PRINCIPAL INVESTIGATOR: Alice P. Chen, M.D.

STUDY TITLE: Phase II Study of Cediranib (AZD2171) in Patients With Alveolar Soft Part Sarcoma

STUDY SITE: NIH Clinical Center

Cohort: Standard

Consent Version: 11/15/2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

Alice P. Chen, Principal Investigator: 240-781-3320

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 find out what effects, good and/or bad, the drug AZD2171 (Cediranib) has on you and your alveolar soft part sarcoma. This study will also help to find out how AZD2171 works in patients who have alveolar soft part sarcoma. AZD2171 is an experimental drug, not yet approved by the Food and Drug Administration. The drug blocks the creation of new blood vessels. All solid tumors need new blood vessels to grow. We hope to inhibit tumor growth with AZD2171 by preventing the growth of new blood vessels. We will ask to take a small biopsy of your tumor before the drug is given and then again after a few days of treatment to help us learn about how this drug works in your tumor. However, tumor biopsies are optional. So far, more than 500 patients have taken part in clinical trials of AZD2171.

More than 35 patients have been treated with alveolar soft part sarcoma. The tumors of many of the patients with alveolar soft part sarcoma decreased in size or remained stable without growth for a prolonged period of time.

Up to 73 patients with alveolar soft part sarcoma will take part in this study; up to 13 children will be enrolled. In February 2013, we met the study objectives for adult patients and so we have stopped enrolling adult patients.

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

If you are accepted and you choose to take part, you will begin taking AZD2171 by mouth once a day, every day for the duration of the study. The treatment will be given in cycles. Each cycle is 28 days long. You are to swallow the tablets whole with about 8 ounces of water at the same time every day, on an empty stomach, 1 hour before or 2 hours after meals. You should write down the number of pills you take and the time you took then in the diary that your study team will give you. If you miss doses, please write this in your diary. If you remember your missed dose within 3 hours of the time you usually take a dose, you can take enough pills to make up for the missed dose; if not, do not make up the missed dose. The dose will be changed if you have any serious side effects. This will be determined by your study team. AZD2171 can be taken while you are an outpatient.

Standard procedures being done because you are in this study; these may be done more often because you are in the study:

- **Clinic visit** to ask how you are feeling and to evaluate you with a physical examination every 2 weeks. If you are tolerating treatment well, these visits will be required less frequently the longer you are on study.
- **Vital signs:** You will need to have your vital signs (measurement of your temperature, breathing rate, and blood pressure) measured each time you are seen in the outpatient clinic. We will also ask you to have your blood pressure measured by a health care provider weekly for the first 2 cycles. If you have high blood pressure and need medication to control it, the study doctor will tell you how often you will need to have your blood pressure checked during the study.
- **Blood tests:** Measurement of your white blood cells, red blood cells and platelets, and measurements of your blood sugar and electrolytes and of how your liver and kidneys work will be done weekly during cycles 1 and 2 and every 2 weeks during all other cycles. If you have been on study for more than a year and are tolerating treatment well, blood tests may be required less frequently. Doing all of these blood tests will require 1-2 tablespoons (20-30 mL) of blood each time.
- **Urine test:** You will be asked to give a urine sample for testing weekly during cycles 1 and 2 then once during every course after that. If you have been on study for more than a year and are tolerating treatment well, urine tests may be required less frequently. Depending on the results, you may be asked to collect your urine for 24 hours for further testing.
- **EKGs** (a recording of the heart's electrical activity) to check your heart will be done if needed to check for signs of possible damage to your heart.
- **Echocardiogram** to check your heart will be done before starting AZD2171 and if needed every 1 to 2 cycles to check for signs of possible damage to your heart.
- **CT scans** (a computerized x-ray examination) or other imaging tests such as ultrasound (an examination using sound waves) or MRI (an examination using magnetic field and radio waves) that detect your tumor will be done every 2 cycles while you are receiving study drug (after 18 cycles, CT scans will be done every 3 cycles; after 36 cycles, every 4 cycles; after 60 cycles, every 6 cycles).

