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|  |  **(Annexure 8)** **Study completion/ Final report format** Rajiv Gandhi Centre for Biotechnology |

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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. |
|  | Date of Start of Study: Click here to enter a date. Date of study completion:Click here to enter a date. Duration of the study:       |
|  | Provide details of:a) Total no. of study participants approved by the EC for recruitment:      b) Total no. of study participants recruited:      c) Total number of participants withdrawn from the study (if any):       Provide the reasons for withdrawal of participants1:        |
|  | Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)       |
|  | Describe the main Ethical issues encountered in the study (if any)       |
|  | State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study periodDeviations:       Violation:       Amendments:       |
|  | Describe in brief Plans for archival of records / Record Retention:       |
|  | Is there a plan for post study follow-up Yes  No If yes, describe in brief:       |
|  | Do you have plans for ensuring that the data from the study can be shared/ accessed easily? If yes, describe in brief:       Yes  No   |
|  | Is there a plan for post study benefit sharing with the study participants? Yes  No If yes, describe in brief:       |
|  | Describe results (summary) with Conclusion2:      |
|  | Number of SAEs3 that occurred in the study:       |
|  | Have all SAEs been intimated to the EC: Yes  No  |
|  | Is medical management or compensation for SAE provided to the participants? Yes  No If yes, provide details      |

Signature of PI:  Click here to enter a date.

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| 1 Explanation for the withdrawal of participants whether by self or by the PI.2 For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.3SAE – Serious Adverse Events. |