PRINCIPAL INVESTIGATOR: Alice P. Chen, MD

STUDY TITLE: Phase II Trial of the γ-secretase Inhibitor Nirogacestat (PF-03084014) in Adults with Desmoid Tumors/Aggressive Fibromatosis

STUDY SITE: National Cancer Institute

Cohort: Standard Adult

Consent Version: 5/18/2023

WHO DO YOU CONTACT ABOUT THIS STUDY?

Dr. Alice Chen, Principal Investigator, can be reached by telephone at (240) 781-3320 or by email at chenali@mail.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). 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.

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.

If the individual being asked to participate in this research study is not able to give consent for themselves, you, as the Legally Authorized Representative, will be their decision-maker and you are being asked to give permission for this person to be in this study. For the remainder of this document, the term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research.

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 find out what effects, good and/or bad, the drug Nirogacestat (which used to be called PF-03084014) may have on you and your tumor. Use of Nirogacestat is experimental. This study will measure whether taking this drug every day makes your tumors smaller. Nirogacestat has been tested in animals and is in the early stages of being tested in patients with different types of cancer. In an earlier clinical trial, some patients with desmoid tumors who took Nirogacestat for several months had their tumors become smaller.

This study may also help us find out whether your tumor has a variation in one of several genes that allow your tumor cells to form and grow. Blood, tissue, and tumor cells contain genes which are made up of DNA and which serve as the "instruction book" for each cell in the body. We know that variations in the genes in desmoid tumors are important for their growth. Identifying these tumor variations is one way scientists are trying to study and treat desmoids and other types of tumors.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you have desmoid tumors that have progressed after receiving at least one line of standard treatment. People with desmoid tumors who are not in a study are usually treated with chemotherapy that has already been approved by the FDA, or surgery, or radiation therapy.

How many people will take part in this study?

About 17 people with desmoids will take part in this study.

Description of Research Study

To take part in this study, you must be willing to provide a tumor block (or slides taken from your tumor block) and one blood sample so that we can look for variations in the genes that allow your desmoids to form and grow. Your study doctor will explain these genetic research studies to you in more detail. **However, these studies may also reveal information about your hereditary risk of developing other diseases or serious illness that, if revealed, might affect your privacy. This is very important.** In order to protect your privacy, all samples collected on this study will be assigned a special unique code to protect your confidentiality. If you agree to allow us to save certain medical information for our research, your information would be kept in a secure computer database and "linked" with the unique code assigned to your samples. To further help protect your

privacy, your medical information would be "unlinked" before we perform detailed genetic analysis of your samples so that we cannot connect the results back to you. The results of the research studies would not be reported to you, your family, or your doctor.

The total amount of blood collected at the beginning of the study is about 2 teaspoons.

What will happen if you take part in this research study?

During the study, you will take Nirogacestat by mouth twice a day every day. The study team will give you a diary to write down what time you take the drug each day as well as any side effects you may have. The team will also give you a chart describing the tests and procedures that will be done each day during the study.

Study tests, and procedures:

- CT scans to measure how your tumors are responding to Nirogacestat treatment will be done before you begin the study and then every 6 cycles (about every 4 months)
- Magnetic resonance imaging (MRI) scans are no longer mandatory and may be performed at the PI's discretion prior to start of study treatment, at the end of cycle 1, and then every 6 cycles (about every 4 months) to measure your tumors

  MRI uses a strong magnetic field and radio waves to take pictures of the body. We will obtain pictures of your body for this study. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRI, you will lie on a table that can slide in and out of the cylinder. We will place soft padding or a coil around your body segment being scanned. You will be in the scanner about 60 minutes. You may be asked to lie still for up to 60 minutes at a time. While in the scanner you will hear loud knocking noises, and you will be fitted with earplugs or earmuffs to muffle the sound. You will be able to communicate with the MRI staff at all times during your scan, and you may ask to be moved out of the machine at anytime.

  During part of the MRI you will receive gadolinium, a contrast agent, through an intravenous (IV) catheter. It will be done for research purposes.
- It is not known if MRI with contrast is completely safe for a developing fetus. Therefore, all women of childbearing potential will have a pregnancy test performed no more than 24 hours before each MRI scan with contrast. The scan will not be done if the pregnancy test is positive. You will be asked to complete health-related quality of life and symptom questionnaires at each Clinical Center visit so that we can learn about symptoms from your disease, treatment-related symptoms commonly experienced by patients, and how these symptoms affect how you feel and are able to function. Filling in these questionnaires will take about 10 minutes each time.

Most of the exams, tests, and procedures you will have are part of your regular care such as a complete medical history, blood tests, and scans to measure your tumors. We would also do a pregnancy test in women who are able to become pregnant.

If you choose to take part in this study, then we will also ask you to consider some optional extra tests and procedures. **None** of these tests are part of the usual approach for desmoid tumors: these tests are being done for research to help us learn more about desmoids. If you choose not to have these optional research tests you will still receive study drug and have other tests that are part of the study.

- If you agree, we would also like to collect tumor biopsy samples before Nirogacestat is given and again after you have been taking the drug for several weeks. We would also like to collect some of your medical information (without personal identifiers), such as what type of tumor you have, what drugs you have taken, and whether or not your tumor responded to these drugs, but not your name or any other personally identifiable information.

How long will I be in this study?

If you are accepted and you choose to take part in this study, you will begin taking Nirogacestat by mouth twice a day. Nirogacestat is given in cycles; each cycle is 21 days (3 weeks) long. All of the people taking part in this study will initially be given the same dose of drug; this dose may be changed by your study doctor based on any side effects that you may experience. You will stay in the study as long as you are tolerating the drug and your tumors are either stable or getting better, but you can choose to leave the study at any time.

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 an effective form of birth control before starting study treatment, during study treatment, and for 6 months after you finish study treatment. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

Effective forms of birth control include:

- abstinence
- intrauterine device (IUD)
- hormonal [birth control pills, injections, or implants]
- tubal ligation
- vasectomy

Risks or Discomforts of Participation

If you choose to take part in this study, there is a risk that you may:

- Lose time at work or home and spend more time in the hospital or doctor's office than usual
- Be asked sensitive or private questions which you normally do not discuss

The drug given in this study may affect how different parts of your body work, such as your liver, kidneys, heart, and blood. Your study doctor will be testing your blood and will let you know if changes occur that may affect your health. There is a risk that you could have side effects.

Here are important points about side effects:

- Your study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and your study doctor can make side effects less of a problem:

- Tell your study doctor or medical team if you notice or feel anything different so that the team can see if you are having a side effect.
- Your study doctor may be able to treat some side effects.
- Your study doctor may change the dose of the study drug to try to reduce side effects.

The table below shows the most common and the most serious side effects of Nirogacestat that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Risks of Nirogacestat (PF-03084014)

Approximately 169 participants with cancer have received nirogacestat as a single therapy in completed clinical studies that include the double-blind phase of NIR-DT-301 for the treatment of advanced tumors, of which 95 of these participants had desmoid tumors/aggressive fibromatosis. The most commonly reported side effects occurring in approximately 10% or more of participants were:

Common Side Effect (some may be serious)	**Nirogacestat (n=169)** **Number of participants experiencing the side effect out of 169 (%)**
Ovarian dysfunction in women able to have children (e.g., hot flashes and missed cycles)	27 out of 36 women able to have children (75%)[1]
Diarrhea	122 (72%)
Nausea	91 (54%)
Fatigue	81 (48%)
Hypophosphatemia (low level of phosphate in the blood that may result in muscle weakness and feeling tired)	72 (43%)
Vomiting	50 (30%)
Headache	42 (25%)
Cough	36 (21%)
Aspartate aminotransferase increased (increased liver enzyme which may be a sign of liver damage)	33 (20%)
Decreased appetite	33 (20%)
Rash maculo-papular (flat or raised red bumps)	33 (20%)
Rash	32 (19%)
Hypokalemia (Low level of potassium in the blood resulting in muscle weakness/cramps, and abnormal cardiac rhythm in severe cases)	31 (18%)
Mouth sores	29 (17%)
Alanine aminotransferase increased (increased liver enzyme which may be a sign of liver damage)	27 (16%)
Abdominal (stomach) pain	27 (16%)
Fever	27 (16%)
Dry mouth	25 (15%)

Common Side Effect (some may be serious)	Nirogacestat (n=169) Number of participants experiencing the side effect out of 169 (%)
Dermatitis acneiform (small, raised, acne-like bumps)	25 (15%)
Hot Flush	24 (14%)
Dyspnea (difficulty breathing)	22 (13%)
Anemia (low level of iron in the blood resulting in feeling tired)	21 (12%)
Constipation (difficulty passing stool)	19 (11%)
Upper respiratory tract infection (an infection of the nose, sinuses, or throat, like a cold or flu)	18 (11%)
Epistaxis (nosebleed)	18 (11%)
Arthralgia (joint pain)	18 (11%)
Dry skin	17 (10%)
Dizziness	17 (10%)
Hypertension (high blood pressure)	17 (10%)
Insomnia (difficulty falling asleep or staying asleep)	17 (10%)
Pruritus (itchy skin)	17 (10%)

[1] Number and percent of participants reporting ovarian dysfunction from the NIR-DT-301 study which included 36 women able to have children.

