



INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

IEC No. of the Project:

Annexure 1 AX 01/SOP 05-C/V 7.1 Application form for Expedited Review

Date:

Study Title:

Principal Investigator (Name, Designation & Affiliation):

1. Choose reason why expedited review from EC is requested?

- i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples.
- ii. Involves clinical documentation materials that are non-identifiable (Data, Documents, Records).
- iii. Modification or amendment to approved protocol (Administrative Changes/Correction of typographical errors and change in researcher(s)).
- iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposals.
- v. Minor deviation from originally approved research causing no risk or minimal risk.
- vi. Progress/Annual Report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee.
- vii. For Multicentric research where a designated EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
- viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017).
- ix. Any Other (Please Specify)

2. Is waiver of consent being requested? Yes No

3. Does the research involve vulnerable persons? Yes No

If Yes, give details

Signature of Principal Investigator (PI) with date:

Comments of EC Secretariat:

Signature of Member Secretary with date: