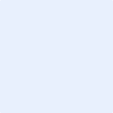
|  |  |
| --- | --- |
|  | **(Annexure 2)**  **Application Form for Expedited Review**  Rajiv Gandhi Centre for Biotechnology  **EC Ref. No*. \*(****for office use):* |

|  |
| --- |
| IHEC Proposal Number:  Title of study:  Principal Investigator (Name, Designation and Affiliation): |

|  |  |
| --- | --- |
| 1. Choose reasons why expedited review from EC is requested1? | |
| 1. Involve non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples |  |
| 1. Involve clinical documentation materials that are non-identifiable (data, documents, records). |  |
| 1. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)) |  |
| 1. Revised proposals previously approved through expedited review, full review or continuing review of approved proposals |  |
| 1. Minor deviations from originally approved research causing no risk or minimal risk |  |
| 1. 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. |  |
| 1. 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. |  |
| 1. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). |  |
| 1. Any other (please specify) |  |
| 1. Overview of the research   (Lay summary in 300 words)   1. Is waiver of consent being requested ? Yes  No | |
| 1. Does the research involve vulnerable person*2*? Yes  No   If Yes give details: | |

Signature of PI:  Click here to enter a date.

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

*2For details, refer to application for initial review, Section-C, 5(b)*

*\*In case this is first submission, leave it blank*

*\*SAE – Serious Adverse Events*