



Study completion/Final report format

Panineeya Mahavidyalaya Institute of Dental Sciences & Research Center

EC Ref. No.ECR/267/Indt/AP/2016

Title of study:

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Principal Investigator (Name, Designation and Affiliation):

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1. Date of EC approval:

2. Date of start of study:

Date of study completion:

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c) Total number of participants withdrawn from the study (if any):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 participants²³ :

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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 Serious Adverse Events (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:

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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.