



# **INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES** **SHEIKHPURA, PATNA - 800014**

## **PARTICIPANT INFORMATION SHEET (PIS)**

The protocol 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 simple **understandable layman's language in English & Hindi**, which can be understood by them:

- i) Title of the study/project.
- ii) IGIMS and methods of the research.
- iii) Expected duration of the subject participation.
- iv) The benefits to be expected from the research to the subject or to others.
- v) Any risk to the subject associated with the study.
- vi) Maintenance of confidentiality of records.
- vii) Provision of free treatment for research related injury.
- viii) Compensation of subjects for disability or death resulting from such injury.
- ix) Freedom of individual to participate and to withdraw from research at any time. Without penalty or loss of benefits to which the subject would otherwise be entitled.
- x) Amount of blood sample to be taken should be mentioned in PIS in Tea Spoon Full.
- xi) Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned in the PIS.
- xii) Telephone number/contact number of the candidate and one of the investigators must be mentioned in the PIS.
- xiii) In case of drug trials:
  - a) The chemical name of the drug, date of its manufacturing and batch number must be mentioned
  - b) Initial Bio equivalent study of the drug / references should be provided
- xiv) Self certification should be given that translation to vernacular is accurate.