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