**Yenepoya Ethics Committee-1**

**Ann07/SOP19/v4**

**Checklist: Considerations for Genetic Research**

**Note to PI:** *Genetic research is still poorly understood and there is much to be learned by the scientific community, for a fuller and more comprehensive understanding of the genetic functions of the human body. Potential participants may have difficulty in understanding the research details and thus give informed consent on less-than-optimal understanding.  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 to review 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: Genomic study or gene therapy |  |
| 6 | Will the samples be made anonymous to maintain confidentiality? | Yes/No  Comment: |
| 7 | Will the results be disclosed to the participant or legally authorized representative? | Yes/No  Comment: |
|  | 1. If yes, has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research results? | Yes/No  Comment: |
|  | 1. If yes, will the results be used in management of the current condition of the patient? | Yes/No  Comment: |
| 8 | Has the appropriateness of the various strategies for recruiting participants and their family members been considered? | Yes/No  Comment: |
| 9 | Does the proposed study population comprise family members? | Yes/No  Comment |
| 10 | Will family members be implicated in the studies without consent? | Yes/No  Comment |
| 11 | Will the samples be destroyed in the future? | Yes/No  Comment |
| 12 | Will the samples be used for future research? | Yes/No  Comment |
| 13 | Will the human biological sample or the data associated with it, be shared with other researchers? | Yes/No  Comment |
| 14 | Will genetic counselling be offered? | Yes/No  Comment |
|  | Signature of the principal investigator with date  *(PI to confirm that all the relevant descriptions are included in the protocol)* |  |
|  | **For YEC-1 use only** | |
|  | Comments of the Reviewer: |  |
|  | Signature of the reviewer with date |  |