PRINCIPAL INVESTIGATOR: Avindra Nath, M.D.

STUDY TITLE: HERV-K Suppression using Antiretroviral Therapy in Volunteers with Amyotrophic Lateral Sclerosis (ALS)

STUDY SITE: NIH Clinical Center

Cohort: Standard Consent
Consent Version: 07/13/2021 (M)

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Avindra Nath, MD, 301-496-1561, avindra.nath@nih.gov

Study Coordinator: Amanda Wiebold, RN, 301-594-5194, amanda.wiebold@nih.gov

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). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

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 study is to learn how drugs usually taken for HIV infection affect people with Amyotrophic Lateral Sclerosis (ALS).

BACKGROUND

Some people with ALS have a high level of a protein called HERV-K in their blood. We do not think this protein causes ALS. We do not know why some people with ALS have this high level of HERV-K.

We are doing this study because we want to know if HERV-K can be suppressed by medications. The study drugs are darunavir, ritonavir, dolutegravir, and tenofovir alafenamide fumerate (TAF). These drugs are used to treat HIV infection. We are using them in this study in people with ALS who do not have HIV, because very few patients with both HIV and ALS-like symptoms had improvement when their HIV infection was treated. None of the study drugs are approved by the FDA to treat ALS. In this study, we will look at the effects of a combination of all of these drugs on blood levels of HERV-K, on other blood chemistries, and on symptoms of ALS. We will also see if they are safe to take by people with ALS.

STUDY POPULATION

Up to 200 people will enroll and up to 25 eligible people will be in this study.

STUDY VISITS

Study overview

You will have up to 11 study visits over a period of approximately 48 weeks. You will have 1 visit before starting the study drugs and 10 visits after you start study drugs. You will have 2 visits during the first 4 weeks you are on the study drugs and then once a month after that for up to 24 weeks. You will have 3 visits after you have stopped taking the study drugs. The visits and tests that will be done are described below.

Screening Visit and starting the study drugs

We will continue to screen you to see if you are eligible to participate. This screening visit will last about six hours.

At the screening visit, you will have:

a) A history and physical examination
b) Blood and urine tests. Women who are able to get pregnant will also have a pregnancy test
c) A breathing test to measure how much air you can hold in your lungs.
d) Nerve and muscle tests
e) Questionnaires
f) Lumbar Puncture

The blood tests will include blood chemistries, blood counts and tests for the viruses HIV and HTLV. We will not repeat these tests if they were already done in the past year. We may also do a genetics test to look for one mutation that is associated with ALS and also to screen for other genetic mutations. Blood will also be used for other research purposes. For some visits you will need to fast for 8 hours and have nothing but water after midnight before you have your blood drawn. The tests are described below.

We will repeat the blood test for the HERV-K level.

If you have a high HERV-K level, your screening tests show that you are eligible to participate, and if it has been within 24 weeks from your first HERV-K blood test, we will schedule you to start taking the study drugs. You will take 4 different study drugs for up to 6 months. The medications

will be given as pills.

Additional study visits

After starting study drugs, you will have study visits at Weeks 1 and 4 and then every 4 weeks until Week 28. Participants who do not live locally may have their blood collected at a location near them for Weeks 1, 4, 8, 16, 20, and 28. We will send you all the supplies you need and cover any costs.

You will stop taking all of the study drugs at the Week 24 visit.

For Weeks 28, 36, and 48 we want to follow up to see how you are doing after stopping the study drugs.

During each of these visits, we will ask you about how you are doing. We will ask about any side effects and about your ALS symptoms. For visits at NIH we will do an exam. At the weeks 12, 24, and 36 visits, we will also perform nerve and muscle tests, measure your breathing, collect a urine specimen, and rate your ALS symptoms. In addition to the tests above, at week 24 we will repeat the lumbar puncture. At each visit except Week 48, you will have blood tests and we will measure the level of the HERV-K. Each visit will last about 1-2 hours, except Week 24 which will last about 4-6 hours and Weeks 12, 24, and 36 could last 2-4 hours. At each NIH visit, bring all the study drug bottles even the empty ones.

STUDY TESTS

Interview and Exam

We will ask you about your medical history and you will have a physical exam. Please note that this exam is for research only and does not replace any exam you would receive from your own doctors.

Blood and Urine Tests

Blood will be drawn through a needle in your arm. We will draw no more than nine tablespoons of blood at any one time. No more than 550 mL (2 cups and 5 tablespoons) will be drawn over a 8-week period. Please tell the study staff if you are participating in other studies that have blood draws. Urine will be collected. Participants who are physically able to become pregnant will have a pregnancy test at each study visit. If you become pregnant while in this study, we will stop the study drugs immediately. We will refer you to the NIH OB/Gyn service for evaluation and counseling. You will still come for study visits and may have other study procedures. We will continue to follow you until you are no longer pregnant.

Breathing Test

You will blow into a tube that measures how much air you can hold in your lungs.

ALS Questionnaires

You will answer questions on paper and pencil and during an interview about symptoms that people with ALS often have. They will ask about how you are feeling physically and emotionally.

Nerve Conduction Study (optional)

We will measure how your nerves conduct electrical impulses and the connection between nerves and muscles by doing a "nerve conduction study." We will place sticky pads or small metal disk electrodes attached to wires onto your skin to record muscle and nerve activity. We will stimulate nerves using a small electrical shock. The shock will tingle or sting and may be painful. The shock may make the muscle twitch.

Electromyography (optional)

Electromyography (EMG) measures the electrical activity of muscles. A thin needle will be put into your muscles to record their electrical activity. Your muscle activity will be recorded.

Muscle Ultrasound (optional)

Ultrasound uses sound waves to look at the muscle. For the ultrasound, a gel will be placed on your skin. A probe, like a small microphone, will be moved on the skin to look at your muscle.

Electrical Impedance Myography

Electrical impedance myography (EIM) gives us information about the muscles. We will place a sensor on your body and sticky pad electrodes to see how quickly a small electrical current can pass through your muscles. You will not feel the electrical current. This test will take about 30 minutes.

Lumbar Puncture

For the lumbar puncture, you will lie on your side, curled up with your knees at your chest, or you will sit upright. Your lower back will be cleaned. A medicine will be injected into your back to make the area numb, which may sting for a few seconds. A needle will be inserted through the numbed skin and into the space between the bones in your back. You may feel a sensation of pressure. About 30ml of cerebrospinal fluid (CSF) will be removed. It usually takes 5 to 20 minutes to collect the CSF. After the fluid is collected, the needle will be removed and you may get up and move around as soon as your doctor says you may.

Genetic Testing

Purpose of genome and exome sequencing

We are requesting your permission to perform whole exome and/or whole genome sequencing and link this to your medical and/or family history. Your blood and tissue samples contain genes, which are made up of DNA (deoxyribonucleic acid) which serves as the "instruction book" for the cells that make up our bodies. Sequencing whole exome or genome will determine the exact order of the base pairs (chemical letters) in your blood. Your sample(s) will help us understand how changes in the genes may cause symptoms.

After the sequencing and analysis are complete, you may meet again with the study team and the genetic counselor to discuss the results. Results about known or likely disease-causing gene variations will be given to you as part of genetic counseling. Because we are not studying all genes, you cannot assume that there are no changes in any gene that we do not mention. For example, because we are not likely to look at genes that predispose to cancer, you could have a mutation in

a cancer gene that would not be identified by our testing or genetic counselors.

Incidental and secondary findings

Gene changes will be identified that are not related to this research study. These may include

- Changes in genes that are related to diseases other than ALS.
- Changes in genes that are not known to cause any disease. These are known as normal variations.
- Changes in genes that are new and of uncertain clinical importance. This means that we do not know if they could cause or contribute to a disease or if they are normal variations.

If we find a change in a gene that is important to you or your family's health, the results will need to be confirmed in a clinical laboratory. We will contact you to let you know. We may discover this information as part of our primary analysis but will not continue to look for genetic changes and contact you into the future. If you want this to be done, we will draw an additional blood sample and send it for confirmatory testing either an NIH or another lab. Once the results are available, we will offer to have you come to NIH to have a genetic counselor provide you with genetic education and counseling to explain the results.

If you choose not to receive genetic counseling from NIH, we will help you find a local genetic healthcare provider who can explain it to you (at your expense).

If you are not contacted, you should not assume that you do not have any gene variants that might be related to a disease.

We do not plan to give you any individual research results from your genome or exome sequencing. This is because it will probably take a long time for this project to produce health-related information that we will know how to interpret accurately. However, we will tell you if we find that you have a communicable disease that we are required by law to report to a registry.

Benefits

You will not benefit personally from genomic sequencing because this kind of research usually takes a long time to produce medically useful results. However, your participation will increase our understanding about ALS. We think the information gained during this study may contribute to the medical care, treatment and prevention of problems for others in the future.

HIV Testing

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 be in this study. We will tell you what the results mean, how to find care, and how to avoid infecting others. We will also tell you how we report HIV infections and the importance of informing your partners at possible risk because of your HIV infection.

RISKS, INCONVENIENCE AND DISCOMFORTS

Risks of Darunavir

The most common side effects of darunavir are diarrhea, nausea, headache, and stomach pain.

More than 6% of people have these side effects. There is a rare possibility of serious skin rashes.

If you notice a new rash, stop all of the study drugs and contact us right away. Other rare problems associated with darunavir when used with ritonavir include liver disease, high blood sugar or diabetes, abnormal bleeding in people with hemophilia, and increased cholesterol.

