PRINCIPAL INVESTIGATOR:	Scott Norberg, DO
STUDY TITLE:	A Phase I Trial of T Cell Receptor Gene Therapy Targeting KK-LC-1 for Gastric, Breast, Cervical, Lung and other KK-LC-1 Positive Epithelial Cancers
STUDY SITE:	National Institutes of Health (NIH) Clinical Center
Cohort:	*Screening*
Consent Version:	*12/20/2024*

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Scott Norberg, DO
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Email: scott.norberg@nih.gov

KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at the NIH is your choice.

You are being asked to be screened for this study because you have been diagnosed with metastatic or refractory/recurrent KK-LC-1 positive epithelial cancer.

This consent form requests your permission for us to determine your eligibility for our study involving treatment with KK-LC-1 TCR T cells plus aldesleukin for the treatment of metastatic KK-LC-1 positive epithelial cancers.

The use of KK-LC-1 TCR T cells in this study is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat metastatic or recurrent/refractory epithelial cancers. However, the FDA has given us permission to use KK-LC-1 TCR T cells in this study.

There are other treatments that may be used to treat your disease, and these can be prescribed/given by your regular cancer doctor, even if you are not in this study. These treatments may include radiation, chemotherapy or immunotherapy.

The goal of this study is to find out if it is possible to treat patients with your type of cancer with the experimental KK-LC-1 TCR T Cell treatment. We hope it will shrink the cancer, but we do not know if this will be the case.

This consent is for "screening." We would like to "screen" you to find out if you are able to take part in this study.

If you decide to be screened for this study, here are some of the most important things that you should know that will happen.

We will first do some basic tests to make sure you qualify for the trial. These basic tests involve blood tests, x-rays, images, and physical exams, etc. Other tests are described further on in this consent form. It is important that you read these.

Please be aware that the test that will be used in this study to determine your KK-LC-1 type is experimental (Investigational Device) and is limited by United States law to experimental use. Experimental means that the test is not approved by the U. S. Food and Drug Administration (FDA) and is still being tested in research studies. Some of your identifiable information will be shared with investigators at Rutgers University to assist with this testing.

There is a chance that you may experience side effects from the tests to be done (for example: pain from blood draws where the needle enters the skin). However, these will be rare.

You will not benefit from this screening evaluation.

You may choose not to be tested for eligibility or to have any other studies done.

You are free to stop participating in the trial at any time.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine the safety of escalating doses of KK-LC-1 TCR T cells plus aldesleukin for the treatment of metastatic or refractory/recurrent KK-LC-1 positive epithelial cancers.

We are asking you to join this research study because you have been diagnosed with metastatic or refractory/recurrent KK-LC-1 positive epithelial cancer.

You may not be eligible for our study with KK-LC-1 TCR T cells for several reasons, such as the presence of certain other diseases, infections, or blood counts which are not in the correct range to be eligible.

In order to see if you are eligible to take part in the research, we are asking you to first take part in this screening portion of the study.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in the screening portion of this study, you will be asked to supply a complete list of your current medications to the study doctor. This includes over-the-counter medications and herbal supplements. Some medications may interfere with the study drugs and it is important that your study doctor and prescribing physician be aware of any potential risks so that they can prescribe alternative medications as necessary. If you do not already do so, please carry a list of your medications at all times

- Blood samples may be drawn at your local medical doctor's office, your local laboratory, or at the NIH. Samples drawn at an outside location will be sent to the NIH.
- The following tests are needed to determine whether you are eligible for this trial:
    - HLA typing (this blood test determines if KK-LC-1 TCR T cells can recognize your cancer)
    - KK-LC-1 expression testing of tumor
    - Routine blood tests
    - Pregnancy test (blood or urine) if you are a able to bear children
    - Complete physical exam, performance status, vital signs.
    - Evaluation of your veins that are used for drawing blood samples
    - Electrocardiogram (ECG) – a test for your heart
    - Imaging (e.g. CT scan, MRI scan, PET scan) and/or CT-guided biopsy under anesthesia.
- As part of this study, we will test you for infection with HIV, the virus that causes AIDS. If you are infected with HIV, you will not be able to take part in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report HIV infections, and the importance of informing your partners at possible risk because of your HIV infection.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this screening, your involvement will last for the length of time to see if you are eligible to take part in the research treatment phase of the study. The length of time may range anywhere from a couple weeks to several months. You will be required to come to NIH at least one-time during screening and the visit may last anywhere from 1 to 7 days.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Up to 100 individuals will be screened on this study.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

Listed below are possible risks and discomforts with being in this screening part of the study:

Blood samples

The risk for taking blood samples involves the withdrawal of between 2-4 teaspoons and a half-cup of blood and the potential for bruising or infection that occurs with any blood draw. Each time a blood sample is needed, a needle will be put into a vein in your arm (or into your central venous catheter, if you have one). You may feel pain when the needle goes through the skin. Other side effects associated with drawing your blood for blood tests may include infection, bruising, redness, discomfort or bleeding at the site of the needle stick, and possible lightheadedness and fainting.

Electrocardiogram (ECG)

An electrocardiogram or ECG is a test that records the electrical activity of the heart. It is used to measure the rate and regularity of heartbeats as well as the size and position of the heart chambers, and the presence of any damage to the heart. For this test, you will be asked to lie down, and small patches that have an adhesive edge with a gel in the middle, called electrodes, will be placed on your arms, legs, and chest. The areas where the electrodes are placed will be cleaned and, if needed, some hair may be shaved or clipped to allow for better attachment of the electrodes. The adhesive from the patches may irritate your skin.

Biopsy

Your tumor tissue may be obtained from prior surgeries/biopsies or from a biopsy that you might elect to have for purposes of determining if you are eligible for this study. Any biopsy or other procedure would be done only if needed and only after you sign an additional informed consent related to the specific procedure.

Risks associated with the biopsies are pain and bleeding at the biopsy site.

X-ray examination

An x-ray examination of your chest will be performed. The risk related to radiation exposure is discussed below under “What are the risks of radiation from being in the study?”

CT Scan

The CT scanner is a donut-shaped machine that uses x-rays to make computer pictures of the inside of your body. During the procedure, you will need to lie still on a table inside the CT machine. The table will move you in and out of the machine during the scan, and you will be told to hold your breath. The scan itself will only take a few minutes, and the entire visit will take about 30 minutes.

Because of the potential risk of radiation to a developing fetus, all people who could become pregnant will have a pregnancy test done no more than 24 hours before a CT scan with contrast. We will not do the scan if your pregnancy test is positive.

The risk related to radiation exposure is discussed below under “What are the risks of radiation from being in the study?”

IV contrast may be injected. You may feel discomfort when the contrast is injected. You may feel warm or flushed. You may get a metallic taste in your mouth or, rarely, you may vomit or feel sick to your stomach.

You could have an allergic reaction to the contrast, which may cause side effects ranging from mild itching or a rash, to severe trouble breathing, shock or rarely, death. The contrast may also cause kidney problems. The study doctors will do a blood test to make sure it is safe for you to get the contrast.

You may also drink oral contrast. You may have vomiting, nausea, cramping, bloating, constipation, or diarrhea after drinking the contrast.

MRI

An MRI makes pictures of the inside of your body using strong magnets instead of x-ray energy. At the time of each scan, you will be asked to fill out a screening form to verify that it is safe for you to have the scan. You will also be asked to remove any metallic objects you are wearing (for example, watches, earrings, or piercings). We may ask you to change into a hospital gown.

Then you'll be asked to lie on a narrow bed that will move into the MRI scanner. The scanner is a long, narrow tube that is open at each end. Once you are comfortable, the table will be moved into the scanner. You will need to lie still on the table during the scan. You will hear normal "hammering" or clicking and squealing noises during the scan. We will give you earplugs or earmuffs to muffle the sound. You will be able to communicate with the technician running the scan the entire time. We will also give you an emergency button to squeeze at any time if you want the scan to stop.

People are at risk for injury from the MRI magnet if they have some kinds of metal in their body. It may be unsafe for you to have an MRI scan if you have pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metal prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, tattoos, an implanted delivery pump, or shrapnel fragments. Welders and metal workers may have small metal fragments in the eye. You will be screened for these conditions before having any MRI scan. If you have a question about metal in your body, you should inform the staff. You will be asked to complete an MRI screening form before each MRI scan you have.

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, you should let us know right away.

There are no known long-term risks of MRI scans.

Gadolinium

During part of the MRI we will give you gadolinium, a contrast agent, through an intravenous (IV) catheter (small tube).

We do not know if MRI with contrast is completely safe for a developing fetus. Therefore, all people who could become pregnant will have a pregnancy test done no more than 24 hours before each MRI scan with contrast. We will not do the scan if your pregnancy test is positive.

Mild symptoms from gadolinium happen in less than 1% of people who get it. Symptoms usually go away quickly. Mild symptoms may include:

- your arm being cold during the injection,
- a metallic taste,
- headache, and
- nausea.

More severe symptoms have been reported in an extremely small number of people (fewer than 1 in 300,000 people). These symptoms include:

- shortness of breath,
- wheezing,
- hives, and
- lowering of blood pressure.

You should not get gadolinium if you ever had an allergic reaction to it. We will ask you about any allergic reactions before giving you gadolinium.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis (NSF)." NSF always involves the skin and can also involve the muscles, joints, and internal organs. NSF has resulted in a very small number of deaths. We may do a blood test of your kidney function within 30 days before an MRI scan with gadolinium contrast. You will not get gadolinium for a research MRI scan if your kidney function is below the safe level.

