



# Adverse Event/Serious Adverse Event Reporting Form

## Yenepoya Ethics Committee-3 (YEC-3)

EC Ref. No.

(For office use)

Title of study: .....

Principal Investigator (Name, Designation and Affiliation): .....

### 1. Participant details :

Initials and ID

Age at the time of event

Gender

Weight: ..... (Kgs)

Male ☐ Female ☐

Height: ..... (cms)

1. Suspected SAE diagnosis:.....

2. Date of onset of SAE:

Describe the event <sup>1</sup>:

Date of reporting SAE:

### 3. Details of suspected intervention causing SAE <sup>2</sup>

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

If Follow-up report, state date of Initial report

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

<sup>1</sup>Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious

<sup>2</sup>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)

6. 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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7. 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	<input type="checkbox"/>	Increased Hospital Stay	<input type="checkbox"/>	Death	<input type="checkbox"/>	Congenital anomaly/birth defect	<input type="checkbox"/>
Persistent or significant disability/incapacity	<input type="checkbox"/>	Event requiring intervention (surgical or medical) to prevent SAE	<input type="checkbox"/>	Event which poses threat to life	<input type="checkbox"/>	Others	<input type="checkbox"/>

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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 ☐

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

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10. Outcome of SAE

Fatal	<input type="checkbox"/>	Recovered	<input type="checkbox"/>
Continuing	<input type="checkbox"/>	Unknown	<input type="checkbox"/>
Recovering	<input type="checkbox"/>	Other (specify)	<input type="checkbox"/>

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

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

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Signature of PI: .....

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