Title: Standard Operating Procedures (SOPs) for research projects involving vulnerable populations.

1. **Purpose of these SOPs-** To define the vulnerable populations and lay down procedures to deal with research projects involving vulnerable populations.
2. **Scope:** These SOPs shall apply to research being conducted on vulnerable populations.
3. **Definition of Vulnerable Population**: As per the ICMR guidelines 2017-

   Individuals/ groups/ populations are considered vulnerable if they are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or other reasons.

   Individuals are considered to be vulnerable if they are:

   1. Socially, economically, or politically disadvantaged and susceptible to exploitation
   2. Incapable of making a voluntary informed decision for themselves or if their autonomy is compromised temporarily or permanently (e.g., people who are unconscious, differently abled)
   3. Able to give consent, but their voluntariness or understanding is compromised due to their situational conditions.
   4. Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate, which may lead them to give consent.
4. **Responsibility of the IEC:**

   a. To ensure that the researcher/s must justify the inclusion/exclusion of a vulnerable population.

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Document No. 2	Document Type: SOP	Version: 1
Prepared by: Dr. Jitender Aneja	Section: Vulnerable Populations	
Revision No: 0	Revision Date:	Issued by: Dr. Jitender Aneja, Convenor
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b. The IEC may invite a community representative to EC meetings to make sure the research is responsive to their needs and the informed consent process is appropriate.

c. Additional precautions will be taken by all stakeholders such as researchers, ECs and sponsors to avoid exploitation of vulnerable participants.

d. Informed consent process will be well documented and additional measures adopted if required, such as audio-visual/audio recording of assent/consent/reconsent.

e. Research proposals shall undergo review in a full committee meeting.

f. Protection of privacy and dignity as well as provision of quality health care will be ensured in dealing with vulnerable people, especially the minorities.

g. Research involving children, in addition, should follow the National Ethical Guidelines for Biomedical Research Involving Children, ICMR, 2017.

h. Due approvals from competent authorities before entering tribal areas will be sought.

i. Research involving cognitively impaired individuals or those with mental illness will be done carefully, especially if there is risk to themselves, to others or suicidal ideation.

j. The IEC shall carry out the benefit–risk analysis and examine risk minimization strategies.

Annexures: The following annexures (adapted from IEC/PGIMER/Chandigarh) shall apply to certain groups of vulnerable population and must be filled in complete by the principal investigator and shall be reviewed by the IEC.

Annexure 1: IEC/AIIMS/BTI/SOP/VP/ANNEX14- CHECKLIST- Requirements for research involving children.

Joseph Mathew
30 Nov 2023

Annexure 2: IEC/AIIMS/BTI/SOP/VP/ANNEX15- Checklist- Requirements for research involving pregnant women and foetuses.
Annexure 3: IEC/AIIMS/BTI/SOP/VP/ANNEX16- Checklist- Requirements for research involving cognitively impaired adults.
Annexure 4: IEC/AIIMS/BTI/SOP/VP/ANNEX17- Checklist- Requirements for research involving students, employees, or interns/junior/senior residents.
Annexure 5: IEC/AIIMS/BTI/SOP/VP/ANNEX18- Checklist- Requirements for genetic research.

Annexure 1: IEC/AIIMS/BTI/SOP/VP/ANNEX14-
CHECKLIST- Requirements for research involving children.

Name of Principal Investigator:

Study Title:

S. No.	Questions	Yes	No	NA
1.	Does the research pose greater than minimal risk to the children?			
2.	If yes: Are convincing scientific and ethical justifications given?			
3.	If yes: Are adequate safeguards in place to minimize these risks?			
4.	Does the study involve healthy children?			
5.	If yes: Is the inclusion of healthy children justified?			
6.	Are the studies conducted on animals and adults appropriate and justified?			
7.	If **No:** Is the lack of studies conducted on animals and adults justified?			

Joseph Mathew
30 Nov 2023

8.	Will older children be enrolled before younger ones?			
9.	Is permission of both parents necessary?			
10.	If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
11.	If Yes: Are the conditions acceptable?			
12.	Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?			

13.	Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
14.	Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?			
15.	Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
16.	Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
17.	Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
18.	Does the research involve possibility of findings which may have implications for other family members? (for e.g. genetic risk, HIV infection, Hepatitis C}			

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Document No. 2	Document Type: SOP	Version: 1
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Revision No: 0	Revision Date:	Issued by: Dr. Jitender Aneja, Convenor
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Joseph Mathew
30 Nov 2023

19.	If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
20.	Are parents required to be present during the conduct of the research? (Are proposed participants' very young?)			

Signature of Principal Investigator: _____

Date:

Comments of Primary Reviewer:

_____

_____

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Document No. 2	Document Type: SOP	Version: 1
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Revision No: 0	Revision Date:	Issued by: Dr. Jitender Aneja, Convenor
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Joseph Mathew
30 Nov 2023

Annexure 2: IEC/AIIMS/BTI/SOP/VP/ANNEX15-
Checklist- Requirements for research involving pregnant women and/or foetuses prior to delivery.

Name of Principal Investigator:

Study Title:

Sr. No.	Questions	Yes	No	NA
Section A	**This research involves pregnant women or fetuses prior to delivery**			
1.	Where scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women have been conducted and provide data for assessing potential risks to pregnant women and fetuses?			
2.	Where The risk to the fetus not greater than minimal, or any risk to the fetus, which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?			
3.	Any risk that is least possible for achieving the objectives of the research?			
4.	Where the woman's consent or the consent of her legally authorized representative obtained in accordance with the informed consent provisions, unless altered or waived.			
5.	Where the woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant			

Joseph Mathew
30 Nov 2023

	child?			
6.	Where no inducements, monetary or otherwise, be offered to terminate a pregnancy?			
7.	The decision of investigator determining the viability of a fetus will not have an effect if the woman participates in the research.			

