

Annexure 2 AX 02 / SOP 07/V6.1

(Annexure 3)



Continuing Review / Annual 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: Validity of approval:
2. Date of Start of study: Proposed date of Completion:
Period of Continuing Report: ---- to -----
3. Does the study involve recruitment of participants? Yes No
(a) If yes, Total number expected..... Number Screened: Number Enrolled:
Number Completed:..... Number on followup:.....
(b) Enrolment status - ongoing / completed/ stopped
(c) Report of DSMB¹⁶ Yes No NA
(d) Any other remark.....
.....
(e) Have any participants withdrawn from this study since the last approval? Yes No
If yes, total number withdrawn and reasons:
4. Is the study likely to extend beyond the stated period ?¹⁷ Yes No
If yes, please provide reasons for the extension.
5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?
If No, skip to item no. 6 Yes No
(a) If yes, date of approval for protocol and ICD :
(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes No
If yes, when / how:

¹⁶ In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.

¹⁷ Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC

6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes No

If yes, discuss in detail:
.....
.....

7. Have any ethical concerns occurred during this period? Yes No

If yes, give details:.....
.....

8. (a) Have any adverse events been noted since the last review? Yes No

Describe in brief:
.....
.....

(b) Have any SAE's occurred since last review? Yes No

If yes, number of SAE's :..... Type of SAE's:
.....
.....

(c) Is the SAE related to the study? Yes No

Have you reported the SAE to EC? If no, state reasons Yes No
.....
.....

9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations
Have you reported the deviations to EC? If no, state reasons Yes No
.....
.....

10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes No NA

11. Are there any publications or presentations during this period? If yes give details Yes No

.....
.....

Any other comments:.....
.....

Signature of PI:

dd	mm	yy
----	----	----