|  |  |
| --- | --- |
|  | **(Annexure 9)**  **Premature Termination/ Suspension/ Discontinuation 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) |

|  |  |  |
| --- | --- | --- |
|  | 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 appropriate  Premature 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| Enrolled:       Consent Withdrawn:       Reason(Give details): | |
| Withdrawn by PI:       Reason(Give details): | |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.