



(Annexure 14)

Application / Notification Form for Amendments

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:

dd mm yyyy

Date of start of study

dd mm yyyy

2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol / ICD 18

3. Impact on benefit-risk analysis

Yes No

If yes, describe in brief: _____

4. Is any re – consent necessary?

Yes No

If yes, have necessary changes been made in the informed consent?

Yes No

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants)

Full review by IHEC (There is an increased alteration in the risk to participants)

6. Version number of amended Protocol / Investigator's brochure / ICD: _____

Signature of PI: _____ dd mm yyyy

¹⁸Location implies page number in the ICD¹⁸ / protocol where the amendment is proposed.