

## Study completion/Final report format

**Title of study:**

PI (Name, Designation and Affiliation):

Date of EC Approval:

Date of Start of Study:

**Date of study completion:**

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- c) Total number of participants withdrawn from the study (if any):

- 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
- 7. Describe in brief Plans for archival of records / Record Retention:
- 8. Is there a plan for post study follow-up –
- 9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?
- 10. Is there a plan for post study benefit sharing with the study participants?
- 11. Describe results (summary) with Conclusion:
- 12. Number of SAEs that occurred in the study
- 13. Have all SAEs been intimated to the EC:
- 14. Is medical management or compensation for SAE provided to the participants?