



(Annexure 12)
Study completion/ Final report format

EC Ref. No. (for office use):

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval:

2. Date of Start of Study: Date of study completion:

3. Provide details of:

a) Total no. of study participants approved by the EC for recruitment:

b) Total no. of study participants recruited:

c) Total number of participants withdrawn from the study (if any):

Provide the reasons for withdrawal of participants²³:

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

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

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:

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

Yes No

If yes, describe in brief:

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

If yes, describe in brief:

Yes No

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 Conclusion²⁴:

²³ Explanation for the withdrawal of participants whether by self or by the PI

²⁴ For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.

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

Signature of PI:

Date: