



# INSTITUTIONAL ETHICS COMMITTEE

(Annexure 6)

PANJAB UNIVERSITY (PUIEC), CHANDIGARH-160014

## Serious Adverse Event Reporting Format (Biomedical Health Research)

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 <input type="checkbox"/> Female <input type="checkbox"/>	Height:.....(cms)
.....	.....		

### 2. Suspected SAE diagnosis:.....

3. Date of onset of SAE: <input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yy"/>	Describe the event <sup>19</sup> :
Date of reporting SAE: <input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yy"/>	
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### 4. Details of suspected intervention causing SAE <sup>20</sup>

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5. Report type: Initial  Follow-up  Final

If Follow-up report, state date of Initial report

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

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<sup>19</sup>Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious

<sup>20</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)

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

.....

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