

Institutional Ethics Committee
Institute of Human Behaviour & Allied Sciences, Delhi

Version 2; 31 May, 2022

Annexure 15. Serious Adverse Event Reporting Form (Clinical trials)

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Participant details:

Initials and Case No./Subject ID	Age at the time of event	Gender	Weight: (Kg)
		Male <input type="checkbox"/>	Height: (cm)
		Female <input type="checkbox"/>	

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

If Follow-up report, state date of Initial report [Click here to enter a date.](#)

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

By PI- Related <input type="checkbox"/>	By sponsor - Related <input type="checkbox"/>	By EC - Related <input type="checkbox"/>
Unrelated <input type="checkbox"/>	Unrelated <input type="checkbox"/>	Unrelated <input type="checkbox"/>

3. Describe the event and specify suspected SAE diagnosis:

4. Date of onset of SAE: [Click here to enter a date.](#) Date of reporting: [Click here to enter a date.](#)

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:

Institutional Ethics Committee
Institute of Human Behaviour & Allied Sciences, Delhi

Version 2; 31 May, 2022

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

IV. Therapy start date: [Click here to enter a date.](#)
to enter a date.

Stop date: [Click here](#)

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 study drugs history and lab investigations:

I. Concomitant study drug (s) and date of administration: [Click here to enter a date.](#)

II. Relevant test/laboratory data with dates: [Click here to enter a date.](#)

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 ☐

Life threatening ☐

Hospitalization-initial or ☐

prolonged ☐

Disability ☐

Congenital anomaly ☐

Required intervention to prevent ☐

permanent impairment / damage ☐

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 ☐

Continuing ☐

Recovering ☐

Recovered ☐

Unknown ☐

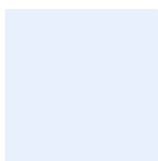
Other (specify) ☐

Institutional Ethics Committee
Institute of Human Behaviour & Allied Sciences, Delhi

Version 2; 31 May, 2022

15. Was the research subject continuing the trial? Yes ☐ No ☐ NA ☐
16. Provide the details about PI 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)

Signature of PI:



Click here to enter a date.