**Yenepoya Ethics Committee - 1**

**Ann04/SOP10/v4**

**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 | YEC-1 Protocol No. | |  | |
| 2 | Title: | |  | |
| 3 | Type of Study | |  | |
| 4 | Name of the Principal Investigator: Department and Institution: | |  | |
| 5 | Names of all the Co-Is (guides):  Department and Institution: | |  | |
| 6 | Names of Research Assistants/Data Coordinators | |  | |
| 6 | Validity of approval by YEC-1 | | From: | To: |
| 7 | Extensions of approval *(add rows for each extension)* | | From: | To: |
| 8 | Protocol amendment *(add rows for each amendment)* | | From: | To: |
| 9 | Date for periodic review (as per YEC-1 communication) | |  |  |
| 1. **Protocol timelines** | | | | |
| 1 | Date of first recruitment: | |  | |
| 2 | Date of the last recruitment: | |  | |
| 1. **Participant details** | | | **Number** | **Date** |
| 1 | Sample size approved | |  | |
| 2 | Number of participants screened/date of last screened (or samples/data selected) | |  |  |
| 3 | Number of screen failures/date of last screen failure | |  |  |
| 4 | Number of participants/biological samples/data recruited/ collected | |  |  |
| 5 | Number of ongoing participants/biological samples | |  |  |
| 6 | Completed participants/date when last participant completed | |  |  |
| 7 | Participants who withdrew the consent/date of last withdrawal/or samples/data rejected  *(Provide reasons for withdrawal/rejection)* | |  |  |
| 8 | Participants who were discontinued from the study by PI or sponsor/date of last discontinuation  *(Provide reasons for discontinuation)* | |  |  |
| 9 | Participants with adverse events/dates for all adverse events  (Provide details of each adverse event – attach separate sheet if necessary) | |  |  |
| 10 | Number of SAE reported  Dates for all SAEs reported (details) | |  |  |
| 1. **Changes in the protocol/ risk to participants:** | | | | |
| 1 | Whether approved protocol version followed (provide protocol number): | Yes / No  Protocol version number: | | |
| 2 | Any changes made in the selection criteria of participants | Yes / No (If yes, please provide details) | | |
| 3 | Any changes made in the protocol | Yes / No (If yes, please provide details) | | |
| 4 | Any changes made in the study team; any change in guide | Yes / No (If yes, please provide details) | | |
| 5 | Any changes in the sample size | Yes / No (If yes, please provide details) | | |
| 6 | Any changes in the funding status | Yes / No (If yes, please provide details) | | |
| 7 | Whether approved version followed:   1. PIS 2. ICF 3. Data collection form: | Yes / No                           Version number | | |
| 8 | Any increase in risk to participants based on the findings of the current study/new information in literature | Yes / No (If yes, please provide details) | | |
| 9 | Any protocol deviations noted | Yes / No (If yes, please provide details) | | |
| 1. **Monitoring/ data analysis** | | | | |
| 1 | Has interim data analysis been done? | Yes / No (If yes, provide the report) | | |
| 2 | Has the data safety and monitoring board reported? | Yes / No (If yes, provide the report) | | |
| 3 | Has YEC-1/ regulatory authorities conducted a site monitoring/ audit? | Yes / No (If yes, provide the report) | | |
| 1. **Any other:** | | | | |
| 1 | Have any investigator(s) developed a CoI during the conduct of the study: | Yes / No (If yes, provide the report) | | |
| 2 | Have any research team members faced any difficulties/events during the study | Yes / No (If yes, provide the report) | | |
| 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)