



INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth G. S. Medical College and KEM Hospital, Mumbai.

Annexure 2 AX 02/SOP 07/V 7 Continuing Review/Annual Report Format

Date:

IEC No. of the Project:

Study Title:

Principal Investigator (Name, Designation & Affiliation):

1. Date of EC Approval:

2. Date of Start of Study: Proposed Date of Completion:

Period of Continuing Report: to:

3. Does the study involve recruitment of participants?

a. If Yes, Total number of participants approved by IEC:

Number Screened: Number Enrolled:

Number Ongoing: Number Completed:

b. Report of DSMB/Sponsor site monitoring report during this period. Yes No

If yes, state the number:

4. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during this continuing review period? Yes No

a. If no, Skip to point no. 5

b. If Yes, date of approval for Protocol and ICD;

c. In case of amendment in the ICD was re-consent sought from participants? Yes No

If yes, state the number:

5. Is any new information that is available does it change the benefit-risk analysis of human participants involved in this study during this continuing review period? Yes No

If yes, discuss in detail:

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6. Have any ethical concerns occurred during this continuing review period Yes No

If yes, give details:

7. a. Have any adverse events been noted during this continuing review period? Yes No

If yes, state the number:

b. Have any SAE occurred during this continuing review period? Yes No

If yes, number of SAE:

c. Have you reported the SAE to EC during this continuing review period? Yes No

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8. Has there been any protocol deviations/violations that occurred during this continuing review period?
Yes No

If yes, number of deviations

Have you reported the deviations to EC? Yes No

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9. In Case of Multicentric trials, have reports of off-site SAEs been submitted to the EC during this continuing review period? Yes No NA

10. Are there any publications or presentations during this continuing review period? Yes No

If yes, give details

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Signature of Principal Investigator (PI) with Date: