Annexure 8
AX 08/SOP 05/V6

Sample Format of an Informed consent document in English
(This template should be customized according to the requirement of individual research project)

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No. .....

I Project title:

To test the efficacy and tolerability of XXXXXXXX (an antihypertensive test drug) as compared to XXXXX (a standard antihypertensive drug)

II Introduction:

You are invited to participate in a research study. It is important that you read this description of the study and understand your role in it including the nature and risks of participation.

Please give your consent to participate in this clinical study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant.

III Purpose of the study:

It is well known that people who suffer from high blood pressure are at high risk for cardiovascular disease, including heart attacks, strokes and even death. Anti-hypertensive medications are commonly prescribed to such patients to prevent the occurrence of cardiovascular events. XXXX is a new drug, which has been found to decrease the blood pressure in initial studies. The study plans to study the efficacy and safety of this drug in patients having high blood pressure.

IV Number of research participants and expected duration of each participant in the study:

You will be one of approximately XXX people who will participate in this study. You will be in the study for about XXX days. (In multicentric study, mention that the study is also being carried out at xxx other centers).

V Study procedures to be followed:

If you agree to participate in this study you will a) be asked about previous medical problems, your current health and your medications; b)have a brief physical examination (to give details);c) need to undergo baseline investigation such as XXXXXX(to give details)

The study staff will review the results of these evaluations & test. If you are eligible to participate you will be randomly assigned (like the flip of a coin) to a study group to receive one of the two study treatments.

The study would require a total of XX visits. At each visit XX ml (mention1-2 tsp/tbsp as applicable) of your blood will be withdrawn after fasting for XX hours. The blood samples that are drawn, will be used to check your blood sugar levels, kidney and liver function etc. (mention whatever is applicable).

Regardless of the group to which you have been assigned, you will return to the study centre after XXXX days / weeks / months. It is important that you bring all of your study medications, diary etc. along with you.

At each visit, a) you will be asked about your health, side effects of medications, b) your physical examination will be carried out c) you will be given a new supply of study drug.

VI Risks and discomforts of participating:

The study testing 2 different therapies in high risk people that may prevent heart attacks, strokes or death from cardiovascular causes:

Based on studies in animals and other studies with people, the drug(s) used in this study may cause some side effects. The known risks and side effects associated with the drugs proposed for use here are summarized below.

Side effects of test drug – XXXXX (Give Details) (for interventional trial)

Side effects of standard drug – XXXXX (Give Details) (for interventional trial)

Other side effects that you may experience could include injection site reactions, allergic reactions to the medication, itching rash and pain at the injection site (if the drug is to be administered parenterally). While collecting blood from your vein, you will have to undergo the discomfort of brief pain or rarely develop bruising or even a minor infection. In case this occurs appropriate management will be provided

Finally new problems or side effects other than those that have been seen before could occur during this study. You will therefore be asked about side effects at each visit. It is important that you report any of the side effects described in this form or any other ones to the study physician immediately at the numbers listed below.

Because the safety of the study drugs for an unborn fetus or newborn is unknown, if you intend to become pregnant, are pregnant or are breastfeeding you cannot participate in this study. If you are a woman who is able to have children, you will be required to undergo a urine pregnancy test. If you are no pregnant you will be asked to take precautions to prevent pregnancy until the end of the study. The doctors will discuss the contraception options with you. Pregnancy test may be repeated during the study. If you become pregnant despite these precautions you should immediately notify the study team. Pregnancy will be a reason to stop study treatment.

Any new important information that is discovered during the study and which may influence your decision to continue in the study will be provided to you or your legally acceptable representative in a timely manner. You will be told of any new risks or side effects.

VII Possible benefits of the study:

By participating in this study, you may have a possible cure or improvement in your condition. However, there is no guarantee that you will receive direct health benefit from being in this study your participation in this study may provide information that may in the future help other patients suffering from high blood pressure.

VIII What happens when the research trials stops?

Because this is a research trial, the test drug will not be available at the end of this trial for treatment of this disease. Alternate therapy, if appropriate, will be provided once the trial is finished. Occasionally the company sponsoring the research may stop the study early – if this occurs the reason(s) will be explained to you.

IX Compensation for participation:

Participation in this study will be at no cost to you. The medication and clinic visits will be provided free of charge. No compensation will be provided for your participation. Payment for things such as lost wages is not available. (Wherever applicable give details e.g. reasonable travel assistance will be provided for your participation etc.)

X Treatment and Compensation for study related injury: (for interventional trial)

You will be provided medical treatment at this institute for any physical injury or illness that occurs as a direct result of your participation in this study. This medical treatment will be at no cost to you. The study doctor/sponsor will compensate anyone in case there is temporary/ permanent disability or death as a direct result of participation in this trial In case of death, their dependents are entitled to material compensation.(provision of insurance coverage by the sponsor for study related injury, if available, may be stated here). You will not give up any of your legal rights by signing this form.

Any injury or death of the participant occurring in clinical trial due to following reasons shall be considered as clinical trial related injury or death and the subject or his/her nominee (s) as the case can be are entitled for financial compensation .

a) adverse effect of investigational product (s)
b) violation of the approved protocol, scientific misconduct by the sponsor or the investigator.

c) failure of the investigational product to provide intended therapeutic effect
d) Use of placebo
e) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol.
f) For injury to child in utero because of the parents participation in the trial
g) Any clinical trial procedure involved in the study.

[**Paragraph from ICMR 2006 guidelines** –

Obligation of the sponsor to pay: The sponsor whether a pharmaceutical company, government, or an institution, should agree, before the research begins, in the a priori agreement to provide compensation for any physical or psychological injury for which participants are entitled or agree to provide insurance coverage for an unforeseen injury whenever possible.]

[**As per the notification from the office of DC(I) (Notification GSR NO 53 (E) Dated 30-01-2013, 122 DAB),** it is mandatory for the sponsors to comply the following requirement :

A. "In event of any injury occurring to the clinical trial subject, such subject shall be provided free medical management as long as required.
In the event of a trial related injury or death, the sponsor or his representative should provide financial compensation for the injury or death . The financial compensation will be over and above any expenses incurred on the medical management of the subject.

In case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and same should be included in Patient Information Sheet / Informed Consent Form"].

B. Date of Birth /Age ……..
Address of the subject…….
Qualification…….
Occupation- student/self-employed/service/housewife/other (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)
C. Name of the witness ……..
(copy of the Patient information sheet and duly filled ICF shall be handed over to the participant or his/her **attendant)**

XI Right to withdraw from the study:

Participation in this study is entirely voluntary. You may choose not to take part or you may leave the study at any time. Your decision will not affect your further treatment at this institute. If you decide to leave the study, you may have to undergo some tests and/or procedures, which will be done to protect your safety.

XII Confidentiality:

All study records will be kept confidential at all times. Your identity will not be revealed except as required by law, DSMB and IEC. The results of your treatment (details: laboratory tests, photographs, x-rays etc.) may be published for scientific reasons. Your identity will not be revealed in these publications.

XIII Contact for further information:

Thank you for taking the time to read (or have read to you) the information about this study. Before you sign this document, you should ask questions about anything that you do not understand. The study staff will answer questions before, during & after the study.

If you have questions about this study or how it is being run, drug side effects or a possible research related illness or injury, you can contact the study doctor XXXXXXXX, designation, department XXXXXXXX at telephone number XXXXXX during the office hours, or at XXXXX at outside office hours.

If you have any questions about your rights as a research participant, or complaints regarding the research study, you should call XXXXXXX who is the Member Secretary of Institutional Ethics Committee on the following telephone number on working days. Tel. no.: 91 22 2410 7000, Ext. 7515, 91 22 24107515, 91 22 24122188 (Monday to Friday- 9:00am to 4:00pm; Saturday-9:00am to 1:00pm).

XIV Consent:

[1] I have read or have had read to me the information given in the Informed Consent Document for this study entitled **"XXXXXXX"**

[2] I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the trial and what I will be expected to do. My questions have been answered satisfactorily.

[3] I understand that my participation in the trial is voluntary and that I may refuse to participate or may withdraw from the trial at any time, without penalty or loss of benefits to which am otherwise entitled.

[4] I further understand that any information that becomes available during the course of the study that may affect my willingness to take part will be informed to me.

[5] Institutional Ethics Committee authorities may wish to examine my medical records to verify the information collected. By signing this document, I give permission for this review of my records.

[6] I understand that my identity will not be revealed in any report or publication.

[7] I agree to take part in the above study.

_____	_____	_____
Name of research participants	**Signature/ thumb impression of research participants**	**Date**

_____	_____	_____	_____
Name of Legal Representative (LAR)	**Relation to research participants**	**Signature / Thumb Impression of LAR**	**Date**

_____	_____	_____
Name of the Impartial Witness	**Signature of the Impartial Witness**	**Date**

_____	_____	_____
Name of the person Administering consent	**Signature of the person administering consent**	**Date**

PLEASE NOTE THAT THE INFORMED CONSENT DOCUMENT SHOULD HAVE PAGE NUMBERS