Risks of Ritonavir

The most common side effects of ritonavir are diarrhea, nausea, tiredness, vomiting, stomach pain, muscle and joint aches, dizziness, high triglycerides, excessive gas, itching, elevated liver function tests, blurry vision, and swelling. More than 5% of people have these side effects. There are rare possibilities of pancreatitis, abnormal heart rhythm, liver disease, high blood sugar or diabetes, change in fat distribution, muscle disease, and abnormal bleeding in people with hemophilia.

Risks of Dolutegravir

The most common side effects of dolutegravir are trouble sleeping, headache, and tiredness. More than 2% of people have these side effects. Dolutegravir can rarely cause muscle or liver problems. Dolutegravir has rarely caused a serious skin rash. It has also rarely caused a muscle breakdown that led to kidney disease, serious drug reactions, stomach irritation, liver disease, skin hypersensitivity, kidney disease, and suicidal thoughts and behavior.

Risks of TAF

The most common side effects of TAF are headache, stomach pain, tiredness, cough, nausea, and back pain. More than 5% of people have these side effects. Kidney disease is less common but has been reported.

Risks of Interview, Questionnaires, Physical Exam, and Breathing Tests

There is minimal medical risk from these tests. Some of the questions on the ALS scales may make you feel uncomfortable. You do not have to answer any questions you do not want to.

Risks of Blood and Urine Tests

When blood is drawn, you may have some discomfort and bruising at the site of needle entry. There is a very small risk of fainting. Infection in the area of the needle insertion is rare. There is minimal medical risk or discomfort from giving a urine sample.

Risks of Genetic Testing

Psychological or Social Risks Associated with Return of Incidental or Secondary Findings

As part of the research study, it is possible that you could learn that you have genetic risks for another disease or disability. This may be upsetting and, depending on what you learn, might create a need to make challenging decisions about how to respond.

Although your genomic information is unique to you, you share some genomic similarities with your children, parents, brothers, sisters, and other blood relatives. Therefore, learning your research results could mean something about your family members and might cause you or your family distress. Before joining the study, it may be beneficial to talk with your family members about whether and how they want you to share your results with them.

Genetic counseling is available at NIH to help you understand the implications of your genetic testing.

Because of the psychological or social risk, some people do not want to know the results of genetic testing. It is our policy to not disclose the results of research genetic testing unless it may have direct medical implications for you or your family.

Results of the research genetic testing in this study are often difficult to interpret because the testing is being done for research purposes only and the laboratories are not clinically certified.

Your genetic information will be kept confidential to the extent possible. The results of your genetic testing will be kept in a locked and secured manner at the NIH.

Problems, such as with insurance or employment discrimination, may occur if you disclose information about yourself or agree to have your research records released. We will not release any information about you to any physician, insurance company or employer unless you sign a document allowing release of the information.

Privacy Risks Associated with Genetic Testing

It may be possible that genetic information from you could be used by law enforcement agencies or other entities to identify you or your blood relatives.

Protections against misuse of genetic information

This study involves genetic testing on samples. Some genetic information can help predict future health problems of you and your family and this information might be of interest to your employers or insurers. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component.

Risks of Nerve Conduction Studies

The nerve stimulation may cause discomfort or pain. If it is too uncomfortable, we will try to turn the strength of the stimulation down. You can ask to have the test stopped at any time.

Risks of EMG

You may have pain when the needles are inserted. There is a very small risk of infection or bleeding.

Risks of Muscle Ultrasound

There is minimal medical risk or discomfort from the ultrasound.

Risks of EIM

There is minimal medical risk or discomfort from EIM.

Risks of Lumbar Puncture

You may have a brief pain or tingling sensation in your legs during the lumbar puncture if the needle brushes against a nerve. If this happens, please let us know immediately and the needle will be adjusted. Some people get a mild backache at the site of needle insertion. About one-third of people have a headache for a few days after a lumbar puncture. Usually the headache is not severe and improves without treatment other than a mild pain reliever.

Headaches lasting longer than 7 days develop with one in 50 to 200 lumbar punctures and usually improve gradually over 2 weeks. In rare cases, headaches persist longer. Prolonged headaches may be due to persistent leakage of CSF from the area of the lumbar puncture. If your headache is prolonged, you may get a "blood patch." For the blood patch, we will remove blood from a vein in your arm and inject it into the area of your back where the lumbar puncture was performed to seal off the leak of CSF.

This research study may involve exposure to radiation if the lumbar puncture is performed under fluoroscopy. The amount of radiation adults will receive in this study if the lumbar puncture is performed under fluoroscopy is 0.024 rem per scan, which is below the guideline of 5 rem per year allowed for research subjects by the NIH Radiation Safety Committee. To compare this to environmental radiation exposure, the average person in the United States receives a radiation exposure of 0.3 rem per year from natural sources, such as the sun, outer space, and the earth's air and soil. If you would like more information about radiation, please ask the investigator for a copy of the pamphlet, An Introduction to Radiation for NIH Research Subjects.

Please tell the research team if you have had or expect to have any radiation exposure in the past or coming year, either from other research studies or from medical tests or care, so we can make sure that you will not receive too much radiation. Radiation exposure includes x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy, as well as nuclear medicine scans in which radioactive materials were injected into your body.

USE OF STORED SAMPLES AND BLOOD

Blood collected during the course of this study will be stored in secured freezers at the NIH. DNA will be taken from these samples and it too will be stored in secured freezers at the NIH. We will remove your name and information that could identify you. We will assign the samples a code. The key to the code will be kept in a separate, secure area.

Your samples and data may be used for other research projects related to understanding neurological diseases, including diseases other than ALS. If you do not want your samples used in other studies, you should not take part in this study.

If you withdraw from this study before it is complete, test results and blood samples taken prior to your withdrawal from the study will be kept and your privacy will be protected.

CONTRACEPTION

The drugs used in this study can be harmful to a developing fetus. Therefore, sexually active participants who are able to get pregnant must agree to use an effective method of contraception (birth control) from the time you enroll in the study until 12 weeks after you have completed taking the study drugs.

Effective methods of contraception for this study include

1. hormonal contraception (injected hormones or vaginal ring),
2. intrauterine device
3. barrier methods (condom or diaphragm) combined with spermicide.
4. surgical sterilization (hysterectomy, tubal ligation, or vasectomy in a partner.

If you are using oral contraceptives as a method of contraception, you may be eligible for the study, however you must also use an effective method of contraception listed above because oral contraceptives may not be effective when used with the study drugs. It is important for you to know that no method of birth control is totally effective in preventing pregnancy except for surgical sterilization (hysterectomy or tubal ligation for women and vasectomy for men) and total abstinence from sexual relations.

ANTICIPATED BENEFITS

You will receive no direct benefit from participating in this research study. We hope to learn more about ALS. This information may help people with ALS in the future.

RIGHT OF WITHDRAWAL AND CONDITIONS FOR EARLY WITHDRAWAL

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. The investigator can remove you from the study at any time if she or he believes that continuation is not in your best medical interest or if you are unable to comply with the requirements of the study.

If you decide you want to stop taking the study drug after Week 16, we will ask you to complete all of the study visits. This will allow us to follow you for your safety, and to gather information for the research study.

If you take the study drug for less than 16 weeks, we will ask you to come back for at least 1 follow up visit. This follow up visit will be scheduled as soon as possible. You will be asked if you had any side effects since you last visited NIH. You will be asked about your health and have a physical exam. We will draw blood from you for clinical and research purposes.

RESULTS FROM THIS STUDY

We will discuss the results of the research tests with you. If we receive information from this study that may be important for your health, we will share that information with you.

STUDY TERMINATION

The study may be terminated early if we find that serious side effects are happening frequently. In this event, information gathered during participation in this study will be made available to you and your private physician.

ALTERNATIVES TO PARTICIPATION OR TREATMENT

Riluzole and edaravone are FDA-approved treatments for ALS. In order to participate in this

research study, you can be on riluzole or edaravone however you must have been on a stable dose for at least 30 days before the screening visit. Please tell us about the drugs you are currently taking. There are no other approved medications for ALS. You may also choose not to participate or pursue other investigational therapies or off-label treatment with your own physician.

The study drugs are FDA-approved for the treatment of HIV but not for ALS. This means that they may be available outside of this trial.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

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

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

Reimbursement of travel will be offered consistent with NIH guidelines.

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.

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.

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.

Gilead Sciences, Inc. is providing tenofovir alafenamide (TAF) for this study to NIH without charge. No NIH employee involved in this study receives any payment or other benefits from Gilead Sciences, Inc.

GeNeuro SA is providing financial support for NINDS studies at NIH. No NIH employee involved in this study receives any payment or other benefits from GeNeuro SA.

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 National Institute of Neurological Disorders and Stroke 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
- Qualified representatives from Gilead Sciences, Inc, the pharmaceutical company who produces tenofovir alafenamide fumerate (TAF).

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

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 research information that we collect under the authority of the Public Health Service Act during your participation in this research study. This study's data will be stored under system 09-25-0200, Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH). 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 NIH staff (such as contractors and volunteers), 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 morbidity, mortality, disease, or tumor registries, when authorized by the Secretary of HHS, 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. If you do not want to share your information with us, then you cannot participate in this study.

POLICY REGARDING 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, Avindra Nath, MD, avindra.nath@nih.gov, 301-496-1561. 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 to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

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: _____ .