**INFORMED CONSENT {To be edited as per your study} To be also translated into regional Language**1. Checklist of informed consent documents for clinical trial subject,–
1.1 Essential elements:

(i) Statement that the study involves research and explanation of the purpose of the research.
(ii) Expected duration of the participation of subject.
(iii) Description of the procedures to be followed, including all invasive procedures.
(iv) Description of any reasonably foreseeable risks or discomforts to the Subject.

(v) Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
(vi) Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
(vii) Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.
(viii) Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).
(ix) Statement describing the financial compensation and the medical management as under:
(a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.
(b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.
(x)An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.
(xi) The anticipated prorated payment, if any, to the subject for participating in the trial.
(xii) Responsibilities of subject on participation in the trial.
(xiii) Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.
(xiv) Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.
(xv) Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

(xvi) Any other pertinent information.

1.2 Additional elements, which may be required:
(a)Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.
(b)Additional costs to the subject that may result from participation in the study.
(c)The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
(d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.
(e). A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable.
(f) Approximate number of Subjects enrolled in the study.
2. Format of informed consent form for Subjects participating in a clinical trial –
Informed Consent form to participate in a clinical trial
Study Title:
Study Number:
Subject's Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject's Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Date of Birth/Age: \_\_\_\_\_\_\_\_\_
Address of the Subject \_\_\_
Qualification \_\_\_\_\_\_\_\_\_\_\_\_\_
Occupation: Student or Self-Employed or Service or Housewife or Others (Please click as appropriate) .
Annual Income of the subject:
Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of
trial related death).
 Place Initial box (Subject)

(i) I confirm that I have read and understood the information [ ]
Sheet dated \_\_\_\_\_\_\_\_\_\_\_ for the above study and have
had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and [ ]
that I am free to withdraw at any time, without giving any reason,
without my medical care or legal rights being affected.
(iii) I understand that the Sponsor of the clinical trial, others [ ]

 working on the Sponsor's behalf, the Ethics Committee
and the regulatory authorities will not need my permission
to look at my health records both in respect of the current
study and any further research that may be conducted in
relation to it, even if I withdraw from the trial.
I agree to this access. However, I understand that
my identity will not be revealed in any information

released to third parties or published.
(iv)I agree not to restrict the use of any data or results that arise [ ]

from this study provided such a use is only for scientific purposes

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: Date: \_\_\_\_\_/ \_\_\_\_ /
Signatory’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of the Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ /
Study Investigator’s Name: \_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of the Witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ /
Name of the Witness:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant.