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, in a narrative form, directed to participant / LAR, covering all the points given on 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 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.