Annexure 1
AX 01 / SOP 08/V6.1

Study completion/Final report format

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No. ....

Title of study: ....
....
....

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

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   c) Total number of participants withdrawn from the study (if any): ....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[24] : ....
   ....
   ....

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:...
   ....
   ....
   ....
   ....

[24] *Explanation for the withdrawal of participants whether by self or by the PI*

Version 1.0

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?   Yes ☐ No☐

   If yes, describe in brief: ....

   ....

   ....

   ....

   ....

10. Is there a plan for post study benefit sharing with the study participants?   Yes ☐ No☐

   If yes, describe in brief: ....

   ....

   ....

   ....

   ....

11. Describe results (summary) with Conclusion ✱ : ....

   ....

   ....

   ....

   ....

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: .... | dd | mm | yy |