YENEPOYA ETHICS COMMITTEE 2
Yenepoya (Deemed to be University)
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DCGI Registration No.: ECR/1337/Inst/KA/2020
DHR registration No.: EC/NEW/INST/2023/KA/0276

Annexure 2: YEC2/Ann02/SOP19/v1

Checklist: Requirements for Research Involving Pregnant Women & Fetuses

Name of the Principal Investigator:

Study Title:

When research involves pregnant women or fetuses:

Sl.No.	**Checklist item**	**Yes**	**No**	**NA**
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	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?			
3	Any risk that is the least possible for achieving the objectives of the research.			
4	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?			
5	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?			
6	Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?			
7	Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?			
8	Do individuals engaged in the research have a part in determining the viability of a fetus?			

If the response to any of the above is **NO**, the research should not be approved by YEC 2.

When the research involves neonates after delivery:

Sl. No	Checklist item	Y	N	NA
1	Are scientifically appropriate, preclinical and clinical studies, conducted and provide data for assessing potential risks to neonates?			
2	Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate?			
3	Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?			
4	Do individuals engaged in the research have a part in any decisions as to the timing, method or procedures used to terminate pregnancy?			
5	Do individuals engaged in the research have a part in determining the viability of a fetus?			

Fetus of uncertain viability:

Sl. No	Checklist item	Y	N	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 **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?			
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?			

Non-viable fetus:

Sl. No	Checklist item	Y	N	NA
1	Will vital functions of the neonate be artificially maintained?			
2	Is there any risk to the neonate resulting from the research?			
3	The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means			

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.)			

If the response to any of above is **NO,** the research should not be approved by the YEC 2.

<u>This type of research can be conducted only after YEC 2 determines 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.

Signature of the Principal Investigator:

Date:

YEC 2 Office use only	
Comments of Primary Reviewer:	
Primary Reviewer's Signature and Date:	