

## Annexure - 5

### 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 Tamil, in a simple layman's language, in a narrative form, directed to Participant / Legally Authorised Representative (LAR), covering all the points given on the website, which can be understood by them:

Title of the study / project

Investigators name

Purpose of the study

Study details

Statement mentioning that it is research

Purpose and methods of the research in simple language

Expected duration of the participation and frequency of contact with estimated number of participants to be enrolled, types of data collection and methods

Benefits to the participant, community or others that might reasonably be expected as an outcome of research

Any foreseeable risks, discomfort or inconvenience to the participant resulting from participation in the study

Extent to which confidentiality of records could be maintained, such as the limits to which the researcher would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality

Payment/reimbursement for participation and incidental expenses depending on the type of study

Free treatment and/or compensation of participants for research-related injury and/or harm

Freedom of the individual to participate and/or withdraw from research at any time

without penalty or loss of benefits to which the participant would otherwise be entitled

10. The identity of the research team and contact persons with addresses and phone numbers ( example, PI/Co PI for queries related to the research and Chairperson/Member Secretary/ or helpline for appeal against violations of ethical principles and human rights)