Study completion/Final report format

Surat Municipal Institute of Medical Education and Research (SMIMER)

Opp. Bombay Market, Umarwada, Surat - 395 010. (Gujarat - India).

Ph: (0261) 2368040 to 43; Fax: (0261) 2343241

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
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   c) Total number of participants withdrawn from the study (if any): .....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[23] : .....

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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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[23] *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 [24] : .....

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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