(Annexure 7)

Premature Termination/Suspension/ Discontinuation Report Format

Institute Ethics Committee

Indian Institute of Technology, Delhi

**EC Ref. No.** *(For office use):*



Title of study: ……………………….......…………………………………………………………………......................………………….……………………………..

…………………………………………………………………………………………………………………………………………………............................……………………

……………………………………………………………………………………………………………………………………………............................………………………… Principal Investigator (Name, Designation and Affiliation): ……………………………………...................……………………………………..

……………………………………………………………………………………………………………………………………………............................…………………………

……………………………………………………………………………………………………………………………………………........……....................……………………

1. Date of EC approval:

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

1. Date of last progress report submitted to EC:
2. Date of termination/suspension/discontinuation:

Date of start of study:

1. Tick the appropriate

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

Premature Termination  Suspension  Discontinuation 

Reason for Termination/Suspension/Discontinuation: ………………………………................................…………………………………………

………………………………………………………………………………………………………….......................................……………………………………………………

………………………………………………………………………………………………………….......................................……………………………………………………

………………………………………………………………………………………………………….......................................…………………………………………………… Action taken post Termination/ Suspension/Discontinuation (if any): ……………………………………………………………………………

………………………………………………………………………………………………………….......................................……………………………………………………

………………………………………………………………………………………………………….......................................……………………………………………………

………………………………………………………………………………………………………….......................................……………………………………………………

5. Plans for post study follow up/withdrawal21 (if any): ……………………................................……………………………………………………….

………………………………………………………………………………………………………….......................................……………………………………………………

…………………………………………………………………………………………………………............................................……………………………………………….

6. Details of study participants:

Total participants to be recruited: …….......……………. Screened: ………...........………… Screen failures:………..........……………..

Enrolled:………………............……….. Consent Withdrawn:…….......……………….. Reason (Give details): …………...……………..

………………………………………………………………………………………………………….......................................……………………………………………………

…………………………………………………………………………………………………………............................................……………………………………………….

Withdrawn by PI:…………............................………. Reason(Give details): ……………………………………………………………......………………

………………………………………………………………………………………………….......................................…………………………………………………….........

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

*Version 2.0*

Active on treatment: ……………..........… Completed treatment : ………..........…… Participants on follow-up: …………........……

Participants lost to follow up: ………………….......…… Any other: ……………..........……….. Number of drop outs:…………..............

Reasons for each drop-out: …………………………………………………………………………………………………………....................................………..

………………………………………………………………………………………………….......................................………………………….………………………….........

………………………………………………………………………………………………….......................................……………………….…………………………….........

………………………………………………………………………………………………….......................................……………….…………………………………….........

7. 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

1. Have there been participant complaints or feedback about the study? Yes  No If yes, provide details:……………………………………………………………………………………………………...................................………………………

…………………………………………………………………………………………………………………………………......................................……………………………

1. Have there been any suggestions from the SAE Sub Committee? Yes  No If yes, have you implemented that suggestion? Yes  No
2. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes  No (e.g., making arrangements for medical care of research participants): If Yes, provide details

………………………………………………………………………………………………….......................................…………………………………………………….........

………………………………………………………………………………………………….......................................…………………………………………………….........

Summary of results (if any): ………………………………………………….………………………..................................……………………………………….

………………………………………………………………………………………………….......................................…………………………………………………….........

………………………………………………………………………………………………….......................................…………………………………………………….........

………………………………………………………………………………………………….......................................…………………………………………………….........

………………………………………………………………………………………………….......................................…………………………………………………….........

………………………………………………………………………………………………….......................................…………………………………………………….........

Signature of PI: …………………………………………………………………………………..............….

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

*Version 2.0*