PRINCIPAL INVESTIGATOR: Scott Norberg, DO

STUDY TITLE: A Phase II Study of Avelumab in Subjects with Recurrent Respiratory Papillomatosis

STUDY SITE: NIH Clinical Center

Cohort: *Affected Patient*

Consent Version: *12/1/2020*

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Scott Norberg, DO
Phone: 301-275-9668
Email: scott.norberg@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.

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 described 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 needed 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 main purpose of this study is to see if Avelumab works in treating recurrent respiratory papillomatosis (RRP). Another goal of this study is to look at the safety of the study drug. Avelumab is designed to block the activity of a certain protein in the body, PD-L1, which has been associated with allowing abnormal or infected cells to avoid detection and elimination by the immune system.

Avelumab is an investigational drug, which means that the Food and Drug Administration (FDA) has not approved it for sale or for marketing for recurrent respiratory papillomatosis. This study is

a Phase 2 clinical trial. Phase 2 trials test the effectiveness (if the drug works) and safety of an investigational drug.

Avelumab belongs to a family of molecules called anti-PD-L1 antibodies. PD-L1 is a protein on the surface of cells that regulates whether that cell can be killed by immune system cells. PD-L1 is thought to be able to stop or decrease the response of the immune system to different kinds of diseased cells, such as cancer cells or cells infected with a virus. Avelumab interferes with the activity of PD-L1 and is thought to have an effect on the immune system (in particular white blood cells) that may cause an immune response or increase the effectiveness of the response.

Avelumab has been tested at different dose levels to see which dose is safe and well tolerated when given once every two weeks. Based on this information it was determined that 10mg/kg drug strength would be used in this research trial.

Additional purposes of the trial are to study the side effects of avelumab and to find out whether avelumab can reduce papillomas. Another goal of the study is to learn more about your disease and your response to this investigational drug. To do this, we will draw blood and collect tissue to measure certain "biomarkers". "Biomarkers" refer to different types of markers found in the blood and tissue that are associated with the disease and/or your response to the investigational drug. For this, samples of your blood and papilloma will be collected. The purpose of this research is to find out if there are any disease-related markers which may help in predicting how subjects respond to avelumab. This is described in more detail below.

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS STUDY?

You are being asked to take part in this trial because you have aggressive recurrent respiratory papillomatosis and your disease may not have responded adequately to available treatments.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 40 patients will be enrolled on this trial.

DESCRIPTION OF RESEARCH STUDY

WHAT WILL HAPPEN IF YOU TAKE PART IN THIS RESEARCH STUDY?

Before you begin the study

Before receiving the investigational drug, you will have several tests performed to check whether the trial is suitable for you. Your doctor will review your medical history and the drugs that you are currently taking as well as the previous treatments of your disease to determine whether you can participate in this trial. A small part of tumor tissue that was previously collected from you, will be used to confirm the diagnosis of recurrent respiratory papillomatosis. Some of these tests or procedures are part of regular care and may be done even if you are not being considered to join the study. If you have had some of these tests or procedures recently, they may or may not have to be repeated. The following tests and procedures will be performed prior to starting treatment:

1. Complete history and physical examination, including height, weight and vital signs (temperature, blood pressure, heart rate, breathing rate).
2. Blood tests (about 1 tablespoon) to check your blood counts, blood chemistries and viral studies.

3. For females of child-bearing potential, a pregnancy test will be done. You will not be able to participate if you are pregnant.
4. An endoscopy procedure in the clinic called flexible nasopharyngolaryngoscopy. For this procedure, the doctor uses a flexible endoscope (a small tube with a built-in camera) to look at the structures inside the nose, throat, larynx (voice box) and upper windpipe. This is a procedure to assess your throat and larynx; you will likely have already had this procedure before.

During the study

Before Treatment

If you are determined eligible to be in the study, you will have the following additional tests that will be performed for research purposes only:

1. Endoscopy procedure under anesthesia (sedation or general anesthesia). This procedure allows us to make sure we know where all of your papilloma disease is located, to make sure that your airway will be open enough to undergo the experimental treatments and to get biopsies of your papilloma. If we are concerned that your papilloma may cause breathing issues while you receive the experimental treatment, we may remove some of the papilloma to make your breathing safer. This pre-treatment biopsy is required because it will confirm the diagnosis and provide information that is critical to the goals of this study.

   The biopsy will be studied in the research laboratory to evaluate additional proteins and characteristics in your papilloma. You will not receive results of the research testing because they are being conducted in a research lab and are not valid for treatment purposes. The research testing on the biopsy may include growing cell lines (cells which keep dividing and growing in the laboratory, sometimes for years allowing us to continually study those cells).

   In addition, a portion of the biopsy will be reviewed by the pathologist at your study site to confirm your diagnosis of benign papilloma. You will receive the results of this review.
2. You will have blood collected (approx. 2 tablespoons) for research testing. You will not receive results of the research testing.
3. Voice Handicap Index-10 assessment questionnaire.
4. CT scan of chest (if necessary) to evaluate any papillomas in your lungs.
5. You will have an apheresis procedure for research. The apheresis procedure involves inserting a catheter (tube) into your vein to allow your blood to be collected. White blood cells will be separated from the rest of your blood and stored until the time they are used for research and the rest of the blood will be returned to you through the same catheter it came out of or through second needle in your other arm. We will try to use IV catheters already in place, but may need to give you an additional IV catheter. You will be asked to sign a separate consent for this procedure.

After the research samples have been collected, you will begin treatment. Your participation in the Study Treatment Period may continue for as long as you are receiving benefit and you do not meet any of the withdrawal criteria.

Avelumab will be administered at a dose of 10 mg/kg every other week (Day 1 of a 14-day cycle (weeks 1, 3, 5, 7, 9 and 11) for up to 12 weeks total (6 cycles). Avelumab will be given as an infusion through a vein (IV) over a 60-minute period.

You will be monitored closely while you are participating in this trial. Some medications may interact with avelumab and should be avoided. You will need to inform your study doctor about any prescription and non-prescription medications you are taking. Your doctor will help determine whether you should continue these drugs, whether you need to change the way you are taking these drugs, or whether you need to switch to another medication.

Some of the tests done before starting treatment will be repeated 6 and 12 weeks after starting treatment to check on how the treatment is working.

Every 2 weeks while receiving study treatment:

- Physical examination which may include flexible nasopharyngolaryngoscopy in the clinic.
- Vital signs and weight.
- Pregnancy test in women of childbearing potential.
- Blood tests (about 1 tablespoon) to check your blood counts, blood chemistries and other tests to monitor your health.
- Blood collection (approx. 3-4 tablespoons) for research testing.
- Review of side effects that you have experienced and medications that you are taking.
- Voice Handicap Index-10 assessment questionnaire.
- Infusion of avelumab.

Additional studies at a single time point two weeks after the initial dose

- Endoscopy procedure under anesthesia (sedation or general anesthesia) to see if there are clinical signs of inflammation in your airway or if there is blockage of your airway and to obtain biopsies which will be used for research purposes to evaluate how your disease is responding to the treatment.
- Apheresis procedure to collect white blood cells (also called leukocytes) which will be used for research.

Every 6 weeks while receiving study treatment (performed at 6 and 12 weeks after start of treatment):

- Physical examination.
- Flexible nasopharyngolaryngoscopy in the clinic.
- Voice Handicap Index-10 assessment questionnaire.
- CT scan of chest (if used for response assessment) to evaluate your RRP status.

When you are finished taking the study treatment:

- Endoscopy procedure under anesthesia (sedation or general anesthesia) to either perform a biopsy to verify that your papilloma is gone if you had a complete response to the treatment,

or to remove all visible papilloma with normal surgery techniques if you do not have a complete response to the treatment.

- If you respond to the treatment, you will be evaluated every 6 weeks (3 times), then every 12 weeks (3 times), then every 26 weeks (two times) or until you experience disease progression.
- You will be evaluated 30 days after the last dose of avelumab.
- If you do not experience a response to treatment you will be contacted annually to document additional disease recurrence and treatments that you have received.
- Evaluations will include:
    - Physical Exam
    - Pregnancy test in women of childbearing potential
    - Vital signs.
    - Flexible nasopharyngolaryngoscopy in the clinic.
    - Blood tests (about 1 tablespoon) to check your blood counts, blood chemistries and other tests to monitor your health.
    - Blood collection (approx. 3-4 tablespoons) for research testing.
    - Review of side effects that you have experienced and medications that you are taking.
    - Voice Handicap Index-10 assessment questionnaire.

BIRTH CONTROL

If you are a woman who is breast feeding or pregnant, you may not take part in the study because we don't know how this medicine would affect your baby or your unborn child. If you are a woman who can become pregnant, or are the partner of a woman who can become pregnant, you will need to practice two effective forms of birth control (one highly effective method and one other effective method) for at least 28 days prior, throughout the avelumab treatment and for at least 60 days after avelumab treatment. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

<u>Highly Effective Methods</u>

- Intrauterine device (IUD)
- Hormonal (birth control pills, injections, implants) Tubal ligation
- Partner's vasectomy

<u>Other Effective Methods</u>

- Latex condom
- Diaphragm
- Cervical Cap

RISKS OR DISCOMFORTS OF PARTICIPATION

What side effects or risks can I expect from being in this study?

What could be the side effects of the study drug?

In a clinical study like this one, every risk or side effect cannot be predicted. Each person's reaction to a study drug, device or procedure may be different. You may have a side effect or be at risk for symptoms, illnesses and/or complications that could not be predicted by your study doctor or the sponsor of this clinical study. If such side effects occur, you must inform your study doctor immediately.

The following side effects (regardless of relationship to study drug) have been observed in more than 10% of the 1300 patients treated with the study drug. Some of the side effects can be serious.

Common side effects:

- Fatigue
- Nausea, vomiting
- During or after drug infusion having:
  - change in blood pressure
  - fever
  - chills
  - difficulty breathing which might be serious
- Diarrhea
- Constipation
- Decreased appetite
- Weight loss
- Abdominal pain
- Anemia (decrease of red blood cells)
- Cough
- Shortness of breath
- Fever
- Chills (feeling cold)
- Dry mouth*

*With an increased need to drink water and/or use mouthwash or saliva stimulating products, and/or the need for minor diet modifications. On this study, the side effect of dry mouth has been observed in a larger number of participants than has been observed in other studies (>20%). We suspect, but do not know with certainty, that the dry mouth is caused by avelumab.

Less common side effects:

- Inflammation in the lungs (pneumonitis that can be fatal)
- Inflammation of the colon (colitis) which can lead to abdominal pain and diarrhea with or without blood. If left untreated, this may lead to a tear in the wall of the intestine which can be serious and life threatening.
- Inflammation of the liver called hepatitis, that can cause liver failure and death
- Inflammation of the thyroid (thyroiditis)

- Feeling faint, joint and abdominal pain, salt craving, skin darkening like a suntan
- Weight gain
- Anxious, angry
- Can't sleep
- Increased sweating
- Hair loss
- Muscle pain, tenderness and/or weakness
- Inflammation of the heart (myocarditis) (May cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, difficulty breathing, swelling in your legs. You may also experience a fast or irregular heartbeat that can cause dizziness or fainting. Sometimes this condition can lead to death.)
- Skin changes (rash, itchiness, redness)
- Allergic reactions, causing:
    - swelling of the face, lips and throat
    - breathing difficulties which might be serious
    - hives or nettle-like rash
    - change in blood pressure

The side effects listed above may or may not be caused by problems with your lungs, colon, liver, thyroid, adrenal gland, muscles, heart, and skin. They may be temporary, long term, permanent or result in death. However, most of these side effects are reversible. That means they will stop once the drug is discontinued.

Other immune-related events were observed with similar drugs in this class, such as type I diabetes mellitus, pituitary dysfunction, inflammation of the kidney, inflammation of the eyes, inflammation of the joint, inflammation of the brain, inflammation of the pancreas and inflammation of the nervous system.

Allergic reactions or reactions in the context with the infusions might occur during treatment. Infusion related reactions have been observed under treatment with the study drug, as seen for other similar drugs. In general, these reactions are mild to moderate and can be handled with appropriate drugs, but in rare cases, life-threatening and even fatal reactions might occur, which require advanced cardiac life support.

For the prevention of infusion-related adverse effects and possible allergic reactions you will receive a premedication of an antihistamine drug and paracetamol (acetaminophen) before every infusion.

There is a chance the study drug could lead to Tumor Lysis Syndrome (TLS) due to tumor shrinkage. TLS is when cancer cells break down and the body has to get rid of the broken-up cell parts. Sometimes your body can't remove the cell parts quickly enough and the levels of some products in your blood, such as salts and acids, can rise. This can happen especially in participants with large tumors or a high number of white cells in the blood. TLS can lead to serious problems, such as effects on your kidney and heart (including abnormal heart rhythms) or seizures. These side effects can result in needing kidney dialysis (a special machine to remove toxins from the

blood) or be fatal. Your study doctor knows to watch out for signs of this condition and how to treat this condition should it occur.

Any side effects or other health issues occurring during the study will be followed up by the study doctor.

Other side effects linked to medical procedures during the trial

Blood samples

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.

