CHENNAI FERTILITY CENTRE

(Annexure 16)

Serious Adverse Event Reporting Format (Biomedical Health Research)

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 ID	Age at the time of event	Gender	
_____	_____	Male ☐ Female ☐	Weight.....(Kgs) Height..... (cms)
_____	_____		

2. Suspected SAE diagnosis :

3. Date of onset of SAE: dd mm yyyy

Date of reporting SAE: dd mm yyyy

Describe the event[19]:

_____

_____

_____

_____

_____

4. Details of suspected intervention causing SAE[20]

_____

_____

_____

_____

_____

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

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

6. Have any similar SAE occurred previously in this study? If yes, please provide details

_____

_____

_____

_____

_____

_____

[19]Duration, setting, site, signs, symptoms, severity, criteria for regarding the serious event.

[20]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).

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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).

8. Tick which ever 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).

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

11. Outcome of SAE

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

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

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

Signature of PI: _____ dd mm yyyy