. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

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	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	IEC -AIMSR, Chittoor Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: Genomic study or gene therapy	
6	Will the samples be made anonymous to maintain confidentiality?	Yes/No/Comment:
7	Will the results be disclosed to the participant or legally authorized representative?	Yes/No/Comment:
	a. If yes, has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research results?	Yes/No/ Comment:
	b. If yes, will the results be used in management of the current condition of the patient?	Yes/No/Comment:
8	Has the appropriateness of the various strategies for recruiting participants and their family members been considered?	Yes/No/ Comment:
9	Does the proposed study population comprise family members?	Yes/No/ Comment
10	Will family members be implicated in the studies without consent?	Yes/No/Comment
11	Will the samples be destroyed in the future?	Yes/No / Comment

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12	Will the samples be used for future research?	Yes/No/Comment
13	Will the human biological sample or the data associated with it, be shared with other researchers?	Yes/No / Comment
14	Will genetic counseling be offered?	Yes/No/ Comment
	Signature of the principal investigator with date *(PI to confirm that all the relevant descriptions are included in the protocol)*	
	For IEC - AIMSR, Chittoor **use only**	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

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Ann08/SOP 04/v1.1

Ann 08/SOP 04/v1.1: Reviewer assessment form for Initial full review protocols

Request letter for initial full review of protocols- PART A

To

Name of the primary reviewer/Reviewer:

Dear Sir/Madam,

You have been assigned to review (and lead the discussion on) the given **FULL REVIEW** protocol

1	Review the protocol and related documents as per the guidelines and our SOPs	
2	Inform IEC - AIMSR, Chittoor if you have a Conflict of interest for the protocol on or before	
3	Inform IEC - AIMSR, Chittoor if you are unable to review the protocol within the given time on or before	
4	Inform IEC - AIMSR, Chittoor if any of the protocol or related documents are incorrect/ missing on or before	
5	Fill and sign the assessment form and return the same to IEC - AIMSR, Chittoor on or before	
6	If you are the primary reviewer, be prepared with a brief summary of the protocol i simple language for presentation in IEC - AIMSR, Chittoor meeting to be held on:	

Details of the protocols for initial full review:

1	Protocol No.	
2	Title of the study:	
3	Principal investigator:	
4	Co-I (All names)	
5	Department:	
6	Date of receipt of protocol	
7	Date of IEC - AIMSR, Chittoor meeting	

Signature of the Member-Secretary
Date:

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Part B:

Return of protocol and related documents due to inability to review the protocol I hereby declare that I will not be able to review the protocol for the following reasons: (Please tick the applicable reason)

	I have a conflict of interest	
	Unable to review the protocol within the time given	
	I am unable to attend IEC - AIMSR, Chittoor meeting	

Signature of IEC - AIMSR, Chittoor member with date:

Reviewer assessment form for full review protocols- Part C

Protocol Details:

Protocol Number:			
Title:			
Name of the PI:			
Names of the Co-I's:			
Department:			
Type of study:	Ph D Study	Yes / No	
	External Funded Study	Yes / No	
	Faculty Initiated Study	Yes / No	
	PG Dissertation Study	Yes / No	
	UG study	Yes / No	
	Any other study (specify)	Yes/No	
Number of sites:			
Sample size planned at this site:		Total sample size	
SRB approval:			
Names of the primary reviewers:			

Plain language summary (by primary reviewer) for the benefit of non-medical members

Type of study; department; study design: Introduction to the topic: Sample size; inclusion and exclusion criteria: Details of the intervention:

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Any other remarks:

Section A: Scientific issues

S.No	Scientific issues	Yes/ No	Remarks (please make specific observations)
1.	Background and need for the study are sufficient		
2.	Aims and objectives are clear and well defined		
3.	Study design is appropriate		
4.	Sample size is adequate and justified		
5.	Statistical tests are described		
6.	Inclusion criteria are appropriate		
7.	Exclusion criteria are appropriate		
8.	Discontinuation criteria are appropriate		
9.	Research tool is validated		
10.	Qualification and expertise of the research team is adequate		
11.	Infrastructure is adequate		
12.	Plan for medical management for study related injury is adequate		
13.	Methodology for the intervention is adequately described		
14.	Methodology for data collection is provided		
15.	Data collection form is appropriate		
16.	Informed consent (IC) process: Details on the IC process (who will do it, where will it be done, how long will it take, will privacy be provided, etc)		

Section B: Ethical issues including risk: benefit analysis

S.No	Ethical issues	Yes/ No	Remarks
1.	Method of sampling is fair		
2.	Is there inclusion of vulnerable populations? If yes, please answer the following (a to k)		
	a. Is there adequate justification for involvement of vulnerable populations in the research?		
	b. If yes, whether checklist for inclusion of vulnerable population attached		

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	c. If yes, whether there are adequate safeguards for protection of the vulnerable population		
	d. Can the research be performed in any other non- vulnerable participants?		
	e. Are there additional safeguards for the protection of the vulnerable participants from harm?		
	f. Are there direct benefits to the individual or population under study?		
	g. Do the benefits justify the risks?		
	h. Are the participants selected equitably?		
	i. Have measures to protect the autonomy of the vulnerable population been described?		
	j. Has the IC been appropriately described?		
	k. Have issues about audio-visual recording of informed consent been adequately addressed?		
3.	Exclusion criteria is justified		
4.	Discontinuation criteria is justified		
5	Withdrawal criteria is clear		
6	Voluntary, non-coercive participation is ensure		
7.	Standard of care extended to the intervention group		
8.	Standard of care extended to the control group		
9.	Justification for placebo, if applicable		
10.	Inducements, financial benefits and compensation to the participants		
11.	Protection of privacy of participants		
12.	Maintenance of confidentiality of the data/samples/genomic data		
13.	Disposal, storing, sharing, reuse of samples/ data		
14.	Declaration of conflict of interest by one or more members of the research team		
16	Advertisement/flyer/notice for recruitment are appropriately worded to ensure equitable selection of participants and no inducement		

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Risk: benefit analysis

		Probability of harm			
Risk of harm (As per ICMR guidelines		Not likely		Some what likely	Very likely
Magnitude of harm	Negligible				
	Small				
	Significant				
	Serious				

Risk of harm (As per ICMR Guidelines)
(Kindly mention Yes/No: If yes , give details in respective box/boxes)

Type of harm	Less than minimal risk	Minimal risk	Minor increase over minimal risk	Major increase over minimal risk
Physical harm	Yes/No			
Psychological harm	Yes/No			
Iinformation harm	Yes/No			
Social harm	Yes/No			
Financial harm	Yes/No			
Legal harm	Yes/No			
Genetic Information harm	Yes/No			

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Potential benefit:	Direct Indirect	
Risk: benefit analysis	Favorable Not favorable	
Recommendations to the PI to decrease risk & increase benefit		

Section C: Social, cultural, religious and any other issues

S.No	Ethical issues	Yes/ No	Remarks
1.	Is there a social value?		
2.	Should the community be involved from the start?		
3.	Do you see any cultural issues?		
4.	Religious issues, if any		
5.	Any other		

Section D: Legal aspects

S.No	Legal issues	Yes/ No	Remarks
1.	Permission letters for transport of samples (MTA)		
2.	Insurance policies		
3.	Insurance certificate		
4.	Budget		
5.	Any other		

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	include a list of commonly occurring adverse events - if known)		
14.	Details on how will the PI handle research-related injuries		
15.	Details on reimbursement for time spent and trouble taken		
16	Statement on protection of privacy in presentation, publication or taking of photographs		
17	Adequacy of time provided for comprehension; details on assessment of comprehension; liberty to ask questions		
18	Contact details of responsible member of the research team who is trained in biomedical research and good clinical practices		
19.	Details on all research team members' conflict of interest or receipt of funds for carrying out this study		
20.	Contact details of the Member-Secretary, IEC - AIMSR Chittoor who will address queries related to the rights of the participant in case the participant is not satisfied with the answers provided by the PI		
21.	Statement that a copy each (PIS and ICF) will be given to the participant		

Does the informed consent form address or state the following elements:

S.No	Element		
1.	The participant will be provided enough information (including study title & name of the principal investigator)		
2.	ICF written in a language that the local communities are conversant with		
3.	Adequate time to understand the implications of consenting		
4.	Opportunity to ask questions to PI or study		

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	team member (contact details)		
5.	Assessment of the comprehension of the participant		
6	Voluntary nature of informed consent process that is free of coercion and the use of data/samples post withdrawal		
7	Option to refuse without compromising patient rights		
8.	Option to voluntarily withdraw at any stage of the research without compromising patient rights		
9.	Option for the participant to retain one copy of the consent form		
10.	Assurance of maintenance of privacy of the participant and confidentiality of the data and who can have access		
11.	Consent to publish the data anonymously		
12.	Consent to take photographs while protecting privacy and confidentiality		
13.	Provision for signatures of the participant and researcher. Provision for thumb impression in case the participant is illiterate.		
14.	English version of ICF (with version number)		
15.	Local language translation		
16.	Provision for informed assent (along with parental/LAR consent) written in case the participant is a minor between 12 and 18 years and oral assent in case the participant is between 7 and 12 years		
17.	Provision for audio-visual consent process in case of vulnerable populations being recruited		
18.	Provision for audio recording of the informed consent process in case the vulnerable population is HIV or leprosy		
19.	Provision for online/telephonic/oral consent in relevant situations		

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PART-D

Decision Form for Full Review protocols

Date of IEC - AIMSR, Chittoor meeting:						
Protocol number:						
Title:						
Principal Investigator:						
Department:						
Final decision at IEC - AIMSR, Chittoor meeting:						
1. Approved:						
2. Minor modifications (resubmit for expedited review)						
3. Major modifications (resubmit for full review)						
4. Not approved						
If approved: Frequency of periodic review						
1. 3 monthly						
2. 6 monthly						
3. Annual						
4. Any other						
Site monitoring required: Yes/No						
If yes: 3 months / 6 months / Annual						
If re-submission for expedited review:						
1. Review by initial reviewer(s)						
2. Review by Member-Secretary						
If disapproved: State reasons for disapproval:						
Names of members and decision						
S. No.	Members present	Approved	Minor modifications (resubmit for expedited review)	Major modifications (resubmit for full review)	Not approved	Signature and date
1.						
2.						
3.						
Comments:						

