



# 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 Application/Notification form for Amendments

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: .....