

Annexure 1
AX 01 / SOP 06/V6.1

Protocol/Protocol related documents Amendment request & Assessment form

(Annexure 4)



Application/Notification form for Amendments

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No.

Title of study:

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Principal Investigator (Name, Designation and Affiliation):

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1. Date of EC approval:

Date of start of study

2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD ¹⁰

3. Impact on benefit-risk analysis Yes No

If yes, describe in brief:

.....

4. Is any re-consent necessary? Yes No

If yes, have necessary changes been made in the informed consent? Yes No

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants)

Full review by EC (There is an increased alteration in the risk to participants)

6. Version number of amended Protocol/Investigator's brochure/ICD:

Signature of PI:

¹⁰Location implies page number in the ICD/protocol where the amendment is proposed.