



# INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

IEC No. of the Project: \_\_\_\_\_

## Annexure 1 AX 01/SOP 06/V 7.1 Protocol/Protocol related documents Amendments Request Form

Date: .....

Study Title: .....

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

1. Date of EC approval: ..... Date of start of study: .....

2. Details of Amendment(s)

Sr. No.	Existing Provision	Proposed Amendment	Reason	Location in the Protocol/Informed Consent Document (ICD)

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 Principal Investigator (PI) with date: .....