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|  |  **(Annexure 9)** **Premature Termination/ Suspension/ Discontinuation 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. | Date of start of study: Click here to enter a date.  |
|  | Date of Last Progress Report Submitted to EC: Click here to enter a date. |
|  | Date of Termination/suspension/discontinuation: Click here to enter a date. |
|  | Tick the appropriatePremature Termination  Suspension  Discontinuation  |
| Reason for Termination/Suspension/Discontinuation:      Action taken Post Termination/ Suspension/Discontinuation:       |
|  | Plans for post study follow up/withdrawal**1** (if any):       |
|  | Details of study participants: |
| Total participants to be recruited:       Screened:       Screen failures:        |
| Enrolled:       Consent Withdrawn:       Reason(Give details):       |
| Withdrawn by PI:       Reason(Give details):       |
| Active on treatment:      Completed treatment :      Participants on Follow-up:       |
| Participants lost to follow up:       Any other:       No. of drop outs:       Reasons for each drop-out:       |
|  | Total Number of SAEs reported till date in the study:      Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes  No  |
|  | Have there been participant complaints or feedback about the study? Yes  No If yes, provide details       |
|  | Have there been any suggestions from the SAE Sub Committee? Yes  No If yes, have you implemented that suggestion? Yes  No  |
|  | Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? (e.g., making arrangements for medical care of research participants): If yes, provide details  Yes  No      Summary of Results (if any):       |

 Signature of PI:  Click here to enter a date.

1 Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.