(Annexure 6)

Logo of the Institute

Serious Adverse Event Reporting Format (Biomedical Health Research)

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(Name of the Institution) **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 ID	Age at the time of event	Gender	Weight:.....(Kgs)
.....	.....	Male ☐ Female ☐	Height:.....(cms)
.....	.....		

2. Suspected SAE diagnosis:.....

3. Date of onset of SAE: dd mm yy

Date of reporting SAE: dd mm yy

Describe the event [19]:

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4. Details of suspected intervention causing SAE [20]

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5. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

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

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[19] *Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious*

[20] *Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

7. In case of a multi-centric study, have any of the other study sites reported similar SAEs ?

(Please list number of cases with details if available)

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8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)

A. Expected event ☐ Unexpected event ☐

B.

Hospitalization	☐	Increased Hospital Stay	☐	Death	☐	Congenital anomaly/birth defect	☐
Persistent or significant disability/incapacity	☐	Event requiring intervention (surgical or medical) to prevent SAE	☐	Event which poses threat to life	☐	Others	☐

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In case of death, state probable cause of death.....

C. No permanent/significant functional/cosmetic impairment ☐

Permanent/significant functional/cosmetic impairment ☐

Not Applicable ☐

9. 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).

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10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom).....

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11. Outcome of SAE

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other *(specify)*	☐

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12. Provide any other relevant information that can facilitate assessment of the case such as medical history

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13. Provide details about PI's final assessment of SAE relatedness to research.

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Signature of PI: ..... dd mm yy