Non-interventional studies

Informed Consent Form

Study Title:	
Principal Investigator:	**Study No.:**

1. Study Purpose: You are being invited to take part voluntarily in a research study, the purpose of this project is to *State the study objectives*

2. Duration of Participation: The duration of participation is approximately **(***State period of time***)**

3. 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***)**

4. Study Procedures: *(Describe the activities and procedures to be done in the study)*

5. Risks and inconveniences: (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
You will be informed with any new information occurred that may affect your desire to start or continue the study

6. Costs and compensation for participation in this study: *if there is no compensation you should mention to the subjects*: You will not receive any compensation for your participation in this study, you will not be asked to pay for any procedure, drug, and laboratory test related to the study. (You might be reimbursed for your travel expenses if this applies to your study).

7. 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.

8. 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, 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 he decided 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***)**

9. 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 and related personnel that can have access to record, review and analyze them.

Shall not be used, disclosed, or published
Without written approval from King Abdullah International Medical Research Center

All the information collected in subjects 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, it may be coded in symbols known for research team

10. 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)*

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 subject 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 or Study coordinator	**Signature**	**Date**

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