Informed Consent for Research Study – Interventional Studies

Study Title : .....

.....

Study No. : .....

Principal Investigator : .....

Sponsor : .....

Principal Investigator Address : .....

1. Introduction:

You are being invited to take part voluntarily in a research study because you have **(***State the subject current medical condition***)** / **(***Please mention if study is local , national or part of international multicenter study***)**

2. Study Purpose:

The purpose of this project is to *State primary and secondary objectives of the study*

3. Duration of Participation: *State the duration based on study protocol/proposal*

The duration of participation is approximately **(***State period of time days/months/year***)**, where the following should be done **(***state the procedures***)** for a **(***state Period of time days/months/years***)** and a follow up will be done for **(***state Period of time days/months/years***)**, you will visit the clinic of your doctor for **(***state Period of time days/months/years frequency***)**.

4. Number of Subjects participating/ study Area and settings:

The total number expected to participate on this study is **(***Mention the expected study sample size***)** participants, this study will be conducted in **(***State the study places and settings where the study will be conducted including the study site and the involved departments ie. Laboratory, radiology etc.***)**

5. Study Procedures:

Before you agree to join in this study, Please take time to read the information provided below. (Please read the information carefully and discuss it with any one you want for the right advice. This may include a friend, a relative or family doctor)

Describe the activities and procedures to be done in the study:

If randomization will be done, it should be mentioned to the subject:
You will be randomized to either *Drug/device or procedure A or Drug/device or procedure B or placebo etc.* and there is a *(Mention percentage %)* chance that you will receive *Drug/device or procedure A* and a *(Mention percentage %)* chance that you will receive *Drug/device or procedure B or placebo etc (Depends on the study design)*

If the study is blinded you should mention to the study subject who will be blinded i.e. if double blinded. (Neither you nor the site personnel will not know which study drug (Drug A or Drug B)
For example in clinical trials:
Screening period procedures or baseline visit: *If you agree to be in this study, you will be requested to sign this Informed Consent Form.*
At this visit you are required to attend the (mention the place or the clinic) to perform (list the procedures to know if you are eligible to participate or not

Treatment Period:
Visit# 1
Based on the results of screening stage, you will be asked to attend the (Mention the place or the clinic) to do the following procedures (Mention the procedures)

Visit# 2
You will be asked about medical and surgical histories and all medications that you are currently taking.
You will have a physical examination and your body temperature, blood pressure, pulse rate, weight, and height will be measured.

Visit 3, 4 … etc. *you will be asked to perform the following tests (based on the study protocol)*

Follow up period

6. When my participation will end?

Define at what circumstances the participation will stop.
When study participation completed, *specify if the patient has the right to continue study treatment after the study ends*

7. Risks and inconveniences:

What are the possible adverse effects and risks associated with the study or the study procedures?

(State any inconveniences to the study subjects (i.e. extra clinic visits)
(State the expected Adverse Events) e.g.: post blood sample draws: Bruising or pain can occur at the site of the blood draw. Fainting sometimes occurs and rarely local infection
There might be unknown adverse events occur
You will be informed with any new information occurred that may affect your desire to start or continue the study

8. Important information regarding females participation in the study:

(State the effect of female's or female partner participation on the study and if there will be any possible risks to pregnant / breast feeding women and also any concern regarding the contraception methods needed)

9. Costs and compensation for participation in this study:

You should inform your study investigator immediately about any damages related to the study you are participating in
If there is no compensation you should mention to the subjects: You will not receive any compensation for your participation in this trial.

You will not be asked to pay for any procedure, drug, and laboratory test related to the study. However, in the event of an illness or injury related to the study medication and /or study procedures as per the decision of the principal investigator of the study, all treating procedures, follow-ups hospitalization will be compensated (*Mention the insurance party as per insurance policy number …….)*

10. Benefits:

(State the possible benefits of taking part of this study)
If there is no direct benefits from participation you can use this statement: I know that there will be no direct benefit for me or my relatives from participation in this study but it may help in improvement of knowledge or medical science progress.

11. Alternative Treatment(s):

In this part state the alternative treatments available for the subjects participating in this study along with the risk and benefits if considering the alternative treatment.

12. Information about participation:

Your participation in this study is totally voluntary, you have the right to withdraw at any time you want without mentioning the reasons. If you do not want to take part, you will receive standard care provided by your doctor, and your decision about the study will not affect your current or future medical care.

The study doctor and the study sponsor have the right to withdraw you from the study if they decide that it's better for your medical condition, or you did not comply with study requirements.

If you consider participation of this study you will have to **(***Mention subject responsibilities, i.e, you have to comply with study visits, study drug intake as per instructions and to return all unused study drugs***)**

If you have any other diseases or adverse events the principal investigator will decide whether to continue with participation in the study or not.

13. Confidentiality and Authorization to collect, use and disclose Personal Medical Information:

All information related to you including personal and medical data provided and collected by the study doctor or coordinator and recorded in the study records will be handled as confidential and no one except authorized research team at King Abdullah International Medical Research Center (KAIMRC), Sponsors, Institutional Review Board (IRB), Research Scientific Committee (RC), Ministry of Health auditors including but not limited to US Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Saudi Food and Drug Administration (SFDA), any accreditation bodies and related personnel that can have access to record, review and analyze them.

All the information collected in subject's records belong to King Abdullah International Medical Research Center or industry sponsor, in case any results of the study are published, your personal information will never be mentioned and may be coded in

symbols known to the research team.

14. Communication

In case of any research related inquiries or medical care during study, or any injuries/ emergency cases feel free to contact the study principal investigator *Dr. _____ (P.I Name),* through the *P.I phone number: _____*

In case you have enquiries related to your rights as a research subject you can contact the Institutional Review Board on Tel. 8011111 Ext. 14572.

I've been given the opportunity to discuss my questions about participating in this study and the research team has answered all my questions, if I have any further questions I will call *(name of the principal investigator)*

- I understand that my participation in this research is voluntary and I know that I have the right to withdraw when I decide without affecting the medical care that I usually receive.
- I understand that the principal investigator has the right to end my participation as is deemed appropriate to me.
- I understand that non-compliance with research procedures and/or the visits dates might end my participation of this study.
- I understand that every clinical trial must be registered in a publicly accessible database before recruitment of the first subject. *(Applicable only for clinical trials)*

By signing this informed consent form I acknowledged that I did not give up any of my legal rights, also I confirm that I have received a sufficient information about the study and that I have read and understood the information in this informed consent form and I have had the opportunity to discuss the study and ask questions and have been satisfied with the received explanations.

I understand that after signing this informed consent form I will receive a signed and dated copy.

By signing and dating this informed consent form, I agree to participate in this research study.

Subject Name	**Signature**	**Date**
Name of the legal guardian Type if the patient is minor (less than 18 years)	**Signature**	**Date**
Name of the witness Type if the subject agrees verbally and he/she is illiterate	**Signature**	**Date**
Name of the Principal Investigator	**Signature**	**Date**
Person who discussed the consent	**Signature**	**Date**