(Annexure 9)

Serious Adverse Event Reporting Format (Clinical trials)

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. Participant details :

Initials and Case No./ Age at the time of event Gender Weight: (Kgs)

Subject ID ………………………………. Male  Height: (cms)

………………………………. Female 

………………………………..

1. Report type: Initial  Follow-up  Final 

If Follow-up report, state date of Initial report

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

What was the assessment of relatedness to the trial in the initial report?

|  |  |  |
| --- | --- | --- |
| By PI – Related  | By Sponsor – Related  | By EC – Related  |
| Unrelated  | Unrelated  | Unrelated  |

3. Describe the event and specify suspected SAE diagnosis:……………………………………………...……………………………………….............

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1. Date of onset of SAE: Date of reporting:

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

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

1. Onset lag time after administration of intervention: Location of SAE (Clinic/Ward/Home/Other)

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1. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: …………………………………….............................................…..

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II. Indication(s) for which suspect study drug was prescribed or tested: ……………...........................................……………………..

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1. Route(s) of administration, daily dose and regimen, dosage form and strength : ……………………………………………………….

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1. Therapy start date: Stop date:

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

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

1. Was study intervention discontinued due to event? Yes  No 

*Version 2.0*

1. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes  No 

If yes, provide details about the reduced dose...................................................................................................................................

1. Did the reaction reappear after reintroducing the study drug / procedure? Yes  No  NA 

If yes, provide details about the dose....................................................................................................................................................

1. Concomitant drugs history and lab investigations:

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

* 1. Concomitant drug (s) and date of administration:

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

* 1. Relevant test/laboratory data with dates:

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* 1. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)………………………….......................................................................................…………

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1. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes  No 

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1. Seriousness of the SAE:

|  |  |  |
| --- | --- | --- |
| Death |  Congenitial anomaly |  |
| Life threatening |  Required intervention to prevent |  |
| Hospitalization-initial or prolonged |  permanent impairment / damage |  |
| Disability |  Others *(specify)* |  |

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1. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include infor- mation on who paid, how much was paid and to whom).

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1. Outcome of SAE:

|  |  |  |
| --- | --- | --- |
| Fatal |  Recovered |  |
| Continuing |  Unknown |  |
| Recovering |  Other *(specify)* |  |

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1. Was the research participant continued on the trial? Yes  No  NA 
2. Provide details about PI’s final assessment of SAE relatedness to trial.

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1. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes  No 

Provide details if communicated (including date)

1. Does this report require any alteration in trial protocol? Yes  No 
2. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom)……………………………………………………………………………………………………………….......................................................

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

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

*Version 2.0*