(Annexure 31)

Undertaking by the Principal Investigator

Chennai Fertility Centre and Research Institute

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

1. NAME AND CODE NUMBER OF THE PROJECT.

2. NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR.

3. OTHER MEMBERS OF THE RESEARCH TEAM.

4. NAME AND ADDRESS OF ANY OTHER MEDICAL COLLEGE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE.

5. NUMBER OF ONGOING PROJECTS / CLINICAL TRIALS IN WHICH YOU ARE PI.

1. I confirm that I will initiate the study only after obtaining all regulatory clearances.
2. I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IHEC at the earliest.
3. I confirm that the Co-PI and other members of the study team have been informed about their obligations and are qualified to meet them.
4. I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under ICMR and National Regulatory Guidelines are adhered to.
5. I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit / inspection by IHEC, Regulatory authorities, Sponsors or their authorized representatives.
6. I will inform the IHEC and the Sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.
7. I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
8. I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
9. I will inform IHEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IHEC within 4 weeks of the due date.

Signature of Principal Investigator Date