

Principal Investigator Mobile: _____

Co-Investigator Mobile: _____

Annexure 3

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, the investigator must provide the subjects with the following information in **English and Hindi, in a simple layman's language which can be understood by them, in a narrative form, directed to the participant/ LAR, covering all the points:**

1. Study Title:
2. Aims and methods of the research study:
3. Expected duration of participation:
4. The benefits to be expected from the research to the participant or to others:
5. Any risk or discomfort to the participant associated with the study:
6. Maintenance of confidentiality of records:
7. Provision of free treatment for research related injury:
8. Compensation of subjects for disability or death resulting from such injury:
9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise:
10. Amount of blood sample (quantity in tea spoon full) to be taken:
11. Costs and source of investigations, disposables, implants and drugs/ contrast media:
12. In case of a drug trial:
 - a. Chemical name of drug: _____
 - b. Date of manufacturing and batch number: _____
 - c. References of initial bioequivalence study: _____

I/we certify that all information provided is correct to best of my/our knowledge and translation to vernacular language & back translation is correct.

Signature of PI, Co-PI