PET scans (a scan that detects a small amount of radioactive substance that has been injected through a vein) will also be done at the start of the study and may be repeated. This is done so that any benefit of the drug can be seen, and so that if your cancer is not responding to the drug, the study team can tell you and help you move to a different treatment program (discussed further below).

Tests and procedures that are either being tested in this study or being done to see how the drug is affecting your body:

- **Tumor biopsies:** After you are accepted to take part in the study, you will be asked to have a biopsy of your tumor (removal of a small bit of tissue for examination under a microscope) once before you receive study drug and a second time after 3 to 5 days of treatment. A third optional biopsy after completion of 4 weeks of therapy may be asked with the intention of providing further information about how your disease responds to treatment. We are collecting biopsy samples to study how the drug affects your tumor. Biopsies are a very important part of this trial and are done for research purposes. Depending on what knowledge we gain from patients who have had a tumor biopsy before you, the timing of your subsequent biopsies may change. However, willingness to undergo tumor biopsies is optional and not required for taking part in this study. No more than three biopsy procedures will be performed for this study. After the first biopsy, if you decide not to have further biopsies, you will still receive study drugs and have other tests that are part of the study. You will be asked to sign a separate consent form for each biopsy procedure.

  Tumor biopsies are only collected by trained personnel. Biopsies are collected using a small bore needle under imaging guidance (CT, MRI, or ultrasound as considered appropriate by the interventional radiologist performing the biopsy). Imaging helps the specialized radiologist know that the needle has been placed into the tumor mass.

  Typical risks of biopsy collection include, but are not limited to, bleeding, infection, pain, and scarring. If you experience any complications from the biopsy, medical care will be offered to you. You will be counseled in more detail about biopsies, and you will be asked to sign a separate consent form that will describe the procedures and risks at that time. Your safety is the most important thing at all times. If upon attempting the first biopsy, no tissue can be obtained or it has caused you harm, the second biopsy procedure will not be done.

  After you are enrolled in this study, if for any reason the biopsies cannot be done safely, you may still receive the study drugs but the biopsies will not be done.

  I agree to allow biopsies for research purposes Yes_____ No_____ Initials_____

STUDY CHART

The treatment is given over 28-day periods of time called cycles. The 28-day treatment cycle will be repeated as long as you are not having serious side effects and your cancer is either steady or getting better. Each cycle is numbered. The chart below shows what will happen to you during Cycle 1 and future cycles. The left-hand column shows the day in the cycle and the right-hand column tells you what will happen on that day. This schedule lists what will happen to you after you sign the consent form and start the study.

Before Cycle 1

Day	What to do and what will happen to you
Before starting AZD2171	• Check in at Outpatient Clinic • Get routine blood and urine tests • Have a history taken of how you feel and undergo a physical examination by a Health Care Provider (HCP) • CT and PET scan will be done • EKG (and echocardiogram if needed) will be done to check your heart • Tumor biopsy will be taken (optional)

Cycle 1

Day	What to do and what will happen to you
Days 1-28	• Have a history taken of how you feel and undergo a physical examination by a Health Care Provider (HCP) every 2 weeks; get routine blood tests weekly during cycle 1 • Urine sample for routine tests weekly during cycle 1 • Keep taking AZD2171 once a day if you have no bad side effects and your cancer is not getting worse. Call the research nurse or your study doctor if you do not know what to do. • CT scan will be done every 2 cycles during the first 18 cycles to find out how your tumor is responding to AZD2171; PET scan may also be done. • EKGs and echocardiograms may be done to check your heart. • Optional tumor biopsy will be done during Cycle 1, between day 3 and 5, and at completion of the first cycle.

