

(Annexure 29) Template for Participant Information Sheet (PIS) Participant Information Sheet

Chennai Fertility Centre and Research Institute

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

The project must be accompanied by the participant information sheet addressed to the patient or participant or parent / guardian, in case of minor. While formulating the participant information sheet, investigator must provide the subjects with the following information in English and Tamil, in a simple lay man's language, in a narrative form, directed to Participant / Legally Authorized Representative (LAR), covering all the points given on the website, which can be understood by them:

Title of the study

Name of the research institution

- 1. Purpose of the study.
- 2. Study procedures.
- 3. Risk of participation.
- 4. Benefits of participation.
- 5. Confidentiality.
- 6. Compensation.
- 7. Participant's rights.
- 8. Contacts.
- 9. Amount of blood sample in quantity, in tea spoon full, to be taken should be mentioned.
- 10. Costs and source of investigations, disposables, implants and drugs / contrast media mustbe mentioned.
- 11. In case of drug trials:
 - a. The chemical name of the drug.
 - b. Initial Bio Equivalent study of the drug / references should be provided.
- 12. Self-certification should be given that translation to vernacular is accurate.

(For queries related to the study: PI, name, contact details incl. phone number).

(For queries related to the rights as a study participant, please write to: The Member Secretary, IHEC, CFC & RI, Aminjikarai, Chennai – 600030, Ph: 044-45588822).