

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

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 Hindi, in a simple layman's language, in a narrative form, directed to Participant /LAR, covering all the points given on the website, which can be understood by them:

- i) Title of the Study/Project
- ii) Aims 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 in quantity, in Tea Spoon Full, to be taken should be mentioned.
- xi) Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned. xii) Telephone number/contact number of Principal Investigator and Co investigator at the top of each page.
- xii) 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
- xiii) Self certification should be given that translation to vernacular is accurate.
- xiv) Statement that there is a possibility of failure of IP to provide intended therapeutic effect
- xv) Statement that in case of placebo controlled trials, the placebo administered to the subjects shall not have any therapeutic effect