

**Annexure 01/SOP/7B/V2.1**

**For Expedited Review**

**Additional information to be provided with Application Form**

SMVMCH-EC Ref. No. (for office use) :

Title of study:

Principal Investigator (Name, Designation and Affiliation):

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

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

1. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples.
2. Involves clinical documentation materials that are non-identifiable (data, documents, records).
3. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)).
4. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal
5. Minor deviation from originally approved research causing no risk or minimal risk.
6. 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.
7. 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.
8. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017).
9. Any other (please specify)

Signature of PI with date:

Comments of EC Secretariat:

Signature of Member Secretary with date: