**Ann02/SOP19/v3**

**Checklist: Requirements for Research Involving Pregnant Women & Fetuses**

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.

Study Title:

Name of the Principal Investigator :

**If the research involves pregnant women and/or their fetuses, please fill this form and submit along with the research protocol:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sl.No. | **Checklist item** | **Yes** | **No** | **NA** |
| 1 | Have scientifically appropriate preclinical 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? |  |  |  |
| 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? |  |  |  |
| 3 | Is any risk that is likely to occur, the least possible for achieving the objectives of this study? |  |  |  |
| 4 | Is the woman’s consent or the consent of her legally authorized representative (if the participant herself is unable to give consent) obtained in accordance with the informed consent provisions (as described in the ICMR National Ethical Guidelines for Biomedical Research involving Human Participants - 2017)? |  |  |  |
| 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 | Do individuals engaged in the research have a part in determining the viability of the fetus? |  |  |  |
| 7 | Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate the pregnancy? |  |  |  |
| 8 | Will any inducements, monetary or otherwise, be offered to terminate the pregnancy? |  |  |  |

If the response to items 1-7 is **NO**, the research should not be approved by YEC-1. Response to item no. 8 will be assessed on a case-to-case basis.

**Please fill this section of the checklist if the research involves neonates:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sl No** | **Checklist item** | **Y** | **N** | **NA** |
| 1 | Can this research be performed in any other non-vulnerable participants? |  |  |  |
| 2 | Is there adequate justification for involvement of vulnerable population in the research? |  |  |  |
| 3 | Are scientifically appropriate, preclinical and clinical studies, conducted and provide data for assessing potential risks to neonates? |  |  |  |
| 4 | Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the researchon neonate? |  |  |  |
| 5 | Will any inducements, monetary or otherwise, be offered to terminate the pregnancy? |  |  |  |
| 6 | Do individuals engaged in the researchhave a part in any decisions as to the timing, method or procedures used to terminate pregnancy? |  |  |  |
| 7 | Do individuals engaged in the researchhave a part in determining the viability of a fetus? |  |  |  |

If the response to item no. 1 is **YES** and to item no. 2-7 is **NO**, the research should not be approved by YEC-1.

**Fetus of uncertain viability:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sl No** | **Checklist item** | **Y** | **N** | **NA** |
| 1 | Is the purpose of the researchthe development of important biomedical knowledge which cannot be obtained by other means? |  |  |  |
| 2 | Is any risk the fetus is exposed to, the least possible for achieving the objectives of the research? |  |  |  |
| 3 | Does the researchhold out the prospect of enhancing the probability of survival of the enrolled fetus to the point of viability? |  |  |  |
| 4 | Will 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 be obtained? |  |  |  |

If the response for any of the items no. 1-4 is **NO**, then YEC-1 should not approve the research

**Non-viable fetus:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sl No** | **Checklist item** | **Y** | **N** | **NA** |
| 1 | Will vital functions of the neonate be artificially maintained in the course of the research, despite clinically being pronounced “non-viable”? |  |  |  |
| 2 | Will the research-related risk to the neonate be less than minimal? |  |  |  |
| 3 | Is the purpose of the research the development of important biomedical knowledge that cannot be obtained by other means? |  |  |  |
| 4 | Will the legally effective informed consent of both parents of the neonate be obtained?  Please note: 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-1.

**This type of research can be conducted only after YEC-1 determines that**

1. 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**.**
2. The research will be conducted in accordance with applicable regulatory and ethical guidelines.

Signature of the Principal Investigator: Date:

|  |  |
| --- | --- |
| **YEC-1 Office use only** | |
| Comments  of Primary  Reviewer: |  |
| Primary Reviewer’s Signature and Date: | |