**Checklist: Research Involving Cognitively Impaired Adults (effective date: 22-07-2021)**

1. **Need for the checklist:**

|  |
| --- |
| 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.  Instructions for the PI:   1. *Please download the checklist, type the details, and email the signed copy to* [*ethcom@yenepoya.edu.in*](mailto:ethcom@yenepoya.edu.in)*).* 2. *Please do not delete any of the questions/ sections/options provided by YEC-1 in the checklist.* 3. *Please note that all the details provided here are also reflected in the protocol and informed consent document.* 4. *Do not leave any question without a response. If not applicable, write not applicable* |

1. **Details of the protocol:**

|  |  |
| --- | --- |
| **Protocol Number:** |  |
| **Title of the protocol** |  |
| **Principal investigator** |  |
| **Department** |  |
| **Names of Co-investigators including Guide/Co-Guide** |  |

1. **Checklist items** 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):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Checklist item | Yes, No or NA | Protocol version no., Page no. | YEC-1 remarks |
|  | Is recruitment of participants justified considering the rationale and objectives of the study? |  |  |  |
|  | Have the foreseeable risks to the participants been described in the protocol (methodology and PIS)? |  |  |  |
|  | Are the foreseeable risks to the participants low? |  |  |  |
|  | Have the safeguards to minimize the risk and mitigate the harm been described ? |  |  |  |
|  | Are the safeguards adequate? |  |  |  |
|  | Have direct benefits to the participants been described in the protocol (methodology and PIS)? |  |  |  |
|  | Is the risk justified by the anticipated benefit? |  |  |  |
|  | Is the relation of the anticipated benefit to the risk at least as favourable to the participants as that presented by available alternative approaches? |  |  |  |
|  | Have the discontinuation criteria been described in the protocol (methodology and PIS)? |  |  |  |
|  | Has the proposed plan for the assessment of the capacity to consent been described in the protocol? |  |  |  |
|  | Does the consent document include provision for a legally acceptable representative in case participants are not capable of being consulted? |  |  |  |
|  | Any other concerns like re-consent and fluctuating capacity as applicable to the study been described in the protocol (methodology and PIS) |  |  |  |

Signature of the Principal Investigator: Date:

|  |  |
| --- | --- |
| **YEC-1 Office use only** | |
| Final Recommendation of Primary Reviewer |  |
| Primary Reviewer Signature and Date | |