Title of research study: ***[Insert title of research study here with protocol number, if applicable]***

Investigator: ***[Insert name of principal investigator]***

You are invited to consider participating in this study. The study is called ("Title of Study"). Please take your time to make your decision. Discuss it with your family and friends. It is important that you read and understand several general principles that apply to all who take part in our studies:

Taking part in the study is entirely voluntary;

Personal benefit to you may or may not result from taking part in the study, but knowledge may be gained from your participation that will benefit others;

You may decline to participate or you may withdraw from the study at any time without loss of any benefits to which you are entitled and without jeopardizing your access to care, treatment and health services unrelated to the research.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered, at any time during the research, which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask any questions you have about this study with the staff members who explain it to you. You are urged to take whatever time you need to discuss the study with your physician, hospital personnel and your family and friends. The decision to participate or not is yours. If you decide to participate, please sign and date where indicated at the end of this form. The investigator (person in charge of this research study) is (name of investigator).

Why am I being invited to take part in a research study?

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].***

As applicable, consider providing information about the kind of study being conducted. For example:

- ***Observational Studies: "Learn about the natural history of (name of disease) and its causes and treatments."***
- ***Phase I Studies: "Test the safety of (drug/intervention) and see what effects (good and bad) it has in your (patient's condition)" or "Find the highest dose of (drug) that can be given without causing severe side effects."***
- ***Phase 2 Studies: "Find out what effects (good and bad) (drug/intervention) has on you and your (patient's condition)."***
- ***Phase 3 Studies: "Compare the effect (good and bad) of the (new drug/intervention) with (commonly-used drugs/intervention) on you and your (patient's condition) to see which is better."***
- ***"Pharmacogenomic research studies genetic differences among people and how those differences may affect a response to a specific drug or medicine. That may include genetic***

differences in how people absorb and metabolize drugs. It also may include genetic differences in the targets within cancer cells that a drug is trying to effect."

What should I know about this research?

- Someone will explain this research study 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 the 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 the research, including a brief description or background of the investigational drug being studied. Describe any procedures that are important to the research that will be performed regardless of whether the subject takes part in the research.]

Sample language:

- ***"Currently, there is no effective treatment for this type of condition."***
- ***"We do not know which of these commonly-used treatments is better."***

How long will the research last?

We expect that you will be in this research study for _____ ***[hours/days/months/weeks/years, until a certain event]***.

How many people will take part?

We expect about _____ people will take part in the entire study ***[For multicenter trials, 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 non-technical, simple terms. Include all procedures performed because the subject is taking part in the 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 the research. Describe these procedures in the section titled "Why is this research being done?"

Whenever appropriate include the following items:

- ***A time-line description of the procedures that will be performed. If practical, prepare a time-line chart, calendar or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits. Include in the description:***
  - ***The investigational drug that will be given to the subject, along with a statement as to why the drug is considered investigational***
  - ***Identify experimental procedures as such***
  - ***Any other drugs or devices that will be used (if applicable)***
  - ***All hospitalizations, outpatient visits and telephone or written follow-up***
  - ***The length and duration of visits and procedures***
  - ***How often procedures will be performed***
  - ***What is being performed as part of the research study***
  - ***What is being performed as part of standard care***
  - ***What procedures are part of regular medical care that will be done even if the subject does not take part in the research***
- ***If blood will be drawn, indicate the amount [in metric] and frequency***
- ***With whom will the subject interact***
- ***Where the research will be done***
- ***When the research will be done***
- ***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. Which group you are put in is done by a computer. Neither you nor the study doctor will choose what treatment you get. You will have a/an _____ ***[equal/one in three/etc].*** chance of being given each treatment. ***[For double-blinded research add]*** Neither you nor the people conducting the 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 the research will know.

[For randomized studies, list the study groups and under each describe categories of procedures. Include whether a patient will be at home, in the hospital, or in an outpatient setting. If objectives include a comparison of interventions, list all procedures, even those considered standard.]

[Include if applicable: Please advise the researchers of any medications, over-the-counter drugs, or herbal supplements you are taking.]

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, such as responsibilities to attend research visits, take study drug at the appropriate time, etc.].***

What other choices do I have other than taking part in the research?

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

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

If you decide to leave the research, ***[Describe the adverse consequences].***

If you decide to leave the research, contact the investigator 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 study 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]. In addition to these risks, this research may hurt you in unknown ways. These may be a minor or so severe as to cause death.

[Include for research that involves pregnant women or women of childbearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise, delete]. The procedures in this research can hurt a pregnancy or fetus in the following ways: _____. ***[Omit the previous sentence if there are no known risks].*** The research may hurt a pregnancy or fetus in unknown ways. These may be a minor or so severe as to cause death. ***[Omit the previous two sentences for research whose risk profile in pregnancy is well known].*** You should not be or become pregnant ***[include as applicable "or father a baby"]*** while on this research study.

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

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 study help me in any way?

[Include if there are potential 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 _____. ***[Then describe the potential benefits of participation. First, describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit].***

[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 prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

What happens to the information collected for the research?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Medical records of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study. In addition to the researchers and research institution(s) conducting this study, organizations that may request to inspect and/or copy your research and medical records for quality assurance, data analysis and other research related and operational or administrative purposes, include groups such as ***[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 after the study 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].

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 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 the research without my permission?

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

[describe reasons why the subject may be withdrawn under the protocol, if appropriate].

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

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, about the experimental treatments under investigation in this study, and any information that may affect your interest in remaining in the study.

What else do I need to know?

[Include for sponsored research. Otherwise, delete]. This research is being funded by ***[Insert name of sponsor]***.

If you need medical care because of taking part in this research study, contact the investigator 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].***

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

[Include for research involving 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 study, 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 the research study 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 the biologic specimens obtained could be part of or lead to the development of a commercial product].

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

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used].

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 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

Signature Block for Adult Subject Unable to Consent

Your signature documents your permission for the individual named below to take part in this research.

Printed name of subject

Name and Signature of legally authorized representative | Date

Name and Signature of person obtaining consent | Date

[Add the following block if you will document assent of the subject.]

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

[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)

- ❑ Parent providing permission is literate
- ❑ Long form of consent documentation is being used

Signature Block for Child Subject

Your signature documents your permission for the child named below to take part in this research.

Printed name of child

Name and Signature of parent or individual legally authorized to consent to the child's general medical care | Date

Name and Signature of second parent | Date

If signature of second parent not obtained, indicate why: (select one)

- ❑ The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

Name and Signature of person obtaining consent | Date

[Add the following block if you will document assent of children]

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

[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)

- ❑ Person providing permission is literate
- ❑ Long form of consent documentation is being used