**Checklist: Research Involving Cognitively Impaired Adults**

1. **Need for the checklist:**

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| 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** |  |
| **List of Co-investigators/ Guides/ Co-guides** |  |

1. **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. **Checklist for cognitively impaired in which there is anticipated** **direct benefit to the participant**

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| --- | --- | --- |
| **No.** | **Checklist item** | **Yes, No or Not applicable (NA)** |
| 1 | Is recruitment of participants justified considering the rationale and objectives of the study? |  |
| 2 | Is the risk justified by the anticipated benefit? |  |
| 3 | Is the relation of the anticipated benefit to the risk at least as favorable to the participants as that presented by available alternative approaches? |  |
| 4 | Will the participants be withdrawn if they appear to be unduly distressed? |  |
| 5 | Will consent be taken from participants capable of being consulted? |  |
| 6 | Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted? |  |
| 7 | Is recruitment of participants justified considering the rationale and objectives of the study? |  |
| 8 | Is the risk justified by the anticipated benefit? |  |
| 9 | Is the relation of the anticipated benefit to the risk at least as favorable to the participants as that presented by available alternative approaches? |  |

**b. Checklist: Research Involving Cognitively Impaired Adults in which there is no anticipated** **direct benefit to the participant**

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| **No.** | **Checklist item** | **Yes, No or Not applicable (NA)** |
| 1 | Is the recruitment of participants justified considering the rationale and objectives of the study? |  |
| 2 | Are the foreseeable risks to the participants low? |  |
| 3 | Is the negative impact on the participant‘s well-being minimized and low? |  |
| 4 | Will the participants be closely monitored? |  |
| 5 | Will the participants be withdrawn if they appear to be unduly distressed? |  |
| 6 | Is the proposed plan for the assessment of the capacity to consent adequate? |  |
| 7 | Will consent be taken from participants capable of being consulted? |  |
| 8 | Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted? |  |

Signature of the Principal Investigator: Date:

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