(Annexure 7)

Premature Termination/Suspension/ Discontinuation Report Format

Institute Ethics Committee

National Institute of Technology Meghalaya

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



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

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

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1. Date of EC approval:

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| --- | --- | --- |
| 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 |

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| dd | mm | yy |

Premature Termination  Suspension  Discontinuation 

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

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

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6. Details of study participants:

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

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 Consent Withdrawn:…….......………………..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

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Withdrawn by PI:…………............................……….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

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*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: …………………………………………………………………………………………………………....................................………..

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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:……………………………………………………………………………………………………...................................………………………

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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

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

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

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| dd | mm | yy |

*Version 2.0*