



## Study completion reporting Form

### Yenepoya Ethics Committee-3 (YEC-3)

EC Ref. No.

(For office use)

Title of study: .....

Principal Investigator (Name, Designation and Affiliation): .....

1. Date of EC approval:  dd  mm  yy
2. Date of start of study:  dd  mm  yy      Date of study completion:  dd  mm  yy
3. Provide details of:
  - a) Total number of study participants approved by the EC for recruitment: .....
  - b) Total number of study participants recruited: .....
  - c) Total number of participants withdrawn from the study (if any): .....

Provide the reasons for withdrawal of participants<sup>1</sup> : .....

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4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) .....

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5. Describe the main ethical issues encountered in the study (if any) .....

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6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period  
Deviations: ..... Violation: ..... Amendments: .....
7. Describe in brief plans for archival of records / record retention: .....

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<sup>1</sup> Explanation for the withdrawal of participants whether by self or by the PI

8. Is there a plan for post study follow-up?

Yes  No

If yes, describe in brief: .....

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9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?

Yes  No

If yes, describe in brief: .....

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10. Is there a plan for post study benefit sharing with the study participants?

Yes  No

If yes, describe in brief: .....

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11. Describe results (summary) with Conclusion <sup>2</sup> : .....

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12. Number of SAEs that occurred in the study: .....

13. Have all SAEs been intimated to the EC ?

Yes  No

14. Is medical management or compensation for SAE provided to the participants?

Yes  No

If yes, provide details.....

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Signature of PI: .....

dd mm yy

<sup>2</sup> For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.