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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 of study participants recruited:  c) Total number of participants withdrawn from the study (if any):  Provide the reasons for withdrawal of participants1: |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 period  Deviations:       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. |