CHENNAI FERTILITY CENTRE

(Annexure 19)

Serious Adverse Event Reporting Format (Clinical Trials)

Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use):_____

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.....(Kgs) Height..... (cms)
_____	_____	Male ☐	
_____	_____	Female ☐	

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

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

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

By PI–Related ☐ By Sponsor – Related ☐ By IHEC – Related ☐

Unrelated ☐ Unrelated ☐ Unrelated ☐

3. Describe the event and specify suspected

SAE diagnosis: _____

_____

_____

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

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

_____ _____

6. Details of suspected study drug/s / device/s 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 :_____

_____

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

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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: dd mm yyyy

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

_____

II. Relevant test / laboratory data with dates:

_____

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? Yes ☐ No ☐

If yes, please provide details. _____

_____

12. Seriousness of the SAE:

Death	☐	Congenital 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).

_____

Signature of PI: _____ dd mm yyyy