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

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| 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 Have any participants withdrawn from this study since the last approval?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 If yes, total number withdrawn and reasons:       |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*

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|  | 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*