**Yenepoya Ethics Committee-1**

**Ann01/SOP13/v4**

**Study completion reporting form**

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

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| --- |
| 1. **Protocol details**
 |
| 1 | Protocol No. |  |
| 2 | Title: |  |
| 3 | Name of the Principal Investigator: Department and Institution: |  |
| 4 | Name of the guide (*if 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 | Dates for periodic review |  |  |
| 1. **Protocol timelines**
 |
| 1 | Date of initiation of the study: |  |
| 2 | Date of the last recruitment: |  |
| 1. **Participant details**
 |
| 1 | Sample size approved |  |
| 2 | Number of participants screened  |  |
| 3 | Number of screen failures |  |
| 4 | Number of participants recruited  |  |
| 5 | Number of ongoing participants |  |
| 6 | Number of completed participants  |  |
| 7 | Number of participants who withdrew the consent | (Provide reasons for withdrawal of consent) |
| 8 | Number of participants discontinued from the study by PI or sponsor | (Provide reasons for discontinuation from study) |
| 9 | Number of participants with AEs  | (Provide details of each adverse event) |
| 10 | 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 guideAny 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**
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| 1 | Has interim data analysis been done and reported earlier?  | (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:**
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| 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  |  |
| 1. **Summary of the study (in 500 words)**
 |
| 1 | Introduction |  |
| 2 | Objectives |  |
| 3 | Material and methods |  |
| 4 | Results and analysis |  |
| 5 | Discussion  |  |
| 6 | Conclusion  |  |
| 7 | Utilization of the results  |  |

Signature of the PI: (with name and date)

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