**Yenepoya Ethics Committee-1**

**Ann05/SOP19/v4**

**Checklist-Research Involving Students, Employees or Residents**

**Note to PI:** *Research participants drawn from institutions with hierarchical cultures, 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 dependent participants (employees, students, residents)  *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 | Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not? | Yes/No  Comment: |
| 2 | Have the risks to participants been minimized and are such strategies described in the protocol? | Yes/No  Comment: |
| 3 | Have participants been assured that participation is voluntary (no signs of coercion)? | Yes/No  Comment: |
| 4 | Have participants been assured that privacy and confidentiality will be protected? | Yes/No  Comment: |
| 5 | Is the research team member taking consent directly related to the welfare of the participants? | 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 |  |