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

Investigator: *[Insert name of principal 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 or specific disease or condition that makes subjects eligible for the research. If only healthy subjects will be enrolled, explain the reason why you are collecting data or specimens from potential subjects] (e.g. "…your genetic information could help us in better understanding the causes of diabetes")].***

[In the section below, "Why is this research being done," explain more about genomic research, the relationship of this research to any previous or existing study, and the purpose of this specific research project].

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 and your consent to participate is voluntary.
- 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?

The primary purpose of this research study is to collect and store data and/or specimens for future research use. ***[Tell the subject more about the purpose of the research, including the specific biorepository, database, or other organization that will receive the research data and/or samples. The recipient organization may not necessarily be the investigator's organization].***

[If there are also plans to conduct genomic sequencing, include the following:] Another purpose of this research is to conduct a procedure called genomic sequencing in order to gain more

information about genes and how they influence the development of diseases. Genomic sequencing, also called genetic testing, is where researchers take a blood, tissue or saliva sample and perform an analysis of a person's genetic makeup. The biologic samples contain genes, which are made up of DNA and are like an instruction book for the cells in our bodies. Results from these tests can be used to confirm a diagnosis of a disease or condition, help predict the chance that a person will develop a disease or condition in the future, or help predict the chance that a person's children will develop a disease or condition.

[If there are also plans to conduct genomic sequencing, tell the subject any immediate and long-term goals of the research. Describe any procedures that are important to the research that will be performed regardless of whether the subject takes part in the research. Where applicable, inform the subject which specific genes will be investigated along with how studying the genes might influence the development of possible treatments of specific diseases or conditions].

[If data/samples will go specifically to Qatar Biobank, include the following language]: Your information or samples will be provided to help establish the Qatar Biobank, a database that contains data on the health and genes of the Qatari population. Qatar Biobank enables scientific and applied genetic and public health research to be carried out to see how genes may influence the development of diseases.

[If samples and/or data were collected in a prior research project, disclose this to the subject along with the name of the prior research project (e.g. "As part of XYZ protocol, you provided medical information and/or samples to the researchers. We are now requesting your participation in a study involving analysis of the samples and data you provided XYZ protocol")].

How long will I be in the study and how long will the research last?

Your involvement in the data/sample collection portion of this research will occur over _____
[Specify number of visits or how long a period of time the investigator will actively interact/intervene with the subject]

We expect that your data/sample will be included in this research study for _____ ***[Use the time period that the researcher or repository will retain the subject's identifiable information. For example, if the biobank will retain identified specimens and data for 25 years and will then de-identify them after 25 years, then the length of time in the research is 25 years].***

What happens if I agree to be in this research?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]

[

- ***A time-line description of the procedures that will be performed.***
- ***The length and duration of visits and procedures***
- ***If blood will be drawn, indicate the amount and frequency, for example:***
    - ***"We will collect a sample from you by drawing 25 mL of blood from a vein in your arm. If you do not want blood drawn, we can instead collect tissue by swabbing cells from the inside of your cheeks."***
- ***If a tissue sample will be collected, indicate procedures relating to the sample collection, including the size of the sample to be obtained***
- ***If data will be collected, explain the data elements to be collected, including whether the researchers will access the subject's medical records and how the records will be accessed (e.g. once, twice, ongoing over a period of time), for example:***
    - ***"We will collect information from your medical records, such as your age and other background information, disease history, and medical treatments. We will access this information only once a few weeks after you give us permission to access your medical record."***
- ***With whom will the subject interact***

- ***Where the research will be done***
- ***When the research will be done***
- ***How often procedures will be performed***
- ***When applicable, indicate whether samples will be coded and how long samples and data will be stored***
- ***Whether samples or data will be shared with future investigators for research use both during the study and after the study ends***
- ***Whether the subject will be contacted for future research and how re-contact is expected to occur, for example:***
    - ***"We may wish to obtain additional samples or follow-up information about your health or medical care in the future. In this case, a person from ABC Institution will contact you to ask whether you would be willing to participate in this additional research."***
- ***Whether de-identified information derived from the sample or data will be provided to a larger database or repository for access to the broader research community, for example:***
    - ***"Genotype and phenotype data will be shared for research purposes through XYZ data repository"***
    - ***"Anonymous information from the analyses will be put in a public database that will be available to anyone on the Internet."***
    - ***Your coded medical information and information from more detailed analyses of your coded samples may be put into a national database that will only be available to researchers who have received approval from the Qatar Ministry of Public Health or designee, such as the Qatar Biobank. Any information put into the database are considered de-identified (e.g. no names, addresses or telephone numbers)]"***
- ***Whether or when subjects will be told the results of the genetic test:***
    - ***For example, if results will not be provided: "We will not give you any individual results from the analysis of the samples you give us because it will likely take a long time for this project to produce health-related information that we will be able to correctly interpret. We will tell you if we find that you have a communicable disease that we are required by law to report. We will also share important general findings from this project and how they are contributing to our understanding of health and disease in our newsletter or website."***
- ***Whether or when counseling will be provided if subjects are told the results of the genetic test***
- ***Whether the research involves long term follow up]***

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?

[Include only if there are alternatives other than participating. Otherwise, delete]. Instead of being in this research study, your choices may include: ***[List alternatives procedures].***

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

[If there are no risks or discomforts]: There are no expected risks or discomforts from being in the research.

[If the study involves one or more blood draws]: You might experience some discomfort from the blood draws. You may feel some pain, bruising, redness and itching at the blood draw site. Fainting is also possible

[If the study involves collection of sensitive data]: The main risk of providing your data is the possible risk of loss of confidentiality.

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

- ***[Physical risks (for example, medical side effect)***
- ***Psychological risks, for example:***
  - ***"You may discover information about yourself or your family that you do not want to know."***
  - ***"You may feel emotional pain if you discover you have a genetic mutation."***
- ***Privacy risks:***
  - ***For example, a study participant may not want others to know that s/he participated in research, and there is a risk that others (e.g. research team, health professionals, biobank employees) might discover this person's participation in the research.***

Suggested: Confidentiality risks (confidential information is disclosed un-intentionally)

  - ***"There is a risk that unauthorized disclosure of your health or genetic information may affect your employability, insurability, social reputation, or some other aspect of your life."***
  - ***If information is held electronically: "There may be physical or computer security breaches arising from keeping information in an electronic format."***
  - ***"People may develop ways in the future to allow someone to link your genetic or medical information in our databases back to you.***
- ***Legal risks (for example, legal prosecution)***
- ***Social risks, for example:***
  - ***"A genetic test result may affect your ability to obtain health, life, disability or some other insurance policy. Certain genetic variations may also be used by law enforcement agencies to identify a person or their relatives, meaning that your genetic information could be used in ways that could cause you distress, such as by revealing that you or a relative carry a certain genetic disease or condition."***
- ***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 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 this language if there are no potential benefits to participation]: We cannot promise any benefits to you or others from your taking part in this research.

[If there are specific benefits to participation]: Possible benefits of being in the research include _____. ***[Describe the potential benefits of participation to subjects, others, or society. For example, if the genetic test results will be shared with the subject, inform the subject***

that knowledge resulting from the test may empower the person or family members to plan for or make specific health decisions. If benefits from participation may not continue after the research has ended, describe them here. Payment and monetary reimbursement for participation is not a benefit].

[Include if there are potential benefit to others or society]. Your participation will help researchers understand more about genes and how they relate to health and disease, which could eventually benefit people in the future if it is discovered that a disease or condition can be managed or treated based on a person or group's genetic make-up.

[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?

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 may inspect and copy your information. Others include ***[Add to this list other organizations that may have access to the subject's data or samples such as collaborative organizations (e.g. the biobank where data or samples will be held), the Qatar Ministry of Public Health, sponsor or contract research organization, sponsor's agent and other collaborating institutions].***

[Describe who will or who will not receive genetic information obtained from the subject, or when the protocol allows it, provide the subject with the choice to indicate who will receive the results (e.g. subject's family physician or family members).

[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].

[If a subject's health record may be accessed as part of future research, include language relating to the confidentiality of such information].

- ***Sample language: "In the future, people who do research on your samples may need to know more about your health. Reports about your health will not have your name, address, phone number, or any other information that will let researchers know who you are. They will be identified by unique numbers that do not allow the researcher the ability to identify from whom samples were obtained.***

[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.

What if I want to withdraw from the research?

A decision to withdraw from the research will not be held against you. If you want to leave the project, please contact ***[Insert contact information for the research team]*** and any remaining tissue sample of yours that has been obtained for the study will be destroyed. ***[If applicable, state the limitations of what samples or data can be destroyed at the point the subject withdraws. For example: " It is possible that the research team can destroy the link between your genetic and medical information, but samples and data generated from your samples that have already been***

provided to other researchers or research centers or are placed in a formal research database cannot be withdrawn"].

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 are injured because of taking part in this research study, contact the research team and medical care will be made available. Generally, this care will be billed to you, your insurance, or another 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.

[If the investigator believes that the biologic specimens or data obtained could be part of or lead to the development of a commercial product]. Once you provide your specimen(s), it (they) will be owned by the researchers, will be used for research purposes only, and will not be sold to others. Although future research that uses your biological samples may lead to the development of new products ***[list out the product(s), e.g., diagnostic tests, drug treatments or commercial product unknown at this time]***, you will not receive any payments for these new products.

[If data/samples will go specifically to Qatar Biobank, include the following language]: Once your biological samples are transferred to Qatar Biobank, the right of ownership of the sample is also transferred to Qatar Biobank.

[When applicable, indicate if subject will be informed of the results of future 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].

[Omit the signature page(s) if the research (1) presents no more than minimal risk of harm to subjects and (2) involves no procedures for which written consent is normally required outside of the research context].

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