Cycle 2 and Future Cycles

Day	What to do and what will happen to you
Days 1-28	• Have a history taken of how you feel and undergo a physical examination by a Health Care Provider (HCP) every 4 weeks; get routine blood tests every 2 weeks in cycles 2 and 3, and every 4 weeks in cycle 4 and further cycles. If you are tolerating treatment well and remain on study for more than a year, these clinic visits may be required less frequently. • Urine sample for routine tests weekly during cycles 2 and 3, then once every 4 weeks in all other cycles. If you are tolerating treatment well and remain on study for more than a year, urine tests may be required less frequently. • Keep taking AZD2171 once a day if you have no bad side effects and your cancer is not getting worse. Call the research nurse or your study doctor if you do not know what to do. • CT scan will be done every 2 cycles during the first 18 cycles to find out

	how your tumor is responding to AZD2171. After 18 cycles, CT scans will be done every 3 cycles; after 36 cycles, CT scans will be done every 4 cycles; after 60 cycles, CT scans will be done every 6 cycles. PET scan may also be done. • EKGs and echocardiograms may be done to check your heart

HOW LONG WILL I BE IN THIS STUDY?

You can take part in this study until either you or your study team decides that AZD2171 is not helping you. Your taking part is voluntary, so you can stop taking AZD2171 at any time, but we ask that you speak to your study team before stopping the study drug. Your study team will be watching you and your cancer while you are taking AZD2171. If your alveolar soft part sarcoma is clearly getting worse, then your study team will stop treatment with AZD2171. At the end of the study, we will check with you or your local doctor for 30 days after you stop taking AZD2171 to see how you are doing. No more testing will be required.

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 disease comes back during 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

In this case, you will be told the reason why AZD2171 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 the Cancer Therapy Evaluation Program (CTEP) at the National Cancer Institute (NCI) 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 cannot be recalled and destroyed.

WHAT POSSIBLE RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

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.
- You may be asked sensitive or private questions which you normally do not discuss.

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

Here are important points about side effects:

- The 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 the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

Studies have shown high blood pressure to be one common side effect of AZD2171. Your blood pressure will be closely watched while you are taking AZD2171. This will include having your blood pressure measured weekly by a health care provider for the first 2 cycles. If you have high blood pressure while taking AZD2171, your study doctor may recommend follow-up with your primary care physician and/or starting or increasing medication to lower blood pressure.

Grapefruit juice has been shown to work with some drugs by blocking the activity of the body's cytochrome P450 (CYP450) system. CYP450 is important in breaking down substances in the body, including many drugs. Because it is not fully known if grapefruit juice interacts with AZD2171 in the body, please avoid grapefruit juice while taking AZD2171.

We do not know if taking AZD2171 will cause other drugs you may be taking to work differently. **It is very important that you talk to a member of the research team before beginning any new drugs, over-the-counter medications, vitamins, or alternative therapies.**

The tables below shows the most common and the most serious side effects 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.

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

Risks and side effects related to AZD2171 include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving cediranib (AZD2171), more than 20 and up to 100 may have:
• Diarrhea, nausea • Tiredness • Loss of appetite • Changes in voice • High blood pressure which may cause headaches, dizziness, blurred vision

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving cediranib (AZD2171), from 4 to 20 may have:
• Pain • Constipation, vomiting • Dry mouth • Difficulty swallowing • Sores in the mouth • Infection • Bruising, bleeding • Weight loss • Dehydration • Muscle weakness • Dizziness, headache • Cough, shortness of breath, sore throat • Redness, pain or peeling of palms and soles • Blood clot which may cause swelling, pain, shortness of breath, confusion, or paralysis

RARE, AND SERIOUS In 100 people receiving cediranib (AZD2171), 3 or fewer may have:
• Anemia, kidney problems which may cause tiredness, bruising, swelling, or may require dialysis • Heart failure which may cause shortness of breath, swelling of ankles, and tiredness • A tear or hole in internal organs that may require surgery • Liver damage which may cause yellowing of eyes and skin, swelling • Non-healing surgical site • Damage to the brain which may cause changes in thinking • Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome) • Kidney damage which may require dialysis • Blood clot in artery which may cause swelling, pain, shortness of breath or change of color in extremity

Reproductive risks:

If you are a female who is breast feeding or pregnant, you may not take part in the study because we do not know how AZD2171 would affect your baby or your unborn child. If you are a female who can become pregnant, or are the partner of a female who can become pregnant, you will need to practice an effective form of birth control. Check with your study doctor or nurse about what kind of birth control methods to use and for how long you should use them after you are no longer taking AZD2171. 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
- hormonal [birth control pills, injections, or implants]
- vasectomy
- intrauterine device (IUD)
- tubal ligation

For more information about risks and side effects, please ask your study team.

