THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Longitudinal Assessment of Cardiovascular Injury and Cardiac Fitness in LA-NSCLC Patients Receiving Model Based Personalized Chemoradiation – an Adaptive Cohort Registration Study

2021-0071

Study Chair: Zhongxing Liao, MD

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

You are being asked to take part in a research study because you have non-small cell lung cancer, small cell lung cancer, or limited stage – small cell lung cancer (L-SCLC).

The goal of this research study is to learn more about the risk of developing heart disease as a result of chemoradiation treatment for lung cancer. Researchers want to learn if the risk can be reduced by using a patient's individual risk profile to guide cancer treatment and help protect the heart.

This is an investigational study.

There may be no benefits for you in this study. Future patients may benefit from what is learned.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential expenses and time commitment.

You can read a list of potential risks below in the Possible Risks section of this

consent.

For the purposes of this study, you will be followed for as long as you are being followed for your cancer diagnosis, which can last up to 10 years. Your medical information, including the results of blood tests and imaging studies, will be collected during this time period.

This study will be performed at no cost to you.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 200 evaluable participants will be enrolled in this study. All will take part at MD Anderson.

If you agree to take part in this study, you will have tests and procedures performed **before your chemoradiation treatment, 3 times during the treatment, 6-8 weeks after the treatment, 4-6 months after the treatment, and then every year after treatment**. At each of these times:

- Blood (about 2 tablespoons) may be drawn for tests of your heart function.
- You will complete two questionnaires about your symptoms and quality of life. These should take about 3-5 minutes to complete.

Before treatment, 2 times during treatment, and 6-8 weeks, 4-6 months, and 1 year after treatment:

- You will have an EKG to check your heart function.
- You will have a 6-minute walk test. For this test, you will be asked to walk for 6 minutes under supervision during your clinic visit.

Depending on your risk for heart disease, you may be referred to cardiologists to be further tested. During these visits, additional blood tests could be drawn, and imaging of the heart and blood vessels could be performed. These are standard procedures and will not be done for the purposes of this research study. However, because you are taking part in the study, the study staff will receive the results of these tests.

You will be followed for both the progress of the cancer treatment and also your heart health. Even if you do not return to MD Anderson, you may be called and asked about your health. You may be followed for as long as 10 years.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which

may create a need for blood transfusions.

EKGs may cause discomfort while lying on the exam table, and the tape on the EKG pads may cause skin irritation.

During a 6-minute walk test, it is possible that you may fall, but this risk is minimal. You will be walking under the supervision of a research staff member to ensure safety.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

Researchers will take appropriate steps to keep your information private. However, there is no guarantee of absolute **privacy**. There is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this CoC cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below).

The CoC cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to.

This study may involve unpredictable risks to the participants.

OPTIONAL PROCEDURES FOR THE STUDY

You do not have to agree to the optional procedures in order to take part in this study. There are no benefits to you for taking part in the optional procedures. Future patients

may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure #1: If you agree, at your visit before treatment, 6-8 weeks after treatment, and 1 year after treatment, you will have a stress test with SPECT/CT imaging to see if researchers can detect the location of heart injury before heart disease development. A radioactive solution will be injected during the SPECT/CT that exposes your body to radiation.

The radioactive solution does not remain in your system for a long period of time. However, you should wait 12 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

You will be asked to walk on a treadmill for this test. If you can't exercise, your doctor will inject a stress medication into your IV line that mimics exercise by increasing blood flow to your heart. This is called a pharmacological stress test.

Optional Procedure #2: If you agree, at your visit before treatment, then 6-8 weeks after treatment, and 1 year after treatment, you will have an echocardiogram (ECHO) to check your heart health.

Optional Procedure #3: If you agree, at your visit before treatment, 6-8 weeks and 4-6 months after treatment, and every year after treatment, you will have a lung function test to check your lung health. For this test, you will take a deep breath in (inhale) and breathe out (exhale) into a machine that checks how much air you can breathe in and out.

Optional Procedure Risks

A stress SPECT/CT stress test is generally safe. Possible side effects may be similar to those caused by exercise, such as flushing or shortness of breath. You might get a nauseous and headache. You may experience dizziness or chest pain. Other possible side effects include shakiness, flushing, shortness of breath, low blood pressure, and anxiety. These signs and symptoms are usually mild and brief, but tell your doctor if they occur.

You may experience an irregular heartbeat that usually go away shortly after the medication wears off. Life-threatening irregular heartbeats are very rare.

Although extremely rare, it is possible that a stress test could cause a heart attack.

You may have an allergic reaction to the radiotracers used for imaging, such as itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, and/or difficulty breathing. You may also experience pain, itching, burning, swelling, and/or a lump under your skin where the needle is placed.

There are no expected risks due to **echocardiograms**.

Lung function tests may cause temporary mild chest tightening, coughing (worsening of asthma symptoms), shortness of breath, dizziness, or feeling faint.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to have a stress test with SPECT/CT imaging at the time points above?

YES **NO**

Optional Procedure #2: Do you agree to have an ECHO at the time points above?

YES **NO**

Optional Procedure #3: Do you agree to have a lung function test at the time points above?

YES **NO**

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or the National Institutes of Health for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Zhongxing Liao, at 832-829-5312) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped at any time by the study chair, the National Institutes of Health, or the IRB of MD Anderson. Possible reasons your participation in this study may be stopped include if you are unable to follow study directions or if the study is stopped.

7. You will be informed of the results of all of your standard tests performed as part of this research.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored and/or supported by: MD Anderson and the National Institutes of Health.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and the National Institutes of Health, and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research. The National Institutes of Health will not receive

leftover samples.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research
Samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - The National Institutes of Health, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The Weatherhead PET Center for Preventing and Reversing Atherosclerosis at the McGovern Medical School at The University of Texas Health Science Center at Houston (UTHealth) will collect information about the PET imaging study portion.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT