Application Form for Expedited review

Title of study: …………………………………………………………………………………………............................……………………………………………………………………………………………………………

Principal Investigator (Name, Designation and Affiliation): ……………………………………...................……………………………………..……………………………………………………………………………………………………………………………………………............................……………………………………………………………………………

1. Choose reasons why expedited review from EC is requested1?
   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.

* 1. 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 full committee common review 
  2. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). 

ix. Any other (please specify)

1. Is waiver of consent being requested? Yes  No 
2. Does the research involve vulnerable persons2 ? Yes  No 

If Yes give details:

……………………………………………………………………………………………………

Signature of PI:

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

Comments of EC Secretariat:

Signature of Member Secretary:

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

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

2 For details, refer to application for initial review, Section-C, 5(b) \* In case this is first submission, leave it blank