Potential Risks Related to Research-Related Imaging Studies:

During your participation in this research study, you will be exposed to radiation from up to 3 CT-guided research tumor biopsies and 2 CT scans or FDG-PET/CT scans each year. The amount of radiation exposure you will receive from these procedures is equal to approximately 4.8 rem. A rem is a unit of absorbed radiation.

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

The CT-guided biopsies and CT scans that you get in this study will expose you to roughly the same amount of radiation as 16 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.

Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every1000 people who get a very large amount of extra radiation.

Potential Risks for FDG-PET/CT

In addition to the radiation risks described above, there is a chance of developing an allergic reaction from the FDG-PET contrast material, which may cause symptoms ranging from mild itching or a rash to severe difficulty breathing, shock or rarely, death. The contrast material may also cause kidney problems. The study doctors will do a blood test prior to the test to confirm that it is safe you to receive the contrast.

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

The risks of IV insertion include temporary pain and bleeding or bruising at the site where the IV enters the skin. In placing the IV, there is a small chance of fluid leaking into the tissue surrounding the IV and infection, which may cause some swelling and discomfort. Rarely, the IV site may become infected, which might require treatment with antibiotics.

Potential 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.

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

The aim of this study is to see if AZD2171 will cause your tumors 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 tumor or lessening of your symptoms, such as pain, that are caused by the cancer. Because there is not much information about the drug's effect on your cancer, 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 cancer.

WHAT ARE MY OTHER CHOICES 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 cancer without being in a study
- Taking part in another study
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer. It does not treat the cancer directly. Instead, it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to your doctor about these and other options.

WILL YOUR SPECIMENS OR DATA BE SAVED FOR USE IN OTHER RESEARCH STUDIES?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These

studies may provide additional information that will be helpful in understanding cancer, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

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

_____ Yes _____ No

Initials Initials

WILL YOUR SPECIMENS OR DATA BE SHARED FOR USE IN OTHER RESEARCH STUDIES?

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

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

_____ Yes _____ No

Initials Initials

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

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

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.

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.

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.

CONFLICT OF INTEREST (COI)

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

The NIH and the research team for this study are using a drug developed by AstraZeneca Pharmaceuticals through a joint study with your study team 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?

Your privacy is very important to us and the researchers will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept in a central database for research. Your name or contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

In addition to the above which is handled by the study sponsor (the Cancer Therapy Evaluation Program or CTEP), we may put your research data in a large database for broad sharing with the research community. These databases are commonly called data repositories. These data repositories might or might not be located at the NIH. The information in this database could include but is not limited to genetic information, ethnicity and sex. If your individual research data is placed in one of these repositories, it will not be labeled with your name or other information that could be used to easily identify you, and only qualified researchers will be able to look at your data. These researchers must receive prior approval from individuals or committees to access the data.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor and drug companies (makers of copanlisib and nivolumab) supporting the study.
- The Institutional Review Board, IRB, a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

Certificate of Confidentiality

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

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

The Certificate does not protect your information when it:

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

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

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

Privacy Act

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

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

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor Geraldine O'Sullivan Coyne at: 301-402-9122. For questions about your rights while in this study, 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

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date

Signature of Parent/Guardian *(as applicable)*	Print Name of Parent/Guardian	Date

Assent: *(Use this section only when this process is approved by an IRB for older minors. Do not use if an IRB requires a separate assent form for this population.)*

I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor: *(as applicable)*

Signature of Minor	Print Name of Minor	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: _____.