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: _____
[1][Address of the Subject_____
Qualification _____
Occupation: Student/Self-Employed/ Service/Housewife/Others (Please tick as appropriate)
Annual Income of the subject _____
Name and address of the nominee(s) and his relation to the subject _____ (for the purpose of compensation in case of trial related death).]

		Please 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 purpose(s)	[ ]
(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: _____

[1][Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handled over to the subject or his/her attendant.]

1. Ins. by G.S.R 53(E), dt. 30-01-2013