



INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth G. S. Medical College and KEM Hospital, Mumbai.

IEC No. of the Project: _____

Annexure 2 AX02/SOP 11-B/V7

Serious Adverse Event Report (For Biomedical Health Research)

Investigator: IEC No. of the Project:

Study Title:

.....
.....

1. Participant details:

Initials and ID	Age at the time event	Gender	Weight: (Kgs)
.....	Male <input type="checkbox"/> Female <input type="checkbox"/>	Height: (Cms)

.....

2. Suspected SAE diagnosis:

3. Date of onset of SAE:

dd	mm	yy
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 Date of reporting SAE:

dd	mm	yy
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Describe the event:

.....
.....
.....

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
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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 significant disability / incapacity Event requiring intervention (Surgical or medical) to prevent SAE Event which poses threat of life Other

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).

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

11. Outcome of SAE

Resolved Ongoing Death Others (Specify)

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

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

Signature of Principal Investigator:

dd mm yy