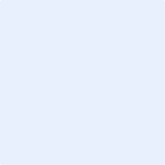
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|  | **(Annexure 5)**  **Continuing Review/ Annual report format**  Rajiv Gandhi Centre for Biotechnology    **EC Ref. No*.(****for office use):* |

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

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| --- | --- | --- |
|  | Date of EC Approval: Click here to enter a date. | Validity of approval: Click here to enter a date. |
|  | Date of Start of study: Click here to enter a date. | Proposed date of Completion: Click here to enter a date. |
|  | Period of Continuing ReportClick here to enter a date. | ---- to *------* Click here to enter a date. |
|  | Funding: Yes  No  Pending  Funded By: | Funding until: |
|  | Does the study involve recruitment of participants? Yes  No   1. If yes, Total number approved by EC       No. Enrolled:       No. Envisaged:     Planned recruitment timeline:       If delayed, state reason:       .   1. Enrolment status – ongoing / completed/ stopped 2. Any other remark | |
|  | 1. Have any participants withdrawn from this study since the last approval? Yes  No  NA   If yes, total number withdrawn and reasons: | |
|  | Is the study likely to extend beyond the stated period*1*? Yes  No  If yes, please provide reasons for the extension | |
|  | Have there been any amendments in the research protocol/informed consent document (ICD) during the past approval period?  **If No, skip to item no. 8**  Yes  No | |
| (a) If yes, date of approval for protocol and ICD : Click here to enter a date. | |
|  | (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants?  If yes, when / how:       Yes  No    If no, why: | |

*1Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

|  |  |
| --- | --- |
|  | Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes  No  If yes, discuss in detail: |
|  | Have any ethical concerns occurred during this period? Yes  No  If yes, give details |
|  | Are there any publications or presentations during this period? If yes give details Yes  No    Any other comments: |
|  | Interim data report (300words) |
|  | **For Clinical Trials Only**   1. Does the study have a DSMB? Yes  No 2. Is the DSMB report attached? Yes  No 3. Have any adverse events been noted since the last review? Yes  No   Describe in brief:  (c) Have any SAE’s3 occurred since last review? Yes  No  If yes, number of SAE’s :       Type of SAE’s:  (d) Is the SAE related to the study? Yes  No  Have you reported the SAE to EC? If no, state reasons Yes  No |
|  | Has there been any protocol deviations/violations that occurred during this period?  If yes, number of deviations  Have you reported the deviations to EC? If no, state reasons Yes  No |
|  | In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC  Yes  No  NA |

Signature of PI:  Click here to enter a date.

*2In case there is a Data Safety Monitoring Board (DSMB) for the study; provide a copy of the report from the DSMB. If not write NA.*

*3SAE – Serious Adverse Events*