INSTITUTIONAL ETHICS COMMITTEE

(Annexure 9)

PANJAB UNIVERSITY (PUIEC), CHANDIGARH-160014

Serious Adverse Event Reporting Format (Clinical trials)

EC Ref. No. *(For office use):*

Title of study: .....

.....

.....

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

.....

.....

1. Participant details :

Initials and Case No./	Age at the time of event	Gender	Weight:.....(Kgs)
Subject ID	.....	Male ☐	Height:.....(cms)
.....		Female ☐	
.....			

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

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

What was the assessment of relatedness to the trial in the initial report?

By PI –	By Sponsor –	By EC –
Related ☐	Related ☐	Related ☐
Unrelated ☐	Unrelated ☐	Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:.....

.....

.....

4. Date of onset of SAE: dd mm yy Date of reporting: dd mm yy

5. Onset lag time after administration of intervention: Location of SAE (Clinic/Ward/Home/Other)

....

6. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: .....

.....

II. Indication(s) for which suspect study drug was prescribed or tested: .....

.....

III. Route(s) of administration, daily dose and regimen, dosage form and strength : .....

.....

IV. Therapy start date: dd mm yy Stop date: dd mm yy

7. Was study intervention discontinued due to event? Yes ☐ No ☐

8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes ☐ No ☐

   If yes, provide details about the reduced dose.....

9. Did the reaction reappear after reintroducing the study drug / procedure? Yes ☐ No ☐ NA ☐

   If yes, provide details about the dose.....

10. Concomitant drugs history and lab investigations:

   I. Concomitant drug (s) and date of administration: dd mm yy

   .....

   .....

   II. Relevant test/laboratory data with dates: dd mm yy

   .....

   .....

   III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc).....

   .....

   .....

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

   .....

   .....

12. Seriousness of the SAE:

Death	☐	Congenitial anomaly	☐
Life threatening	☐	Required intervention to prevent	
Hospitalization-initial or prolonged	☐	permanent impairment / damage	☐
Disability	☐	Others *(specify)*	☐

   .....

13. 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).

   .....

   .....

14. Outcome of SAE:

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

   .....

15. Was the research participant continued on the trial? Yes ☐ No ☐ NA ☐

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

   .....

   .....

17. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes ☐ No ☐

   Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol? Yes ☐ No ☐

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

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