

Instructions for filling consent forms

- Informed Consent Document should comprise Patient Information Sheet and the consent forms in English and Tamil.
- **Purpose of the study and procedures:** The investigator must provide information to the subjects in a simple language (avoid medical jargons). Please avoid copying & pasting from other study protocol. Use simple Tamil words so that participants can understand.
- It should address the subjects, in a dialogue format. (eg. You will be asked some questions regarding. Your data will be extracted from records, You will be asked to...)
- A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable.
- In case of telephonic contact, please add a telephonic script in addition to the PIS format.

Studies involving children

If participants are children, the participant information sheet should address the parents/LAR of the children and should be worded accordingly.

- Children <7 years - include parent / LAR consent form.
- Children 7-12 years - in addition to parent / LAR consent form, record verbal assent in LAR form.
- Children 12 - 18 years of age - include written assent form.
- Assent form should provide information about the study in a simple language comprehensible to a child from 12-18 years.
- Language used should be simpler for children in the age group 7-12 years compared to children in the age group 12-18 years.