Most of the gadolinium contrast will leave your body in the urine. However, the FDA has issued a safety alert that says small amounts of gadolinium may stay in your body for months or years. The long-term effects of the gadolinium that stays in your body are unknown. Some types of gadolinium are less likely to remain in the body than others. In this study, we will use the gadolinium contrast that is less likely to remain in your body, whenever we can. We will also give you additional information called a "Medication Guide." If you ask, we will also give you individual information about any remaining gadolinium we see on your scans.

PET Scans

The PET (Positron Emission Tomography) scanner is a donut-shaped machine that uses x-rays combined with a dose of a radioactive material (tracer) to make computer pictures showing the inside of your body.

Before the scan, we will give you an injection (shot) of radioactive material into a vein your arm. After the shot, you will need to wait for about 1 -2 hours for the material to be absorbed in your body. After this time, you'll lie on a narrow, padded table. We will position your body for the scan. The scan itself is painless and won't make noise. During the scan, you will need to lie very still. The scan will take about another 30 minutes to complete.

Because of the potential risk of radiation to a developing fetus, all people who could become pregnant will have a pregnancy test done no more than 24 hours before a PET scan. We will not do the scan if your pregnancy test is positive.

The risk related to radiation exposure is discussed below under "What are the risks of radiation from being in the study?"

Other Risks

It is possible that other side-effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

What are the risks related to pregnancy?

If you are able to become pregnant, we will ask you to have a pregnancy test before starting this study. You will need to practice an effective form of birth control before starting study treatment, during study treatment, and for twelve (12) months after you finish study treatment (the restricted period). If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to a fetus. You must tell the study doctor if your birth control method fails during the restricted period. If you think or know you have become pregnant during the restricted period, please contact the study team as soon as possible.

If you are a sexually active person with a partner able to become pregnant, it is important that your partner not become pregnant during the restricted period. There may be unknown risks to a fetus or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you think your partner has become pregnant during the restricted period, please contact the study team as soon as possible. If you and your partner plan for your partner to become pregnant after the restricted period, please discuss this with the study team.

What are the risks of radiation from being in the study?

During your participation in this research study, you will be exposed to radiation from a chest x-ray, CT scan, PET scan, or CT-guided biopsy. The amount of radiation exposure you may receive from these procedures is equal to approximately 3.1 rem. A rem is a unit of absorbed radiation.

Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. The average person in the United States receives a radiation exposure of 0.3 rem per year from these sources. This type of radiation is called "background radiation." This study will expose you to more radiation than you get from everyday background radiation. No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The PET and CT that you get in this study will expose you to the roughly the same amount of radiation as 10 years' worth of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You will not benefit from this screening evaluation; however, this will determine if you are eligible to participate in the clinical trial.

Are there any potential benefits to others that might result from the study?

In the future, other people might benefit from this study because the knowledge gained from this study may be used to help treat others who have this cancer.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

You may choose not to be tested for eligibility or to have any other studies done.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

The results from the evaluations for this screening will be reported to you. You will be informed at that time if you are eligible for the main study.

EARLY WITHDRAWAL FROM THE STUDY

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if you are ineligible for the study
- if you become pregnant
- if new information shows that another treatment would be better for you
- if the study is stopped for any reason

In this case, you will be informed of the reason therapy is being stopped.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to our collaborators or designated representatives.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved for use in other research studies?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding metastatic or refractory/recurrent KK-LC-1 positive epithelial cancer, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded specimens and data to be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

Will your specimens or data be shared for use in other research studies?

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials Initials

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for

example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

It is required that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. Usually, these researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

How long will your specimens and data be stored by the NIH?

Your specimens and data may be stored by the NIH indefinitely.

Risks of storage and sharing of specimens and data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

PAYMENT

Will you receive any type of payment for taking part in this study?

You will not receive any payment for taking part in this study.

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

On this study, the NCI will reimburse the cost for some of your expenses such as those for hotel, travel, meals. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. The amount and form of these payments are determined by the NCI Travel and Lodging Reimbursement Policy. You will be given a summary of the policy which provides more information.

If your travel to the NIH Clinical Center (e.g. flight, hotel) is arranged and paid for by the NIH, the agency making the reservations and their representatives will have access to your identifiable information.

COSTS

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

- If some tests and procedures are performed outside the NIH Clinical Center, you may have to pay for these costs.

CONFLICT OF INTEREST (COI)

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

The NIH and the research team for this study are using KK-LC-1 TCR Transduced PBL developed by Center for Cancer Research through a joint study with your study team and the company. This means it is possible that the results of this study could lead to payments to NIH. By law, the government is required to share such payments with the employee inventors. You will not receive any money from the development of KK-LC-1 TCR Transduced PBL.

The company also provides financial support for this study.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor (Center for Cancer Research) or their agent(s)
- Investigators at Rutgers University

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Scott Norberg, DO, scott.norberg@nih.gov, 301-275-9668. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Signature of Witness	Print Name of Witness	Date

NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:

_____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

_____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.