(Annexure 1) Application Form for Expedited Review

Logo of the Institute

(Name of the Institution)

EC Ref. No. *(for office use):

Title of study:

Principal Investigator (Name, Designation and Affiliation):

- 1. Choose reasons why expedited review from EC is requested¹²?
 - i. Involve non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples
 - ii. Involve 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 proposals previously approved through expedited review, full review or continuing review of approved proposals
 - v. Minor deviations from originally approved research causing no risk or minimal risk
 - vi. Progress/annual reports 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 has approved the proposal, a participating EC may review participating centre specific information and modification in the study proposal through full committee meeting/ expedited review depending on the importance of local consent related issues involved specific to the centre.
 - 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 ?
- Does the research involve vulnerable person¹³?
 If Yes give details:

Signature of PI: enter a date.

Comments of EC Secretariat:

Signature	of	Member	Secretary:
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Click here to enter a date.

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Click here to

Yes No

¹²Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2
 ¹³For details, refer to application for initial review, Section-C, 5(b)
 ^{*}In case this is first submission, leave it blank

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