INFORMED CONSENT DOCUMENT (ICD) PART-I

PATIENT / PARTICIPANT INFORMATION SHEET

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Tamil which can be understood by the participant. (Do not copy & paste from the study protocol). Do not use technical terms in the PIS. If participants are children, the participant information sheet should address the parents/LAR of the children and should be worded accordingly.

- Title of the project
- Name of the Student Researcher/Guide/Co-Guides
- Purpose of this project/study
- Procedure/methods of the study
- Expected duration of the subject participation
- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Reimbursement for participating in the study
- Compensation to the participants for foreseeable risks and unforeseeable risks related to research study leading to disability or death.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Possible current and future uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and mobile number of the Student Researcher and Guide:
- Address and Contact details of IEC office –

Signature of the participant: Signature of the investigator:

Place:

Date: