PRINCIPAL INVESTIGATOR: Alice Chen, M.D.

STUDY TITLE: A Phase I Study of Indenoisoquinoline LMP744 in Adults With Relapsed Solid Tumors and Lymphomas

STUDY SITE: NIH Clinical Center

Cohort: Patients

Consent Version: 1/6/2023

WHO DO YOU CONTACT ABOUT THIS STUDY?

Alice Chen, Principal Investigator: [redacted]

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.

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?

This study involves your choosing to take part in a clinical research study. You are being asked to take part in this study because standard therapies have not been effective for the type of cancer you have. We are studying an experimental drug in this trial, LMP744, which damages DNA, resulting in cell death.

This is the first time that LMP744 is being given to humans. LMP744 is an investigational drug and is not approved by the Food and Drug Administration (FDA). The purpose of this study is to test the safety of LMP744 and find out the dose of the drug that can be safely given to humans. We are trying to understand how this drug works, how your body handles the drug, and what side effects occur. We may also ask you to give blood and

tumor biopsy samples to help us learn about how LMP744 works in your body and in your tumor.

Up to 53 patients will take part in this study at several centers across the United States.

WHAT IS THE USUAL APPROACH TO MY CANCER?

You are being asked to take part in this research study because standard medical treatments such as chemotherapy, surgery, and/or radiotherapy have not been very effective for the type of advanced cancer that you have.

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 other therapies that, although might not improve survival, may have other benefits, such as delaying disease progression.
- Taking part in another study.
- Getting no treatment.
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

WHAT ARE THE STUDY GROUPS?

All of the participants in the study will receive the study drug LMP744. Different doses of LMP744 will be given to one or more study participants. The first several study participants will receive the lowest doses. If the drug does not cause serious side effects, it will be given to other study participants at higher doses. The doses will continue to increase until side effects occur that require the dose to be lowered. Once the appropriate dose is identified, several more patients will be treated at that dose.

HOW LONG WILL I BE IN THIS STUDY?

During the study, you will take LMP744 through a central line, a tube placed into your vein. If you already have a central line, it will be used to give you LMP744. If you do not already have a central line, a temporary one will be placed for as long as you are in the study. Treatment will take 60 minutes and will be given once a day for 5 days. LMP744 will be given in cycles. Each cycle is 28 days long, so you will be given LMP744 for 5 days followed by 23 days without drug.

You will continue to receive LMP744 for as long as you are tolerating it and your cancer is either stable or getting better.

Your doctor will continue to watch you for side effects and follow your condition for 30 days after you finish the study, or until any drug-related side effects you may have had have stabilized or resolved.

WHAT EXTRA TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra tests and procedures that you may need to have if you take part in this study that are not part of the usual approach for your type of cancer.

You may have the following extra tests and procedures during the study:

- Central line insertion
    - Prior to starting treatment, you may need to have a "tunneled" catheter inserted. This type of catheter is a thin, long tube made of flexible, silicone rubber that is surgically inserted into one of the main blood vessels leading to your heart. One end of the catheter is inserted through a small incision into the main blood vessel leading into your heart. The other end of the catheter may be tunneled under your skin and comes out through your skin through a second small incision.
    - Your doctor or nurse will explain the procedure in detail, and you will be asked to sign a separate consent. Before you go home, you will be given instructions on how to care for the catheter.
- Imaging tests
    - CT scans or other imaging tests that detect your tumor will be done every 2 cycles (about every 8 weeks) while you are receiving treatment
    - Imaging may be done every 3 cycles if you have been on study for more than 1 year or every 4 cycles if on study for more than 3 years
- Research blood samples
    - Blood samples will be collected before you receive study drug and then at several times during cycle 1 only so that we can measure how your body handles LMP744. The total blood for all these tests will be about 2 tablespoons (about 30 mL)
    - Blood samples will be collected to assess any changes in tumor DNA in your blood. Samples will be collected before you take drug, on the first day of every cycle for as long as you are on study, and if your cancer progresses. Each blood collection is less than 2 tablespoons.
    - Optional blood samples will be collected to find out the effects of the drug on any tumor cells in your blood. Samples will be collected before you first take drug, on day 3 of cycle 1, on the first day of every cycle for as long as you are on study, and when you come off study. Each blood collection is about 2 teaspoons
- An EKG (electrocardiogram) and ECHO (echocardiogram)
    - An EKG and ECHO to check your heart will be done before the study and before cycles 3 and 5, and may be repeated while you are receiving treatment if the study doctor thinks it is needed to check for signs of possible damage to your heart
- A urine or serum pregnancy test for women of childbearing potential is required prior to every cycle
- Tumor biopsies will be required before you receive study drug and again on day 2 of cycle 1 after drug administration. Biopsies are a very important part of this trial and are done for research purposes
    - Willingness to undergo tumor biopsies will be required for taking part. After the initial biopsy, if you decide not to have further biopsies, you will still receive LMP744 and have other tests that are part of the study
    - You will be asked to sign a separate consent form for each optional biopsy procedure

Tumor biopsies are only collected by trained personnel. Biopsies are collected using a small 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. If the interventional radiologist recommends MRI imaging, you may receive gadolinium, a contrast agent, through an intravenous (IV) catheter (small tube). 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.

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, further biopsies 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.

You will be provided with a study chart that shows when you will need to have these tests and procedures done. Neither you nor your health care plan/insurance carrier will be billed for these tests.

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

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. But doctors do not know all the side effects that may happen when taking LMP744 as this drug has never been given to humans. We do not know if taking LMP744 will cause any other medications you may be taking to work differently. It is very important that you tell a member of the research team before starting any new drugs, over-the-counter medications, or alternative therapies.

If you choose to take part in this study, there is a risk that the LMP744 may not be as good as the usual approach for your cancer or condition at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The LMP744 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 test 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(s)/study approach.

Here are important things to know 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, and some may never go away.
- Some side effects may make it hard for you to have children.
- Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects doctors know about. Keep in mind that there might be other side effects doctors 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.

POSSIBLE, SOME MAY BE SERIOUS
• Anemia which may cause tiredness, or may require blood transfusion • Infection, especially when white blood cell count is low • Nausea, vomiting • Death • Bruising, bleeding • Increased liver enzymes (alanine aminotransferase, aspartate aminotransferase, and/or GGT)

Reproductive risks:

The drug used in this study (LMP744) could be very damaging to an unborn baby. You should not get pregnant, breastfeed, or father a baby while in this study. 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 4 months after you finish study treatment. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

Potential Risks Related to Research-Related Imaging Studies:

During your participation in this research study, you may be exposed to radiation from CT scans each year. The amount of radiation exposure from these procedures is equal to approximately 1.6 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." 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 5 years' worth of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

Contrast agent:

Some types of cancer require a contrast agent to be used for imaging studies. There is a chance of developing an allergic reaction from the 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.

For IV 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.

For oral contrast: You may experience vomiting, nausea, cramping, bloating, constipation or diarrhea after drinking the contrast.

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 (NSF)". This condition always involves the skin and can also involve the muscles, joints and internal organs. NSF 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 below the safe level.

Most of the gadolinium contrast leaves the body in the urine. However, the FDA has issued a safety alert that indicates small amounts of gadolinium may remain in the body for months to years. The long-term effects of the retained gadolinium are unknown. Some types of gadolinium contrast drugs are less likely to remain in the body than others. In this study, we will use the gadolinium contrast drugs that are less likely to remain in the body, whenever possible. 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.

Central line insertion:

Central catheter placement is very common and is generally well tolerated. The most common risk is infection which is treated with antibiotics or removal of the catheter. Additional risks include, clots forming inside or along

the outside of the catheter which can break off and travel to the veins near your neck, face, chest, arms or lungs (pulmonary embolism). If you develop blood clots, your doctor will give you the appropriate treatment which may include blood thinners. Uncommon side effects include swelling of the face and arm and/or lung collapse. If the lung collapses, it may be necessary to place a tube between the ribs to allow the lung to re-expand. Rarely the catheter can break or air could enter the catheter and travel to the veins near your neck, face, chest, arms or lungs.

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

This study is unlikely to help you. The knowledge gained from this study may help others in the future who have cancer.

CAN I STOP TAKING PART IN THIS STUDY?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop taking the study drug safely.

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.

The 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.

The study doctor may take you out of the study:

- If your health changes and the study is no longer 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
- If you become pregnant
- If the study is stopped by the sponsor, the IRB (people who review the research to protect the people taking part in the study), or FDA.

STUDY CHART

Day	What to do and what will happen to you
Before starting study drug	• Check in at the Outpatient Clinic • Have a history taken of how you feel and undergo a physical examination by a Health Care Provider • Get routine blood and urine tests • Pregnancy test for women who are able to become pregnant

Day	What to do and what will happen to you
	• CT or MRI scan will be done • Research blood and urine samples will be taken • Tumor biopsy will be taken • EKG and ECHO will be done to check your heart
Cycle 1, Day 1	• Check in at Outpatient Clinic • Get routine blood and urine tests • Receive the first dose of LMP744 through a vein • Blood draws for research will be obtained at multiple times
Cycle 1, Days 2-5	• Check in at Outpatient Clinic • Continue to receive LMP744 through a vein • Blood draws for research will be obtained at multiple times • Tumor biopsy will be taken on Day 2
Cycle 1, Day 8	• Check in at Outpatient Clinic • Have a history taken of how you feel and undergo a physical examination by a Health Care Provider • Get routine blood and urine tests • Blood draws for research will be obtained
Cycle 1, Day 15	• Check in at Outpatient Clinic • Get routine blood and urine tests
Cycle 2, Days 1-5	• Check in at Outpatient Clinic • Have a history taken of how you feel and undergo a physical examination by a Health Care Provider on day 1 • Get routine blood and urine tests • Blood draws for research may be obtained on day 1 • Receive LMP744 through a vein on days 1-5
Cycle 2, Day 15	• Check in at Outpatient Clinic • Get routine blood and urine tests • EKG and ECHO will be done to check your heart before cycle 3 and again before cycle 5
Cycle 3 and onwards, Day 1	• Check in at Outpatient Clinic • Have a history taken of how you feel and undergo a physical examination by a Health Care Provider • Get routine blood and urine tests • Blood draws for research may be obtained • Receive LMP744 through a vein • CT or MRI scans to determine how your tumor is responding to the drug every 2 cycles (less often if you have been on study for more than one year)
Cycle 3 and	• Receive LMP744 through a vein

Day	What to do and what will happen to you
onwards, Days 2-5	
Cycle 3 only, Day 15	• Check in at Outpatient Clinic • Get routine blood and urine tests
After finishing treatment	• You will be followed for 30 days after your last dose of drug is administered • Blood draws for research may be obtained • Between Day 27 and 30 we will contact you by phone to check on you

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.

No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested.

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.
- 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

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, Dr. Alice Chen, [redacted], [redacted]

[redacted]. 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: _____.