If the response to any of the above is NO, the research should not be approved by IEC.

Signature of Principal Investigator: Date:

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Primary Reviewer's Signature and Date:

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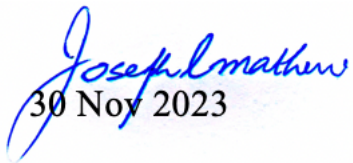

Section B: This research involves fetuses after delivery

Sr. No.	**Questions/** Queries	Yes	**No**	**NA**
1.	Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses			
2.	Where the individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus.			
3.	No inducements, monetary or otherwise will be offere to terminate a pregnancy?			
4.	Women's participation in the research will not influence the decisions by investigator with respect to the timing, method or procedures used to terminate pregnancy; and			
5.	The decision of investigator determining the viability of a fetus will not have an effect if the woman participates in the research			
	AND			
6.	**Fetuses of uncertain viability-**			
6a	A. Does the research hold out the prospect of enhancing the probability of survival of the fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research;			
	OR			
	The purpose of the research is development of important biomedical knowledge which cannot be obtained by other means and there will be nor risk to the fetus resulting from the research.			

Joseph Mathew
30 Nov 2023

	B. The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained?			

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Document No. 2	Document Type: SOP	Version: 1
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Revision No: 0	Revision Date:	Issued by: Dr. Jitender Aneja, Convenor
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Joseph Mathew
30 Nov 2023

7.	**In research involving non-viable fetuses**			
7a	Vital functions of the fetus will not be artificially maintained;			
7b	There will be no risk to the fetus resulting from the research;			
7c	The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and			
7d	The legally effective informed consent of both parents of the fetus will be obtained except that the waiver and alteranate provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. (The consent of a legally authorized representative of either or both parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.)			

If the response to any of above is **NO,** the research should not be approved by IEC.

<u>This type of research can be conducted only after IEC finds that</u>

A. The research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women and/or fetuses.
B. The research will be conducted in accordance with applicable regulatory and ethical guidelines.

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Prepared by: Dr. Jitender Aneja	Section: Vulnerable Populations	
Revision No: 0	Revision Date:	Issued by: Dr. Jitender Aneja, Convenor
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Joseph Mathew
30 Nov 2023

Annexure 3: IEC/AIIMS/BTI/SOP/VP/ANNEX16-
Checklist- Requirements for research involving cognitively impaired adults.

Name of Principal Investigator:

Study Title:

1. **Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the participant** (All items must be "Yes")

Sr. No.	Item	Yes	No
1.	Is the recruitment of participants justified considering rationale and objectives of study?		
2.	Is the risk justified by anticipated benefit to the participants?		
3.	The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches?		
4.	Will the participants be withdrawn if they appear to be unduly distressed?		
5.	The proposed plan for the assessment of the capacity to consent is adequate.		
6.	Assent is required of: (One of the following must be "Yes" A. All participants B. All participants capable of being consulted C. None of the participant		
7.	The consent document includes a signature line for a legally authorized representative.		

Joseph Mathew
30 Nov 2023

2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the participant (All items must be "Yes")

Sr. No.	Item	Yes	No
8.	Is the recruitment of participants justified considering the rationale and objectives of study?		
9.	Are the foreseeable risks to the participants low?		
10.	Is the negative impact on the participant's well-being minimized and low?		
11.	Will the participants be particularly closely monitored?		
12.	Will the participants be withdrawn if they appear to be unduly distressed?		
13.	The proposed plan for the assessment of the capacity to consent is adequate.		
14.	Assent is required of: (One of the following must be "Yes" A. All participants B. All participants capable of being consulted C. None of the participant		
15.	The consent document includes a signature line for a legally authorized representative.		

Signature of Principal Investigator: Date:

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Revision No: 0	Revision Date:	Issued by: Dr. Jitender Aneja, Convenor
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Joseph Mathew
30 Nov 2023

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Annexure 4: IEC/AIIMS/BTI/SOP/VP/ANNEX17-
Checklist- Requirements for research involving students, employees, or interns/junior/senior residents working in AIIMS, Bathinda.

Name of Principal Investigator:

Study Title:

Research involving participants who are students, employees or residents of AIIMS, Bathinda, require special considerations (All items must be "Yes")

Sr. No.	Items	Yes	No
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?		
2.	Have the risks to participants been minimized?		
3.	Have the participants been assured that their participation is voluntary (no signs of coercion)?		
4.	Have the participants been assured that privacy and confidentiality will be protected?		

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Annexure 5: IEC/AIIMS/BTI/SOP/VP/ANNEX18-
Checklist- Requirements for genetic research.

Name of Principal Investigator:

Study Title:

Considerations for genetic research (All items must be "Yes")

Sr. No.	Items	Yes	No
1.	Will samples be made anonymous to maintain confidentiality? If yes, then the following checklist points are not applicable.		
2.	Will the results of individual participants be disclosed to the patient? If yes, a. Has the the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result? b. Will the results be used in management of current condition of patient?		
3.	Has the appropriateness of the various strategies for recruiting participants and their family members been considered?		
4.	Does the proposed study population comprise family members?		
5.	Will family members be implicated in the studies without consent?		
6.	Will the samples be destroyed in the future?		
7.	Is genetic counselling being offered?		

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30 Nov 2023

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