



**Premature Termination /  
Suspension / Discontinuation Report Format**  
Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use): \_\_\_\_\_

Title of study: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Principal Investigator (Name, Designation and Affiliation): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

1. Date of IHEC approval:    Date of start of study

2. Date of last progress report submitted to IHEC:

3. Date of termination / suspension / discontinuation:

4. Tick the appropriate

Premature Termination  Suspension  Discontinuation

Reason for Termination / Suspension / Discontinuation \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Action taken post Termination / Suspension / Discontinuation (if any): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

5. Plans for post study followup / withdrawal<sup>21</sup> (if any): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

6. Details of study participants:

Total No. participants to be recruited: \_\_\_\_\_ Screened: \_\_\_\_\_ Screen failures: \_\_\_\_\_

Enrolled: \_\_\_\_\_ Consent Withdrawn: \_\_\_\_\_ Reason (Give details): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Withdrawn by PI: \_\_\_\_\_ Reason (Give details): \_\_\_\_\_

<sup>21</sup> Describe post-termination / suspension / discontinuation follow up plans if any. Also describe any withdrawal plans for the study.



Active on treatment: \_\_\_\_\_ Completed treatment: \_\_\_\_\_ Participants on follow-up: \_\_\_\_\_

Participants lost to follow up: \_\_\_\_\_ Any other: \_\_\_\_\_ Number of drop-outs: \_\_\_\_\_

Reasons for each drop-out: \_\_\_\_\_

7. Total number of SAEs reported till date in the study

Have any unexpected adverse events or outcomes observed in the study been reported to the IHEC? Yes  No

8. Have there been participant complaints or feedback about the study? Yes  No

If yes, provide details: \_\_\_\_\_  
\_\_\_\_\_

9. Have there been any suggestions from the SAE Sub Committee? Yes  No

If yes, have you implemented that suggestion? Yes  No

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes  No

(e.g., making arrangements for medical care of research participants): If Yes, provide details Yes  No

\_\_\_\_\_

Summary of results (if any) \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Signature of PI: \_\_\_\_\_

dd mm yyyy