Other important side effects of nirogacestat included:

- The following side effects were reported in < 10% of participants:
    - Folliculitis (red, inflamed, itchy, bumpy, rash involving hair roots)
    - Hidradenitis (Small painful lumps in your groin, arm pits, buttocks, or under your breasts)
    - Alopecia (Hair thinning or hair loss)
    - Non-melanoma skin cancer

- Greater than 20% of participants receiving nirogacestat in the double-blind phase of the NIR-DT-301 study had excess protein and glucose (sugar) in their urine, which may be a sign of kidney damage.

Other rare but potentially serious side effects that have been reported in 3 or fewer participants include:

- Anaphylactic shock (severe and potentially life-threatening allergic reaction)
- Atrial fibrillation (irregular and rapid heart rhythm)
- Cholecystitis (gallbladder inflammation)
- Cyst (abnormal, fluid-filled sacs)
- Dehydration
- Febrile neutropenia (fever and lower than normal number of cells that fight infections in the blood)
- Groin abscess (sore between your legs)
- Hypersensitivity (an allergic reaction)
- Infected cyst (infected abnormal, fluid-filled sacs)
- Septic Shock (blood pressure drops very low after infection)

In addition to these risks, taking part in this research may harm you in unknown ways.

Let your study doctor know of any questions you have about possible side effects. You can ask your study doctor and medical team questions about side effects at any time.

What are the risks related to fertility?

Based on animal studies, nirogacestat may decrease fertility in men and women. Events of early menopause, such as feeling hot and missed monthly cycles, have been reported in women receiving nirogacestat. It is unknown if early menopause is reversible (improves) after stopping nirogacestat. The effects on long term fertility are also unknown. If you experience any of these symptoms, please discuss them with your study doctor.

Potential Risks Related to Blood Samples

Possible side effects from drawing the blood sample include mild pain, bleeding, bruising, and infection at the site of the needle insertion. Fainting or light-headedness can sometimes occur, but usually last only a few minutes.

Potential Risks Associated With Gene Sequencing

We will also be performing a full genetic analysis on the tumor samples and blood of patients on this study. This analysis is investigational, and not approved or cleared by the FDA, and is for research purposes only. We will only do this analysis once we have deleted all information that identifies the sample as belonging to you before we perform this analysis. Deleting your information is important because by sequencing your tumor and blood cells for gene variations, we may find information about your hereditary risk of developing disease, such as an increased risk of cancer or other serious illness. Because you share some genetic information with your children, parents, brothers, sisters, and other blood relatives, this information may also tell us about your blood relatives' risk of developing disease. This information could affect your ability or the ability of your family to purchase long term care insurance, disability insurance, and life insurance. Your privacy is very important to us. The best way to protect your privacy is to delete your information from your samples before we do these research tests. This means that we will not be able to tell which patients' tumors have gene variations. We will not know if a given tumor with or without a variation is yours, and therefore will not be able to give you any information we learn. If you have any questions about this, please ask your study team.

While neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative).

There also may be other privacy risks that we have not foreseen.

Will your genomic data be shared outside of this study?

As part of this research study, we will put your genomic data in a large database for broad sharing with the research community. These databases are commonly called data repositories. The information in this database will include but is not limited to genetic information, race and ethnicity, and sex. If your individual data are placed in one of these repositories, they will be labeled with a code and not with your name or other information that could be used to easily identify you, and only qualified researchers will be able to access them. These researchers must receive prior approval from individuals or committees with authority to determine whether these researchers can access the data.

Summary information about all of the participants included in this study (including you) is being placed in a database and will be available through open access. That means that researchers and

non-researchers will be able to access summary information about all the participants included in the study, or summary information combined from multiple studies, without applying for permission. The risk of anyone identifying you with this information is very low.

NIH policies require that genomic data be placed in a repository for sharing. Therefore, we cannot offer you a choice of whether your data will be shared. If you do not wish to have your data placed in a repository, you should not enroll in this study.

Risks for CT

During your participation in this research study, you may be exposed to radiation from CT scans. The amount of radiation exposure from these procedures is equal to approximately 6 rem per year. 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 CT scans that you get in this study will expose you to roughly the same amount of radiation as 20 years' worth of background radiation. Being exposed to too much radiation can cause harmful side effects such as an increase in the risk of cancer. The risk depends on how much radiation you are exposed to. Please be aware that about 40 out of 100 people (40%) will get cancer during their lifetime, and 20 out of 100 (20%) will die from cancer. The risk of getting cancer from the radiation exposure in this study is 0.6 out of 100 (0.6%) and of getting a fatal cancer is 0.3 out of 100 (0.3%).

