**Yenepoya Ethics Commitee-1**

**Ann02/SOP19/v4**

**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*.

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| **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 | YEC-1 Protocol No.  |  |
| 2 | Title: |  |
| 3 | Name of the PI |  |
| 4 | Department  |  |
| 5 | Type of study: **Clinical trial/ academic clinical trial/ observational study** |  |
| 6 | Nature of intervention: Specify (**Drug/device/educational/others)** |  |
| **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 clinical trials on pregnant women, 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? | Yes/ No/ Not applicableComment:  |
| **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 applicableComment:  |
| **3** | Is any risk that is likely to occur, the least possible for achieving the objectives of this study? | Yes/ No/ Not applicableComment:  |
| **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)? | Yes/ No/ Not applicableComment:  |
| **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? | Yes/ No/ Not applicableComment:  |
| **6** | Do individuals engaged in the research have a part in determining the viability of the fetus? | Yes/ No/ Not applicableComment:  |
| **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? | Yes/ No/ Not applicableComment:  |
| **8** | Will any inducements, monetary or otherwise, be offered to terminate the pregnancy?  | Yes/ No/ Not applicableComment:  |
|  | *Note: If the response to items 1-7 is NO, the research should not be approved. Point No 8 will be assessed on a case-to-case basis.* |
| **B** | **Fill in this section if the study involves fetuses of uncertain viability:** If the response for any of the items no. 1-4 is **NO**, then YEC-1 should not approve the research:  |
| **1** | Is the purpose of the researchthe development of important biomedical knowledge which cannot be obtained by other means?  | Yes/No/Not applicable  |
| **2** | Is any risk the fetus is exposed to, the least possible for achieving the objectives of the research? | Yes/No/Not applicable  |
| **3** | Does the researchhold out the prospect of enhancing the probability of survival of the enrolled fetus to the point of viability?  | Yes/No/Not applicable  |
| **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? | Yes/No/Not applicable  |
| **C** | **Fill in this section if the study involves non viable fetuses:** If the response for any of the items no. 1-4 is **NO**, then YEC-1 should not approve the research:  |
|  | Will vital functions of the neonate be artificially maintained in the course of the research, despite clinically being pronounced “non-viable”? | Yes/No/Not applicable  |
|  | Will the research-related risk to the neonate be less than minimal? | Yes/No/Not applicable  |
|  | Is the purpose of the research the development of important biomedical knowledge that cannot be obtained by other means? | Yes/No/Not applicable  |
|  | 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.) | Yes/No/Not applicable  |
|  | **Signature of the principal investigator with date***(PI to confirm that all the relevant descriptions are included in the protocol)* |  |
|  | This type of  research can be conducted only after YEC-1 determines that 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**.** The research will be conducted in accordance with applicable regulatory and ethical guidelines. **For YEC-1 use only** |
|  | Comments of the Reviewer: |  |
|  | Signature of the reviewer with date  |  |