

Annexure 1 AX 01 / SOP 05-B/V6.1

(Annexure 1)



Application Form for Expedited Review 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. Choose reasons why expedited review from EC is requested¹² ?

- 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 proposal.
- 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 multicentre 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 persons¹³ ? Yes No

If Yes give details:

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Signature of PI:

Comments of EC Secretariat:

Signature of Member Secretary:

¹² Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2

¹³ For details, refer to application for initial review, Section-C, 5(b)

* In case this is first submission, leave it blank