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, disease, or condition that makes subjects eligible for the research. Note: Under regulatory policy, the Qatar Ministry of Public Health (MoPH) discourages discrimination between gene therapy research for monogenic versus polygenic disorders. Additionally, MoPH recommends that gene therapy research first be tested in those with end-stage disease. Nevertheless, there is no ethical reason to prohibit gene therapy research in subjects who do not have end-stage disease as long as the same process of risk-benefit consideration is applied and that the patient is fully aware of all consequences of the research. Reviewing committees (e.g. Institutional Review Boards) are tasked with ensuring that there is no bias in the research (e.g. gender or racial bias)].***

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 non-technical description of how gene transfer therapy works, the study agent being researched, and the purpose of this gene transfer

study. Describe any procedures that are important to the research that will be performed regardless of whether the subject takes part in the research.]

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]***. ***[Include if previous trials involved the study agent. Otherwise, delete].*** About _____ people have participated in previous clinical studies involving this study agent.

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 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 study agent that will be given to the subject, along with a statement as to why the therapy 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 pill that looks like the study agent, but contains no study agent. ***[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 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.

Because this research involves gene transfer treatment, the researchers will continue to follow your progress for _____ after you complete the study procedures. ***[Note: Under regulatory policy, the Qatar Ministry of Public Health requires researchers to address long term follow-up in the informed consent form. Address the medical, scientific and ethical requirements to maintain and long-term***

follow-up of patients. Medically, long term follow-up allows new, unexpected adverse effects to be detected. Scientifically, long-term follow-up provides information that may contribute to the improvement of the current gene therapy research. From an ethical standpoint, the benefit-risk balance of the clinical trial can be enhanced by the investigator's commitment to identify and manage any adverse events, even if they occur years after the treatment. MoPH recommends that all gene therapy protocols follow up subjects for up to 15-18 years.

In addition to long term follow up, in order to obtain information about the potential safety and effectiveness of the study agent, we will request that your family and the appropriate authorities grant permission for an autopsy upon your death. The investigator will ensure that material will be secured with the written consent of the pathologist who is in charge of the autopsy.

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 agent 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].

[Describe any possible adverse medical consequences that may occur if the subjects withdraw from the study once the study has started].

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, clearly itemize the probability, frequency, relative severity, 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)]***

[Note: For consistency in reporting, the following definitions are suggested: side effects that are listed as mild should be ones that do not require a therapeutic intervention; moderate side effects require an intervention; and severe side effects are potentially fatal or life threatening, disabling, or require prolonged hospitalization. Other verbal descriptions (e.g., "uncommon", or "frequent" should be explained].

[Include for research that involves procedures whose risk profile is not well known, including all research involving genetic materials used in relatively few or no humans]. 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.

[Note regarding Women of Child-bearing Potential in Gene Transfer Research: Genomic therapy research carries risks of possible integration of the introduced gene into the growing fetus. Therefore, MoPH recommends that somatic gene therapy be deferred until the last semester of pregnancy or post-partum unless the perceived benefits of gene therapy to the mother clearly outweigh the risks to the fetus]. Therefore, include the following 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]. 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 information about the need for contraception by males and females during the active phase of the study and specify the period of time for the use of contraception].***

[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, including direct clinical 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, knowledge may be gained from this study that may benefit others, including_____. ***[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?

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 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 person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include ***[describe reasons why the subject may be withdrawn under the protocol, if appropriate].***

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 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 and the extent to which a subject might be responsible for any costs for medical treatment required as a result of 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

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

Nama 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