**Ann01/SOP19/v4**

**Yenepoya Ethics Committee-1**

**Checklist: Research Involving Children <18 years**

***Note to PI:*** *Children (minors) have reduced capacity to understand and give informed consent. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. 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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|  | **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)** |  |
|  | **Checklist item** | **PI Response**  **Please include these descriptions in relevant sections of the protocol** |
| 1 | **Does the research pose greater than minimal risk to children?: Yes/No** | |
| 1. If yes: Are there convincing scientific and ethical justifications to carry out the research as designed? | Yes/No  Included in protocol: Yes/No  Comment: |
| 1. If yes: Are adequate safeguards in place to minimize these risks? | Yes/No  Included in protocol: Yes/No  Comment: |
| 1. Is there an alternate study design that can achieve the same objectives without involving such vulnerable participants? | Yes/No  Included in protocol: Yes/No  Comment: |
| 2 | **Does the study involve healthy children? Yes/No** | |
|  | 1. If yes, is the inclusion of healthy children justified? | Yes/No  Included in protocol: Yes/No  Comment: |
| 1. If yes, have scientifically appropriate preclinical studies, including studies on animals, and clinical studies, including studies on children and/or adults, been conducted and do these provide data for assessing potential risks to children/minors? | Yes/No/Not applicable  Included in protocol: Yes/No  Comment: |
| 1. If your response is No to b, in the absence of animal studies or studies on adults, is it justified to conduct this study? | Yes/No/Not applicable  Included in protocol: Yes/No  Comment: |
| 1. Will older children be enrolled before younger ones? | Yes/No  Comment |
| **3** | **Is consent of both parents necessary?** | |
|  | 1. If yes, are conditions under which one of the parents may be considered: “not reasonably available”? | Yes/No  Included in protocol: Yes/No  Comment: |
|  | 1. Are the conditions acceptable? | Yes/No  Included in protocol: Yes/No  Comment: |
| **4** | **Is an attempt made to ensure voluntary informed consent of the parent and assent from the child?** | |
|  | 1. Will efforts be made to ensure that parents’ consent to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises? | Yes/No  Included in protocol: Yes/No  Comment: |
|  | 1. Are provisions made to obtain the written assent of children over 12 years, and oral assent of children between 7 and 12 years, and where appropriate, honor their dissent? | Yes/No  Included in protocol: Yes/No  Comment: |
| **5** | **Are specific safeguards available to protect the children included in research?** | |
| 1. Are provisions made to protect participants’ privacy and the confidentiality of information gathered in the course of the research? | Yes/No  Included in protocol: Yes/No  Comment: |
| 1. Are there special problems that call for the presence of an external monitor during consent procedures? | Yes/No  Included in protocol: Yes/No  Comment: |
| 1. Are special needs of adolescents such as counseling and confidentiality accounted for in the research design? | Yes/No  Included in protocol: Yes/No  Comment: |
| **6** | **Does the research involve possibility of findings which may have implications for other family members?(for eg. genetic risk, HIV infection, Hepatitis C)** | |
| 1. Are there adequate mechanisms in place to deal with other members of the family, should there be a risk to such bystanders? | Yes/No  Included in protocol: Yes/No  Comment: |
| 1. Are parents required to be present during the conduct of the research? | Yes/No  Included in protocol: Yes/No  Comment: |
| **7** | **Risk and benefit assessment** | |
|  | 1. What are the anticipated risks to the children from research participation? |  |
|  | 1. Risk assessment | Minimal risk  More than minimal risk |
|  | 1. What are the anticipated risks to the children from research participation? |  |
|  | 1. Benefits assessment | Direct benefit  Indirect benefit |
|  | 1. Risk: benefit ratio: | Favorable  Not favorable |
| **8** | Signature of the principal investigator with date  *(PI to confirm that all the relevant descriptions are included in the protocol)* |  |
| **9** | **For YEC-1 use only** | |
|  | Comments of the Reviewer: |  |
|  | Signature of the reviewer with date |  |

*\*   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*

*\*\* Consent of both parents (and assent) may be needed as applicable*