Annexure 2
AX02/SOP 11-B/V7.1
Serious Adverse Event Report (For Biomedical Health Research)

Investigator: …… **IEC No. of the Project:** ……

Study Title: ……

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1. Participant details:

Initials and ID	Age at the time 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:

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   ……
   ……
   ……

4. Details of suspected intervention causing SAE:

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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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   ……
   ……
   ……

7. In case of a multi-centric study, have any of the 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. Hospitalisation ☐ Increased Hospital Stay ☐ Death ☐ Congenital anomaly/ birth Defect ☐

Persistent or signifi cant disability / incapacity ☐ Event requiring inter- vention (Surgical or medical) to prevent SAE ☐ Event which poses threat of life ☐ Other ☐

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

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 participant (include information on who pays, how much, and to whom) ……

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11. Outcome of SAE

Resolved ☐ Ongoing ☐ Death ☐ Others (Specify) ☐

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12. Provided 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 trial.

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Signature of Principal Investigator: …… dd mm yy