



(Annexure 15)

Protocol Violation / Deviation Reporting Form (Reporting by case)

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. Participant ID: _____ Date of occurrence

3. Total number of deviations / Violations reported till date in the study: _____

4. Deviation / Violation identified by: Principal Investigator / study team Sponsor / Monitor
SAE Sub - Committee / IHEC

5. Is the deviation related to (Tick the appropriate box):

Consenting	<input type="checkbox"/>	Source documentation	<input type="checkbox"/>
Enrollment	<input type="checkbox"/>	Staff	<input type="checkbox"/>
Laboratory assessment	<input type="checkbox"/>	Participant non-compliance	<input type="checkbox"/>
Investigational Product	<input type="checkbox"/>	Others (specify)	<input type="checkbox"/>
Safety Reporting	<input type="checkbox"/>		

6. Provide details of Deviation / Violation: _____

7. Corrective action taken by PI / Co-I: _____

8. Impact on (if any): Study participant Quality of data

9. Are any changes to the Study / Protocol required?

If yes, give details _____

Signature of PI: _____