Risks for CT Scans with Contrast Agent

Risks for IV contrast: 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.

Risks for oral contrast: You may have vomiting, nausea, cramping, bloating, constipation, or diarrhea after drinking the contrast.

Risks for MRI

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.

In addition, all magnetic objects (like watches, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

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.

Risks for Gadolinium-Enhanced MRI

The risks of an IV catheter include bleeding, infection, or inflammation of the skin and vein with pain and swelling.

Mild symptoms from gadolinium infusion occur in fewer than 1% of those who receive it and usually go away quickly. Mild symptoms may include coldness in the arm during the injection, a metallic taste, headache, and nausea. In an extremely small number, fewer than one in 300,000 people, more severe symptoms have been reported including shortness of breath, wheezing, hives, and lowering of blood pressure. You should not receive gadolinium if you previously had an allergic reaction to it. You will be asked about such allergic reactions before gadolinium is given.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis" which has resulted in a very small number of deaths. A blood test of your kidney function may be done within the month before an MRI scan with gadolinium contrast. You will not receive gadolinium for a research MRI scan if your kidney function is not normal or if you received gadolinium within the previous month.

Most of the gadolinium contrast leaves the body in the urine. However, the FDA recently issued a safety alert that indicates small amounts of gadolinium may remain in the body for months to years. The effects of the retained gadolinium are not clear. At this time, retained gadolinium has not been linked to health risks in people whose kidneys work well. Some types of gadolinium contrast drugs are less likely to remain than others. In this study, we will use the gadolinium contrast drugs that are less likely to remain.

Please tell your research team if you have had any MRI scans in the past 12 months. We will also give you additional information called a "Medication Guide." Upon request, we will give you individual information about retained gadolinium we see on your studies.

Potential Benefits of Participation

Are there benefits to taking part in this study?

Taking part in this study may or may not make your health better. 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 tumor or lessening of your symptoms, such as pain, that are caused by the tumor. Because there is very little information about the effect of Nirogacestat on your tumor, 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 desmoids.

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:

- you may choose to have the usual approaches described above
- you may choose to take part in a different study, if one is available, such as chemotherapy or hormonal therapy or the investigational agents imatinib or sorafenib
- or you may choose not to be treated for desmoid, but you may want to receive comfort care to relieve symptoms

Please talk to your doctor about these and other options.

Research Subject's Rights

What are the costs of taking part in this study?

If you choose to take part in the study, the following will apply, in keeping with the NIH policy:

- 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.

Stopping Therapy

You can decide to stop at any time. If you decide to stop for any reason, it is important to let your study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to include your medical information in the study.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Your study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB, or FDA

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.

Optional Biopsy

Tumor biopsy: Only if you have disease that in the opinion of your study doctor can be biopsied safely, will we ask you to consider undergoing a procedure to collect tumor biopsy. If you agree, you will undergo imaging-directed biopsy of your tumor (removal of a small bit of tissue for research purposes) once before you receive the study drug Nirogacestat and again after you have

been taking drug for about 5 months. After the first biopsy, if you decide not to have the second biopsy you will still receive study drug and have other tests that are part of the study.

You will be asked to sign a separate consent form for each biopsy procedure.

Biopsies will be done using a small bore needle under imaging guidance (CT, MRI, or ultrasound as deemed appropriate by the interventional radiologist performing the biopsy). Imaging helps the specialized radiologist know that the needle has been placed into the tumor mass. You will be counseled in more detail about the procedure and its risks at that time. Your safety is the most important thing at all times.

Even if you sign "yes" to have the biopsy, you can change your mind at any time. Please read the sentence below and think about your choice. After reading the sentence, circle and initial the answer that is right for you.

I agree to have my samples collected and used for research, and have some of my medical information (without personal identifiers) stored for research purposes:

Yes No Initials_____

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 cover the cost for some of your expenses. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. Someone will work with you to provide more 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.

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.

All participants in MRI research studies will have an MRI scan read by a credentialed radiologist. Sometimes there are unexpected findings on an MRI scan or on other testing that we will perform. Some findings are of unknown significance or importance to your health, which may make you anxious. We will inform you about any finding that may require further evaluation or care. We are not able to provide evaluation or treatment for these conditions at NIH. If needed, we will refer you to a health care provider.

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 (National Cancer Insititute) or their agent(s)
- Qualified representatives from SpringWorks, the pharmaceutical company who produces Nirogacestat.

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, Alice Chen, chenali@mail.nih.gov, (240) 781-3320. 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

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	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: _____ .