

Annexure 23 A

Checklist: Requirements for Research Involving Children

Name of Principal Investigator:

Study Title:

For the principal investigator		IEC Office
RISK DETERMINATION	BENEFIT ASSESSMENT	IEC ACTION
<input type="checkbox"/> Minimal * <input type="checkbox"/>	Direct benefit	Approvable
	No direct benefit	
<input type="checkbox"/> Greater than minimal risk <input type="checkbox"/>	Potential benefit to child	Approvable
<input type="checkbox"/> Greater than minimal risk <input type="checkbox"/>	No direct benefit, offer knowledge about child's condition/disorder	Approvable on case –by- case basis**

* 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

or occurring during the performance of routine physical or psychological examinations or tests.

** Consent of both parents may be needed as applicable.

	Yes	No	NA
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justifications given?			
If yes: Are adequate safeguards in place to minimize these risks?			
Does the study involve healthy children?			
a) If yes: Is the inclusion of healthy children justified?			
Are the studies conducted on animals and adults appropriate and justified?			
a) If No: Is the lack of studies conducted on animals and adults justified?			
Will older children be enrolled before younger ones?			
Is permission of both parents necessary?			
a) If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
b) If Yes: Are the conditions acceptable?			
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?			
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			

Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve possibility of findings which may have implications for other family members?(for eg. genetic risk, HIV infection, Hepatitis C)			
If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
Are parents required to be present during the conduct of the research? (Are proposed participants' very young?)			

Signature of Principal Investigator: _____ Date _____

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Comments of Primary Reviewer: :	
Primary Reviewer Signature and Date	

Annexure 23B

Checklist: Requirements for Research Involving Pregnant Women and Fetuses

Name of Principal Investigator:

Study Title:

☐ **When research involves pregnant women or fetuses**

	Yes	No	NA
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the risk to the fetus not greater than minimal, or any risk to the fetus which is greater than minimal caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any risk that is the least possible for achieving the objectives of the research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the woman's consent or the consent of her legally authorized representative obtained in accordance with the informed consent provisions, unless altered or waived?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the woman or her legally authorized representative, as appropriate, fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do individuals engaged in the research have a part in determining the viability of a fetus?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

☐ **When research involves neonate after delivery**

	Yes	No	NA
1. Are scientifically appropriate, preclinical and clinical studies, conducted and provide data for assessing potential risks to neonates?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Do individuals engaged in the research have a part in any decisions as to the timing, method or procedures used to terminate pregnancy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Do individuals engaged in the research have a part in determining the viability of a fetus?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A. Fetuses of uncertain viability	Yes	No	NA
1. Does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and is any risk least possible for achieving the objectives of the research ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
OR			
The purpose of the research is development of important biomedical knowledge which cannot be obtained by other means. Will there be a risk to the fetus from the research ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is the legally effective informed consent of either parent of the neonate 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 obtained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. Nonviable fetuses	Yes	No	NA
1. Will vital functions of the neonate be artificially maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is there any risk to the neonate resulting from the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The legally effective informed consent of both parents of the neonate will be obtained except that the waiver and alteration 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 of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

This type of research can be conducted only after The IEC finds that

- (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.

Signature of Principal Investigator: _____ Date _____

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Primary Reviewer's Signature and Date	

Annexure 23 C

Checklist- 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”)		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Is the recruitment of participants justified considering the rationale and objectives of the study?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The risk is justified by the anticipated benefit to the participants.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Will the participants be withdrawn if they appear to be unduly distressed?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The proposed plan for the assessment of the capacity to consent is adequate.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Consent will be taken from participants capable of being consulted.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?

2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the participant (All items must be “Yes”)		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Is the recruitment of participants justified considering the rationale and objectives of the study?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Are the foreseeable risks to the participants low?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Is the negative impact on the participant’s well-being minimized and low?

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Will the participants be particularly closely monitored?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Will the participants be withdrawn if they appear to be unduly distressed?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The proposed plan for the assessment of the capacity to consent is adequate.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Consent will be taken from participants capable of being consulted.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?

Signature of Principal Investigator: _____ Date _____

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Primary Reviewer Signature and Date	

Annexure 23D

Checklist: Research Involving Students, Employees or Residents

Name of Principal Investigator:

Study Title:

Participants who are students, employees or residents require special considerations.

Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
Have the risks to participants been minimized?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
Have participants been assured that participation is voluntary (no signs of coercion)?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
Have participants been assured that privacy and confidentiality will be protected?	<input type="checkbox"/> No	<input type="checkbox"/> Yes

Answers to all the above points should be YES for approval

Signature of Principal Investigator: _____

Date _____

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Annexure 23 E

Checklist: Considerations for Genetic Research

Name of Principal Investigator: Study Title:

	Yes	No
1. Will the samples be made anonymous to maintain confidentiality? If yes, then the following checklist points are not applicable	<input type="checkbox"/>	<input type="checkbox"/>
2. Will the results be disclosed? a) If yes, has 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?	<input type="checkbox"/>	<input type="checkbox"/>
3. Has the appropriateness of the various strategies for recruiting participants and their family members been considered?	<input type="checkbox"/>	<input type="checkbox"/>
4. Does the proposed study population comprise family members?	<input type="checkbox"/>	<input type="checkbox"/>
5. Will family members be implicated in the studies without consent?	<input type="checkbox"/>	<input type="checkbox"/>
6. Will the samples be destroyed in the future?	<input type="checkbox"/>	<input type="checkbox"/>
7. Will the samples be used for future research	<input type="checkbox"/>	<input type="checkbox"/>
8. Is genetic counseling being offered?	<input type="checkbox"/>	<input type="checkbox"/>

Signature of Principal Investigator: _____ Date _____

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