CT scan

During a CT scan, you're briefly exposed to much more radiation than you would be during a plain X-ray. Radiation exposure potentially increases your risk of developing cancer. Although rare, the intravenous (IV) contrast material involved in some CT scans causes medical problems or allergic reactions in some people. Most reactions are mild and result in hives or itchiness. In rare instances, an allergic reaction can be serious and potentially life threatening. Make sure to tell your study doctor if you've ever had a prior reaction to contrast material during medical tests.

Papilloma biopsy under anesthesia

You are required to have general anesthesia three times for this protocol – before treatment starts, two weeks after treatment has started, and after completing treatment. Although rare, serious risks associated with general anesthesia include an adverse drug reaction, stroke, heart attack or death. You will be asked to sign a separate consent prior to each procedure involving anesthesia. Aside from the risk of anesthesia, this procedure carries a risk of post-operative tongue or throat discomfort that may last for several days and a very small risk of a chipped tooth from the instruments in your mouth. We use special tooth guards to prevent this from happening.

Flexible nasopharyngolaryngoscopy

Complications are very uncommon; but may include tearing, gagging, coughing, and, less frequently, nose bleeding due to the scope being passed through the nose.

Apheresis

The most common side effects from this procedure are pain and bruising at the catheter site. You may also experience tingling of the lips and fingers due to the medicine used to keep blood from clotting. You may feel faint or light-headed during or after the procedure. Rarely this procedure may cause bleeding or infection at the catheter site.

Other

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.

POTENTIAL BENEFITS OF PARTICIPATION

Are there benefits to taking part in this study?

The aim of this study is to see if this experimental treatment will cause your papilloma to shrink. We do not know if you will receive personal, medical benefit from taking part in this study. These potential benefits could include shrinking of your papilloma or lessening of your papilloma-associated symptoms. Because there is not much information about the drug's effect on your disease, we do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have papilloma and other types of growths caused by viruses or cancers.

ALTERNATIVE APPROACHES OR TREATMENTS

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Instead of being in this study, you have these options**:**

- Getting treatment or care for your papilloma without being in a study
- Taking part in another study

Please talk to your doctor about these and other options.

STOPPING THERAPY

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

- if he/she believes that it is in your best interest
- if your papilloma progresses while you are receiving treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if new information shows that another treatment would be better for you
- if the sponsor, the FDA, the Institutional Review Board or your doctor decides to stop or interrupt the study
- If you cannot or do not come to your clinic visits or do not follow the study procedures

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 EMD Serono or designated representatives. If you withdraw your consent and leave the trial, any samples of yours that have been obtained for the study and stored at the NCI can be destroyed upon request. However, any samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases can**not** be recalled and destroyed.

USE OF SPECIMENS AND DATA FOR FUTURE RESEARCH

To advance science, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. A researcher who wants to study the information must apply to the database and be approved. Researchers use specimens and data stored in scientific databases to advance science and learn about health and disease.

We plan to keep some of your specimens and data that we collect, use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These specimens and data will be stripped of identifiers such as name, address or account number, so that they may be used for future research on any topic and shared broadly for research purposes. Your specimens and data will be used for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used. Results of research done on your specimens and data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

If you do not want your stored specimens and data used for future research, please contact us in writing and let us know that you do not want us to use your specimens and/or data. Then any specimens that have not already been used or shared will be destroyed and your data will not be used for future research. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

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?

Participants will be reimbursed a minimum of $78 for hotel and meals per day. Receipts must be provided for all expenses.

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.

- You will receive study treatment at no charge to you. This may include surgery, medicines, laboratory testing, x-rays or scans done at the Clinical Center, National Institutes of Health (NIH), or arranged for you by the research team to be done outside the Clinical Center, NIH if the study related treatment is not available at the NIH.
- There are limited funds available to cover the cost of some tests and procedures performed outside the Clinical Center, NIH. You may have to pay for these costs if they are not covered by your insurance company.
- Medicines that are not part of the study treatment will not be provided or paid for by the Clinical Center, NIH.
- Once you have completed taking part in the study, medical care will no longer be provided by the Clinical Center, NIH.

CONFLICT OF INTEREST

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

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

The National Institutes of Health and the research team for this study are using a drug, developed by EMD Serono through a joint study with your researchers and the company. 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
- Qualified representatives from EMD Serono, the pharmaceutical company who produces avelumab.

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 records 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 medical 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.

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, Scott Norberg, 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 to the oral short-form consent process only:

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: _____.