**Yenepoya Ethics Commitee-1**

**Ann04/SOP19/v4**

**Checklist: Research Involving Cognitively Impaired Adults**

Note to PI: *Cognitively impaired adults 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 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: **Clinical trial/ academic clinical trial/ observational study** |  |
| 6 | Nature of intervention: Specify (**Drug/device/educational/others)** |  |
|  | **Research Involving Cognitively Impaired Adults**  *All items should be answered and the substantiation for the same should be evident in the protocol (methodology) as well as in the participant information sheet and informed consent form)* | |
| 1 | Is recruitment of cognitively impaired participants justified considering the rationale and objectives of the study? | Yes/No  Comment: |
| 2 | Is there an anticipated direct benefit to the participant? | Yes/No  Describe the benefit: |
|  | 1. If there is anticipated benefit, is the risk justified by the anticipated benefit? | Yes/No  Comment: |
|  | 1. If there is anticipated benefit, is the relation of the anticipated benefit to the risk at least as favorable to the participants as that presented by available alternative approaches? | Yes/No |
|  | 1. If there is no anticipated benefit, are the foreseeable risks to the participants low? | Yes/No |
|  | 1. If there is no anticipated benefit, is the negative impact on the participant‘s well-being minimized and low? |  |
|  | 1. If there is no anticipated benefit, will the participants be closely monitored? |  |
| 4 | Will the participants be withdrawn if they appear to be unduly distressed? | Yes/No  Comment: |
| 5 | Is the proposed plan for the assessment of the capacity to consent adequate? | Yes/No  Comment: |
| 6 | Will consent be taken from participants capable of being consulted? | Yes/No  Comment: |
| 7 | Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted? | Yes/No  Comment: |
| 8 | **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 |  |