CHENNAI FERTILITY CENTRE

(Annexure 22)

Study Completion / Final Report

Chennai Fertility Centre and Research Institute

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

Title of study: _____

_____

_____

Principal Investigator (Name, Designation and Affiliation): _____

_____

_____

1. Date of EC approval: dd mm yyyy
2. Date of Start of Study: dd mm yyyy Date of study completion: dd mm yyyy
3. Provide details of:

a) Total number of study participants approved by the IHEC for recruitment: _____

b) Total number of study participants recruited: _____

c) Total number of participants with drawn from the study (if any): _____

Provide the reasons for withdrawal of participants[23]: _____

_____

_____

4. Describe in brief the publication / presentation / dissemination plans of the study findings (Also, mention if both positive and negative results will be shared).

_____

_____

5. Describe the main ethical issues encountered in the study (if any).

_____

_____

6. State the number (if any) of Deviations / Violations / Amendments made to the study protocol during the study period.

Deviations:_____ Violation:_____ Amendments: _____

7. Describe in brief plans for archival of records / record retention:_____

_____

_____

_____

_____

[23] Explanation for the withdrawal of participants whether by self or by the PI.

8. Is there a plan for post study follow-up? Yes ☐ No ☐

If yes, describe in brief: _____

9. Do you have plans for ensuring that the data from the study can be shared / accessed easily? Yes ☐ No ☐ If yes,

If yes, describe in brief: _____

10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No ☐

If yes, describe in brief:

11. Describe results (summary) with Conclusion [24]: _____

12. Number of SAEs that occurred in the study: _____

13. Have all SAEs been intimated to the IHEC? Yes ☐ No ☐

14. Is medical management or compensation for SAE provided to the participants ?

If yes, provide details _____

Signature of PI: _____ dd mm yyyy

[24] For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the IHEC once it is ready.