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Request letter for review of protocol
PART A

To
Name of the Reviewer:
Dear Sir/Madam,

You have been assigned to assess the given EXPEDITED REVIEW protocol as a reviewer You are requested to:

1	Review the protocol and related documents as per the guidelines and our SOPs.	
2	Inform the IEC - AIMSR, Chittoor if you have a Conflict of interest for the protocol on or before	
3	Inform the IEC - AIMSR, Chittoor if you are unable to review the protocol within the given time on or before	
4	Inform the IEC - AIMSR, Chittoor if any of the protocol or related documents are incorrect/ missing on or before	
5	Fill and sign the assessment form and return the same to IEC - AIMSR, Chittoor on or before	

Details of the protocols for Expedited review:

1	Protocol No.	
2	Title of the study:	
3	Principal investigator:	
4	Co-PI (All names)	
5	Department:	
6	Date of receipt of protocol	
1	Protocol No.	

Signature of the Member-Secretary with date

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Part B

Return of protocol and related documents due to inability to review the protocol

I hereby declare that I will not be able to review the protocol for the following reason:

(Please tick the applicable reason)

1	I have a conflict of interest	
2	I am unable to review the protocol within the time given	

Signature of the IEC - AIMSR, Chittoor member
Date

Signature of Member-Secretary/Chairperson with date

PART-C:

Reviewer's Decision form for expedited review For initial reviews/re-submissions/amendments

Protocol number:		
Title:		
Principal investigator:		
Department:		
Date of review assignment:		
Date of review completion:		
Reviewer decision:	Approved	
	Resubmission	Review by Member-Secretary
		Review by the Reviewer
	For full review	
If approved/resubmission review by Member-Secretary: Frequency of periodic review		
1. 3 monthly		
2. 6 monthly		
3. Annual		

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4. Any other
If decision referred to IEC - AIMSR, Chittoor meeting: State reasons:

PART-D: Decision form for expedited review
(Member-Secretary)

Protocol number:				
Title:				
Principal investigator:				
Department:				
Date of review assignment:				
Reviewer 1 decision:	Approved:	Re-submission: (Review by Member Secretary)	Re-submission: (Review by the reviewer)	For full review
Reviewer 2 decision:	Approved:	Re-submission: (Review by Member Secretary)	Re-submission: (Review by the reviewer)	For full review
Others' (IC/ other reviewer):	Approved:	Re-submission: (Review by Member Secretary)	Re-submission: (Review by the reviewer)	For full review
Final decision:				
1. Approved:				
2. Re-submission:				
3. Decision in the IEC - AIMSR, Chittoor meeting (for full review)				
If approved:				
Frequency of periodic review	3 monthly	6 monthly	Annual	Any other
Site monitoring schedule:				
If decision referred to IEC - AIMSR, Chittoor meeting: State reasons:				

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Ann 10 /SOP 04/v1: Guidance for Informed Consent process

Steps in the Informed Consent Process
1.Identify the prospective participant (maybe in the OPD, ward, Community)
2.Assess their willingness to participate in your study
3.If they seem willing, ask them for 15-20 minutes of their time
4.Take them (prospective participant and their accompanying person and only 1-2 members of the research team) to a room or a non-crowded area.
5.In case of your study participant is an illiterate person, then an independent witness to be present to view the entire informed consent process and sign the document
6.Make them feel comfortable, be respectful and speak in the language they know and make appropriate eye contact, keep open body gesture, do not speak authoritatively
7.Ask them if they would like to read the participant information sheet on their own or would like to have it read out to them
8.Take them step-by-step through the information in the PIS. Repeatedly enquire if they have understood or like more clarity
9.Encourage them to ask question
10.Stress more on the following points: that this is research and not therapy, explain the risk truthfully, describe clearly what you expect from the participant if they enroll.
11.Encourage them to not agree or disagreeing a hurry. Encourage them to take the PIS home and discuss with family, well-wishers or lawyers
12.Ask them to return when they are ready to sign the informed consent document and enroll. Specify a date, time and place.
13.Both the research team members and prospective participant should sign the document at the same time
14.In case your prospective participant is in the age of 13-18 years, then along with parental consent take written assent from the child and document this in the informed consent form
15. In case your prospective participant is in the age of 7-12 years, then along with parental consent take oral assent from the child and document this in the informed consent form
16. In case your prospective participant is a child in the age of 0-7 years, then take the parental consent (any one parent; no other person)

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17.Hand over one copy of the signed informed consent form to the participant and keep one copy in your records.
18.Take re-consent whenever appropriate
19. Store these documents securely for a period of 3 or 5 years as the case maybe

Prepared by:

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

Verified by:

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

Approved by:

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

Notified by:

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