**Yenepoya Ethics Committee - 1**

**Ann04/SOP10/v3:**

**Periodic/ Continuing Review Application Form**

*(Download the form, type the details, print, sign, scan and send to YEC-1 at* [*ethcom@yenepoya.edu.in*](mailto:ethcom@yenepoya.edu.in)*. Please do not delete any of the text typed in the form)*

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Protocol details** | | | |
| 1 | Protocol No. |  | |
| 2 | Title: |  | |
| 3 | Name of the Principal Investigator: Department and Institution: |  | |
| 4 | Name of the guide  (*wherever applicable*):  Department and Institution: |  | |
| 5 | Validity of approval by YEC-1 | From: | To: |
| 6 | Extensions of approval  *(add rows for each extension)* | From: | To: |
| 7 | Protocol amendment  *(add rows for each amendment)* | From: | To: |
| 8 | Date for periodic review |  |  |
| 1. **Protocol timelines** | | | |
| 1 | Date of initiation of the study: |  | |
| 2 | Date of the last recruitment: |  | |
| 1. **Participant details** | | | |
| 1 | Number of participants screened |  | |
| 2 | Number of screen failures |  | |
| 3 | Number of participants recruited |  | |
| 4 | Number of ongoing participants |  | |
| 5 | Number of completed participants |  | |
| 6 | Number of participants who withdrew the consent | (Provide reasons for withdrawal of consent) | |
| 7 | Number of participants who were discontinued from the study by PI or sponsor | (Provide reasons for discontinuation from study) | |
| 8 | Number of participants with adverse events | (Provide details of each adverse event) | |
| 9 | Number of SAEs reported: | (Provide details of reporting of each SAE) | |
| 1. **Changes in the protocol/ risk to participants:** | | | |
| 1 | Whether approved protocol version followed: |  | |
| 2 | Any changes made in the selection criteria of participants |  | |
| 3 | Any changes made in the protocol |  | |
| 4 | Any changes made in the study team; any change in guide  Any changes in the sample size |  | |
| 5 | Any changes in the funding status |  | |
| 6 | Any increase in the risk to the participants based on the findings of the current study/new information in literature |  | |
| 1. **Monitoring/ data analysis** | | | |
| 1 | Has interim data analysis been done? | (If yes, provide the report.) | |
| 2 | Has the data safety and monitoring board reported? | (If yes, provide the report) | |
| 3 | Has YEC-1/ regulatory authorities conducted a site monitoring/ audit? | (If yes, provide the report) | |
| 1. **Any other:** | | | |
| 1 | Any investigator(s) have developed a conflict of interest during the conduct of the study | (If yes, provide the report) | |
| 2 | Any difficulties/ events faced during the study |  | |
| 3 | Any other information you would like to share with the YEC-1 |  | |

Signature of the PI: (with name and date)

Signature of the guide (if any): (with name and date)