CHENNAI FERTILITY CENTRE

(Annexure 13)

Continuing Review / Annual 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 EC Approval: dd mm yyyy

2. Date of Start of study: dd mm yyyy

Period of Continuing Report: dd mm yyyy

Validity of approval: dd mm yyyy

Proposed date of Completion: dd mm yyyy

---- to ------ dd mm yyyy

3. Does the study involve recruitment of participants?

(a) If yes, Total number expected_____Number Screened:_____Number Enrolled: _____

Number Completed_____Number on followup _____

(b) Enrolment status – ongoing / completed / stopped

(c) Report of DSMB[16] Yes ☐ No ☐ NA ☐

(d) Any other remark _____

_____

(e) Have any participants with drawn from this study since the last approval? Yes ☐ No ☐ NA ☐

If yes, total number with drawn and reasons: _____

_____

_____

4. Is the study likely to extend beyond the stated period? [17] Yes ☐ No ☐

If yes, please provide reasons for the extension _____

_____

5. Have there been any amendments in there search protocol / Informed Consent Document (ICD) during the past approval period? Yes ☐ No ☐

If No, skip to item no. 6

(a) If yes, date of approval for protocol and ICD: dd mm yyyy

(b) In case of amendments in the research protocol / ICD, was re-consent sought from participants? Yes ☐ No ☐

If yes, when / how: _____

_____

[16] In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.

[17] Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the IHEC .

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6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes ☐ No ☐

If yes, discuss in details: _____

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐

If yes, give details: _____

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

Describe in brief: _____

(b) Have any SAE's occurred since last review? Yes ☐ No ☐

If yes, number of SAE's _____ Type of SAE's: _____

(c) Is the SAE related to the study? Yes ☐ No ☐

Have you reported the SAE to IHEC? If no, state reasons Yes ☐ No ☐

9. Has there been any protocol deviations / violations that occurred during this period?

If yes, number of deviations _____

Have you reported the deviations to IHEC? If no, state reasons Yes ☐ No ☐

10. In case of multi Centreic trials, have reports of off-site SAEs been submitted to the IHEC? Yes ☐ No ☐ NA ☐

11. Is there any change in Investigators / Co-Investigators? Yes ☐ No ☐

If yes, give details _____

12. Are there any publications or presentations during this period? Yes ☐ No ☐

If yes, give details

Any other comments:

Signature of PI: _____ dd mm yyyy