***Preliminary Notes to Researchers*:**

Under the "Policies, Regulations and Guidelines For Research Involving Human Subjects" published by the Qatar Ministry of Public Health (MoPH), pregnant women, human fetuses, and neonates are considered vulnerable populations, and additional conditions must be met before these populations participate in human research. Investigators are strongly encouraged to review this MoPH policy document prior to designing and conducting research involving these populations.

Title of research: [insert title of research here with protocol number, if applicable]

Investigator: [insert name of principal investigator]

Why am I being invited to take part in this research?

We invite you to take part in a research study because _____. ***[Fill in the circumstance, disease, or condition that makes subjects eligible for the research].***

[If this research involves neonates, include the following sentence.] If this research involves children, "you" or "your" refers to your child.

What should I know about this research?

- Someone will explain this research to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- If you decide not to take part now or at a later time, your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at ***[Insert contact information for the research team]***.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at ***[Insert IRB Office phone number]*** or ***[Insert IRB Office e-mail address]*** if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

If you want to report a complaint related to your participation in the study, please contact The Qatar Ministry of Public Health Research Department by e-mail at research@moph.gov.qa or by phone at 00974-4407-0981.

Why is this research being done?

[Tell the subject the purpose of this research. Explain the background of the research problem. Explain any potential benefits to other. Describe any procedures that are important to this research that will be performed regardless of whether the subject takes part in this research.]

How long will I be in this research?

We expect that your involvement in this research will last for _____ ***[hours/days/months/weeks/years, until a certain event. As applicable, state that the researchers will monitor subjects for long-term health effects and protection of the confidentiality of their health data]***.

How many people will take part?

We expect about _____ people will take part in this research. ***[For multicenter studies, indicate the total number of participants.]***

What happens if I agree to be in this research?

[Tell the subject what to expect using lay language and simple terms. Include all procedures performed because the subject is taking part in this research, including procedures to monitor subjects for safety or minimize risks. Do NOT describe procedures that will be performed regardless of whether the subject takes part in this research. Describe these procedures in the section titled "Why is this research being done?

When appropriate for your research, include the following items:

- ***A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits***
- ***The drugs or biologics that will be given to the subject***
- ***All devices that will be used***
- ***All hospitalizations, outpatient visits and telephone or written follow-up***
- ***The length and duration of visits and procedures***
- ***If blood will be drawn, indicate the amount [in Metric] and frequency***
- ***With whom will the subject interact***
- ***Where this research will be done***
- ***When this research will be done***
- ***List experimental procedures and therapies and identify them as such***
- ***How often procedures will be performed***
- ***What is being performed as part of this research***
- ***What is being performed as part of standard care***
- ***When applicable indicate that the subject will be contacted for future research.]***

[Include for a clinical trial that involves a placebo. Otherwise, delete]. This study involves a placebo, which means a drug that looks like the study drug, but contains no study drug. ***[Include for a clinical trial that involves randomization. Otherwise, delete.]*** The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an _____ ***[equal/one in three/etc.]*** chance of being given each treatment. ***[For double-blinded research, add]*** Neither you nor the people conducting this research will know which treatment you are getting. ***[For single blinded research, add]*** You will not be told which treatment you are getting, however the people conducting this research will know.

[For research in which a fetus or neonate is involved or could be impacted by the research procedures, describe any foreseeable impact on the fetus or neonate].

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: ***[Describe any responsibilities of the subject.]***

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include: ***[List alternatives procedures or courses of treatment and any important risks or potential benefits of these alternatives. For clinical trials, describe the options that you would normally offer the patient. If applicable, include supportive care as an option.]***

What happens if I agree to be in this research, but I change my mind later?

[Include if there are potential adverse consequences to withdrawing from this research. Otherwise, delete] If you decide to leave this research, ***[Describe the adverse consequences.]***

If you decide to leave this research, contact the research team so that the investigator can ***[Describe the procedures for orderly termination by the subject, if any.]***

[Describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]

Is there any way being in this research could be bad for me?

[The risks of procedures may be presented in a table form.]

[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk.]

- ***[Physical risks (for example, medical side effect)***
- ***Psychological risks (for example, embarrassment, fear or guilt)***
- ***Privacy risks (for example, disclosure of private information)***
- ***Legal risks (for example, legal prosecution)***
- ***Social risks (for example, social ostracizing or discrimination)***
- ***Economic risks (for example, having to pay money out-of-pocket for research or medical expenses, losing health insurance, or being unable to obtain a job)]***

[Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise, delete.] In addition to these risks, this research may hurt you in unknown ways. These may be minor or so severe as to cause death.

[Include for research that involves known risks to an embryo or fetus. Otherwise, delete.] The procedures in this research can hurt a pregnancy or fetus in the following ways: _____. ***[Include for research whose risk profile in pregnancy is not well known. Otherwise, delete.]*** This research may hurt a pregnancy or fetus in unknown ways. These may be a minor or so severe as to cause death.

[Include for research that may result in additional costs to the subjects. Otherwise, delete.] Taking part in this research may lead to added costs to you. ***[Describe what these costs are.]***

[Include for a clinical trial. Otherwise, delete.] You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this research help me in any way?

[Include if there are benefits to participation. Otherwise, delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include _____. ***[Describe the potential benefits of participation. First, describe any direct benefits to the subject, then describe any benefits to others. If benefits from participation may not continue after this research has ended, describe them. Monetary reimbursement for participation is not a benefit.]***

[As applicable, describe any benefits to the pregnancy, the fetus, or the neonate that will be affected by the research.]

[Include for a clinical trial with no benefits to participation. Otherwise, delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include _____. ***[Describe any benefits to others. Monetary reimbursement for participation is not a benefit and should be described in a later section.]***

[Include for research involving pregnant prisoners. Otherwise, delete.] Taking part in this research will not improve your housing or correctional program assignments. Your taking part in this research will not improve your chance of parole or release.

What happens to the information collected for this research?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization will have access to your records. Others include ***[Add to this list other organizations that may have access to the subject's records such as the Qatar Ministry of Public Health, the sponsor, contract research organization, sponsor's agent and other collaborating institutions].***

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

[If data or specimens will be retained for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.]

[For future research, participants will be asked to give their consent for the use of their data or specimens.]

[Include for a clinical trial. Otherwise, delete.] The sponsor, monitors, auditors, the IRB, and the Qatar Ministry of Public Health will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

[Include for research involving pregnant prisoners. Otherwise, delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

Can I be removed from this research without my permission?

[Include for research where this is a possibility. Otherwise, delete.] The person in charge of this research or the sponsor can remove you from this research without your approval. Possible reasons for removal include ***[Describe reasons why the subject may be withdrawn. Include all reasons for withdrawal described in the protocol. For example: failure to follow instructions of the research staff, the investigator decides that this research is no longer in your best interests, or the sponsor ends this research early.]***

[Include for research where this is a possibility. Otherwise, delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

Will I be told about new information related to the research?

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What if I am injured because of taking part in this research?

If you need medical care because of taking part in this research, contact the research team and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. ***[Insert the name of the institution]*** has no program to pay for medical care for research-related injury. ***[Describe any compensation available for research related injury.]***

What will I be paid for taking part in this research?

[Include if subjects will be paid. Otherwise, delete.] If you agree to take part in this research, we will pay you _____ ***[indicate amount]*** for your time and effort. ***[Indicate if the amount is pro-rated for research visit completion.]***

What else do I need to know this research?

[Include for research involving pregnant prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise, delete.] If you are released from jail before you finish this research, you should take steps to get insurance coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in this research after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

[When applicable indicate that the investigator believes that biologic specimens obtained could be part of or lead to the development of a commercial product and that subjects will have no right to the proceeds or profits derived from the developed product].

[When applicable indicate when and how the subject will be informed of the results of the research].

[Omit the signature page if there is no written documentation of consent.]

Signature Block for Adult Subject Able to Consent

Your signature documents your permission to take part in this research.

Printed name of subject	
Signature of subject	Date
Name and Signature of father (when required by the IRB)	Date
Name and Signature of person obtaining consent	Date

[Add the following block if a witness will observe the consent process. E.g., illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Name and Signature of witness to consent process	Date

If signature of a witness not obtained, indicate why: (select one)

- ❑ Subject is literate
- ❑ Long form of consent documentation is being used