



(Annexure 13)

## Study completion/Final report format

Apollo Institute of Medical Sciences & Research, Chittoor Andhra Pradesh.517127

EC Ref. No. (For office use):

Title of study: .....

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

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1. Date of EC approval: 

dd	mm	yy
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2. Date of start of study: 

dd	mm	yy
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 Date of study completion: 

dd	mm	yy
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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  - c) Total number of participants withdrawn from the study (if any): .....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>23</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>23</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>24</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>24</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.