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.