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| **Logo of the Institute** |  **(Annexure 9)** **Serious Adverse Event Reporting Format(Clinical trials)**        ***(Name of the Institution)*****EC Ref. No*.(for office use):*** |

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| Title of study:     Principal Investigator (Name, Designation and Affiliation)       |

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| 1.  | Participant details : |
|  | Initials and Case No./Subject ID      | Age at the time of event      | Gender Male  Female | Weight:     (Kgs) Height:      (cms) |
| 2.  | Report type: Initial  Follow-up  Final If Follow-up report, state date of Initial report Click here to enter a date.What was the assessment of relatedness to the trial in the initial report?

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| --- | --- | --- |
| By PI- Related  | By sponsor - Related  | By EC - Related  |
|  Unrelated  |  Unrelated  |  Unrelated  |

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| 3. | Describe the event and specify suspected SAE diagnosis:      |
| 4. | Date of onset of SAE: Click here to enter a date. | Date of reporting: Click here to enter a date. |
| 5. | Onset lag time after administration of intervention:      | Location of SAE (Clinic/Ward/Home/Other)      |
| 6. | Details of suspected study drug/device/investigational procedure causing SAE:  |
|  | 1. Suspect study drug (include generic name) device/intervention:
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| 1. 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: Click here to enter a date. Stop date: Click here to enter a date.
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| 7. | Was study intervention discontinued due to event? Yes  No |
| 8. | Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes  NoIf yes, provide details about the reduced dose. |
| 9. | Did the reaction reappear after reintroducing the study drug / procedure? Yes  No  NA If yes, provide details about the dose. |
| 10. | Concomitant study drugs history and lab investigations: 1. Concomitant study drug (s) and date of administration: Click here to enter a date.

     1. Relevant test/laboratory data with dates:Click here to enter a date.

     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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| 11. | Have any similar SAE occurred previously in this study? If yes, please provide details. Yes  No      |
| 12. | Seriousness of the SAE: |
|  | Death Life threateningHospitalization-initial or prolonged Disability |  | Congenital anomaly Required intervention to prevent permanent impairment / damageOthers (specify)      |  |
| 13. | Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).      |
| 14. | Outcome of SAE: |
|  | FatalContinuingRecovering |  | RecoveredUnknownOther (specify)      |  |
| 15. | Was the research subject continued on the trial? Yes  No  NA  |
| 16. | Provide the details about PI final assessment of SAE relatedness to trial.      |
| 17. | Has this information been communicated to sponsor/CRO/regulatory agencies? Yes  No Provide details if communicated (including date)       |
| 18. | Does this report require any alteration in trial protocol? Yes No |
| 19. | Provide details of compensation provided/ to be provided the participants (include information on who pays, how much, and to whom)Signature of PI: Click here to enter a date. |