**ANNEXURE.9: Form IV (B)**

**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 Name:

Subject’s Initials:

Date of birth/Age:

Address of 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/her relation to the

subject (for the purpose of compensation in case of trial

related death).

Please initial Box (Subject)

1. I confirm that I have read and understood the information sheet dated\_\_\_\_\_\_\_\_\_\_ for the above study and have had the opportunity [ ] to ask question.
2. I understood that my participation in the study is voluntary and that I am free to withdraw at any time’ without giving any reason. [ ]
3. Without my medical care or legal rights being affected.
4. 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.
5. However, I understand that my identity will not be revealed in any information released to third parties or published.
6. I agree not to restrict the use of any data or result that arise from this study
7. Provided such a use only for scientific purpose(s) [ ].
8. 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Investigator’s Name: \_\_\_\_\_\_\_\_\_\_\_

Signature of the Witness\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_

Signature of the Witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant.