Official Title: LCI-LUN-NSC-SBRT-001: Phase II Prospective Trial of Primary Lung Tumor Stereotactic Body Radiation Therapy Followed by Concurrent Mediastinal Chemoradiation for Locally-Advanced Non-Small Cell Lung Cancer
NCT03141359
IRB-Approved Date: 02/18/2022

ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title:	**Levine Cancer Institute / PHASE II PROSPECTIVE TRIAL OF PRIMARY LUNG TUMOR STEREOTACTIC BODY RADIATION THERAPY FOLLOWED BY CONCURRENT MEDIASTINAL CHEMORADIATION AND ADJUVANT IMMUNOTHERAPY FOR LOCALLY-ADVANCED NON-SMALL CELL LUNG CANCER**
Protocol Number:	**LCI-LUN-NSC-SBRT-001**
Principal Investigator: (Study Doctor)	**John Heinzerling, MD**
Telephone:	[redacted] **(24 Hours)** [redacted] **(24 Hours)**
Address:	**Levine Cancer Institute** [redacted]

INTRODUCTION

The study doctor and his/her associates (the investigators) are asking you to participate in a research study at the study site of patients with locally advanced non-small cell lung cancer (NSCLC) whose primary tumor site will receive a form of radiation therapy called stereotactic body radiation therapy (SBRT) followed by other traditional chemo and radiation therapies. The purpose of this research study is to find out if more intense (higher dose) radiation improves treatment of your cancer with the possibility of causing lesser damage to portions of your lung that are healthy. You are being asked to take part in this study because you have locally advanced non-small cell lung cancer.

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You have also been told that you have the option not to participate. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

This study is being carried out under the sponsorship of Levine Cancer Institute (LCI).

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WHY IS THIS STUDY BEING DONE?

The standard treatment for lung cancer can include radiation therapy, chemotherapy, immunotherapy and/or surgery. Patients like you cannot have surgery because any or all of the following reasons:

i) Location of your cancer
ii) The advanced stage the cancer is in
iii) Other serious health problems which you may have such as emphysema, diabetes, or heart disease

Depending on the location, stage of cancer and other factors, patients who cannot have surgery for lung cancer often receive radiation therapy and/or chemotherapy.

The purpose of this research study is to understand an investigative approach in the treatment of locally advanced non-small cell lung cancer (NSCLC). The standard of care treatment for locally-advanced NSCLC often includes a combination of chemotherapy and traditional radiation treatment (called "chemoradiation") followed by treatment with durvalumab, an immunotherapy drug (a drug that uses your immune system to fight the cancer). The research approach for this study includes a radiation therapy called stereotactic body radiation therapy (SBRT) in addition to traditional chemoradiation and immunotherapy. From it we hope to learn more about the potential benefits of SBRT in the treatment of patients with NSCLC.

SBRT is a type of radiation that delivers an ultra-high dose of radiation per fraction (meaning each time a subject receives a study treatment) targeted to a tumor. The high dose allows for maximal tumor killing effect. The advantages of SBRT are that it delivers very little radiation to the normal tissue surrounding the tumor and takes fewer days of study treatment compared to traditional radiation therapy. In prior research studies of subjects with early stage NSCLC, SBRT has been shown to be associated with favorable primary tumor control rates and improved survival compared to traditional radiation treatment. However, SBRT has not been studied as much in the study treatment of subjects with locally-advanced NSCLC. That is what we hope to learn more about in this study. SBRT is now considered standard treatment for patients with early stage lung cancer, but it is not standard treatment for locally-advanced lung cancer patients. The purpose of this study is to use SBRT to treat the primary tumor in subjects with locally-advanced NSCLC, similar to the way it is now used in early stage NSCLC subjects.

Researchers have found that sometimes the body's own immune system may slow down or control cancer growth. Sometimes though, this natural immune system response stops, and the cancer is not killed by your own immune system. Research has shown that in some patient's cancer cells and immune cells start to express signals that stop the body's immune system from killing the cancer. One such signal is called Programmed Cell Death Ligand 1 or PD-L1 for short. New drugs like durvalumab work to block this signal and to increase the immune response. Durvalumab is an antibody (a protein produced by the body's defense system) and it is hoped that by blocking this signal, the immune cells will once again be able to prevent or slow down cancer growth.

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HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

You will be one of approximately 60 subjects participating in this study.

HOW THE STUDY WORKS

Before you begin the study:

In order to participate in this study, you will need to:

- Review, sign, and date this informed consent document and
- Provide authorization for the release of your medical records for research purposes
- History and physical with a medical oncologist and radiation oncologist. It also includes bloodwork for basic laboratory studies to ensure you are a candidate for chemotherapy.

Visit 1: During this visit we will check if you are eligible to participate and the following will be done:

- Standard imaging including a PET/CT scan, CT scan of your chest, and imaging of your brain (MRI or CT) (if not done within 90 days of starting study treatment). If you are not able to have a PET/CT scan, a CT scan of your abdomen and pelvis will be done.
- Pulmonary function tests to measure your lung capacity (if not done within 6 months of starting study treatment).
- If you are a woman who can have children, a urine or blood pregnancy test will be done. The test results must be negative in order to be in the study. You must also not be breastfeeding to participate in the study.

If you qualify for the study and agree to participate, we will enroll you. If the results of these tests show that you are not eligible for the study, then you may not participate.

During the study (Intervention; number of visits/cycles):

Visit 2: You will have a simulation/planning session for the high dose part of your radiation (SBRT).

- Quality of Life (QOL) questionnaires will be obtained

Visit 3: You will begin the research study treatment with SBRT radiation for your lung cancer.

- QOL questionnaires will be obtained if not obtained at Visit 2
- About 4 tablespoons of blood for research will be obtained prior to SBRT and then 1 ½ tablespoons of blood for research will be obtained once during the course of SBRT
- The first part will consist of high dose radiation to your primary lung tumor. This part of the study treatment course is 3 to 4 total study treatments over 1-2 weeks.

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Visit 4: You will have a simulation/planning session for the radiation study treatment to the lymph nodes in the chest (mediastinal irradiation).

- QOL questionnaires will be obtained

Visit 5: You will start chemotherapy and radiation. The radiation study treatment course will consist of daily study treatments (Monday - Friday), for a total of approximately 30 study treatments. The chemotherapy will be administered either once every week or once every four weeks. About 4 tablespoons of blood will be obtained once during the course of chemotherapy and radiation for research purposes. Your medical oncologist will go over your chemotherapy schedule with you ahead of time.

Visit 6: You will begin treatment with an immunotherapy drug called durvalumab after you have completed treatment with SBRT and chemotherapy/radiation. Durvalumab will be given either every 2 weeks or every 4 weeks (this will be up to your study doctor) in your vein for up to 12 months of treatment, unless your disease worsens or you have unacceptable side effects. An additional 4 tablespoons of blood will be collected once approximately 2-5 weeks after durvalumab is started (before your second dose of durvalumab. If you have already received your second dose of durvalumab or do not start durvalumab, this sample will not be collected.

Specimen Collection for the Purposes of Research during Study Intervention:
Blood: If you agree to participate in this study, blood will be collected (a total of approximately 193 mL = no more than 13 tablespoons throughout the duration of treatment). Your samples may be stored for future research if you provide your consent (see "Storage of Blood Specimens for Future Studies" later on in this consent form). Future blood-based biomarkers not described in this protocol may also be examined.

Tissue: A portion of your previously obtained tissue will be collected and stored for potential future research.

After you complete the SBRT and chemotherapy/radiation (while you are receiving durvalumab): You will have ongoing assessments by your study doctors at specified time points after your study treatment is completed including, but not limited to, study doctors' visits every 3 months for the first 2 years, and then every 6 months for the second year, and then yearly until 5 years after completion of chemotherapy/radiation. Standard post-study treatment imaging studies will also be performed as well as assessment of your lung function. QOL questionnaires will be obtained at the completion of chemotherapy and radiation study treatment, and at the 3 month, 6 month, and 12 month follow-up visits. The QOL questionnaires may be completed in the clinic or over the phone with research staff.

RISKS

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects

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that may happen. **The research may involve risks that are currently unknown**. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. There is a chance the radiation therapy regimen (SBRT followed by chemoradiation) in this study may be no more effective than the standard radiation therapy at curing or controlling your lung cancer.

Risks of Radiation Therapy

The side effects of radiation can be either ***early*** (which occur during or shortly after radiation study treatment and usually go away after the completion of therapy) or ***late*** (which occur several weeks, months or years after the completion of radiation.) The most common known side effects of radiation therapy are listed below.

Possible early side effects:

- Skin changes which may include dryness, redness, burning, swelling, or peeling of the skin
- Decrease in weight, low blood counts, loss of appetite, nausea, diarrhea, and fatigue.
- Irritation of the esophagus causing pain when swallowing
- Swelling/inflammation of the lung causing pain, fever, cough, or shortness of breath or difficulty breathing
- ***Rare:*** Ulcerations of the skin in the irradiated area.

Possible late side effects although rare:

- Changes in the color or texture of the skin or hair in the treated area
- Ulcers or scars on the skin in the treated area
- Scars or shrinking of the lung that could cause shortness of breath
- Narrowing of the esophagus that could cause swallowing problems
- Bone damage that may lead to small cracks (fracture) in the bone
- Damage to the heart muscle, heart sac, or arteries that may lead to heart attack or heart disease or the need for surgical correction

Risks and side effects associated with chemotherapy

Your study doctor will discuss with you the side effects of the specific chemotherapy drugs that you will receive. Below is a list of general side effects experienced by subjects who receive chemotherapy.

- Likely
  - Low pulse
  - Low blood pressure
  - Loss of hair
  - Tingling, numbness, burning pain in hands and feet
  - A decrease in white blood cells, which could lead to infection
  - A decrease in platelets, which could lead to bleeding

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- Skin redness or rash
- Fatigue
- Nausea and/or vomiting
- Mouth sores
- Diarrhea
- Anemia, a lower than normal number of red blood cells
- Swelling of the legs, arms, or feet
- Cardiovascular changes on EKG (test that measures electrical signal of heart)
- Temporary changes in blood tests which measure kidney or liver function
- Low sodium in the blood, which could result in bloating and puffiness in the face and fingers, nausea, vomiting, muscle weakness, headache, and disorientation
- Low magnesium in the blood, which could result in increased irritability of the nervous system with spasms of the hands and feet, muscular twitching, and cramps
- Low calcium in the blood, which could result in numbness or tingling around the mouth or in the feet and hands, as well as in muscle spasms in the face, feet, and hands
- Low potassium in the blood, which could result in muscle weakness, cramping, muscle limpness, and/or irregular heartbeat

- **Less Likely**
  - Injection site reaction
  - Blurred vision
  - Skin or nail darkening
  - Aches and pains in muscles and joints
  - Fever
  - Tingling, numbness, burning pain in hands and feet, which may be persistent or permanent
  - Inflammation of the lung, which could lead to cough and shortness of breath

- **Rare but serious**
  - Temporary changes in blood tests measuring liver function
  - Abnormal heart rhythms, which could be life threatening
  - Severe allergic reactions
  - Temporary "bright spots" in vision
  - Severe rash called "Stevens- Johnson Syndrome" that can cause fever and severe eruptions of blisters which can occur on the skin of the trunk of the body, mouth, eyes, and genitals
  - Hemolytic-uremic syndrome (HUS), a disorder that results in the destruction of red blood cells and platelets with decreased kidney function

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- A risk of developing a second cancer unrelated to the treated lung cancer, which may occur months or years after initial study treatment
- Death

Risks and side effects associated with durvalumab

The study drug may cause side effects. You may experience none, some or all of those listed below.

The study drug durvalumab works by boosting the immune system. This may cause side effects, which can occur when the drug is given or after the drug is given (within hours, days or weeks after). Some side effects usually get better without any treatment. However, some side effects may become serious or life-threatening and have resulted in death in patients who have received treatment with durvalumab. It is important to tell your study doctor immediately if you have any side effects so that you can receive the necessary treatment.

Most of the possible side effects listed below are mild to moderate. However, some side effects can be very serious and life-threatening and may even result in death. Some side effects do not need treatment while others generally get better with treatment. Some patients may need to delay doses of durvalumab to allow the side effects to get better. The most important possible side effects, which are listed below, may occur because of the way durvalumab works on the immune system and they have been seen in patients treated with durvalumab in clinical studies. Side effects like these have also been seen in clinical studies with other drugs that are very similar to durvalumab. Management of these side effects may require the administration of drugs such as steroids or other agents that can affect your immune system and reduce inflammation.

- **Very Common** (affects more than 1 in 10 patients treated):
  - Diarrhea
  - Rash/dry itchy skin
  - Abdominal pain
  - Upper respiratory tract infections
  - Cough
  - Fever
  - Underactive thyroid gland that can cause tiredness or weight gain (Hypothyroidism): This is when the thyroid gland produces less thyroid hormone than it should which causes the metabolism to run too slow. Symptoms may include but are not limited to fatigue, increased sensitivity to cold, constipation, dry skin, unexplained weight gain, puffy face, muscle weakness, slow heart rate, thinning hair, impaired memory. The condition can be treated with replacement thyroid hormone.

- **Common** (affects more than 1 in 100 and 1 in 10 patients treated):
  - Inflammation in the lungs (pneumonitis): Symptoms may include but are not limited to a new or worsening cough, shortness of breath possibly with fever.

- Overactive thyroid gland that can cause fast heart rate or weight loss (Hyperthyroidism): This is when the thyroid gland produces too much thyroid hormone. Symptoms include anxiety or nervousness, weight loss, frequent and loose bowel movements, breathlessness, feeling hot and possibly having heart palpitations. Depending on the severity of the symptoms, treatment may include just monitoring the symptoms, treating the symptoms themselves and/or giving medicine to block the thyroid hormone.
- Changes in lab tests related to kidney and liver function
- Pain in muscles and joints (myalgia)
- Infusion Related Reactions: Reactions may occur during or after the infusion of durvalumab. The reaction may cause fever or chills and a change in blood pressure or difficulty in breathing which might be serious. Tell your study doctor right away if you experience any of these symptoms even if it has been several days after the infusion has been completed.
- Accumulation of fluid causing swelling in the legs
- Hoarse voice
- Painful urination
- Night sweats
- Pneumonia
- Oral thrush (fungal infection in the mouth)
- Dental and oral soft tissue infections
- Influenza

- **Uncommon** (affects between 1 in 1000 and 1 in 100 patients treated):
  - Scarring of lung tissue (interstitial lung disease)
  - Inflammation of the kidney (nephritis)
  - Inflammation of the skin (dermatitis)
  - Inflammation of the thyroid (thyroiditis)
  - Inflammation of the pancreas (pancreatitis): Pancreatitis usually causes symptoms of persistent upper abdominal pain (sometimes made worse by eating and drinking), nausea, vomiting and general weakness. Pancreatitis usually settles with simple measures but it can be a serious condition and can be fatal. You should immediately tell your study doctor if you develop any of these symptoms. You may get an increase of lipase and amylase levels in a blood test (related to the pancreas) but not have any symptoms or feel unwell. Lipase and amylase are enzymes or protein markers that measure the function of your pancreas.
  - Inflammation of the liver (hepatitis) Signs and symptoms of this include yellowing of the skin or whites of the eyes, dark urine, severe nausea and vomiting, pain in the

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upper right side of your abdomen, skin itchiness, not feeling hungry and bleeding or bruising more easily than normal.

- Inflammation of the intestine (colitis). It may cause abdominal pain and diarrhea with or without blood. Fever may be present. It may require you to receive additional fluids. If left untreated, in rare occasions this may lead to a tear in the wall of the intestine which can be serious and life threatening. Tell your study doctor right away if you have any of these symptoms
- Decreased secretion of hormones produced by the adrenal glands (Adrenal Insufficiency): May cause stomach pains, vomiting, muscle weakness and fatigue, depression, low blood pressure, weight loss, kidney problems, and changes in mood and personality. These complications may be permanent and may require hormone replacement.
- Inflammation of the muscles (Myositis). Symptoms can include muscle weakness and aches, tired feeling when standing or walking, muscle pain and soreness that does not resolve after a few weeks .

- **Rare** (affects between 1 in 10,000 and 1 in 1000 patients treated):
  - Imbalance of body fluids and electrolytes (Diabetes Insipidus)
  - Type 1 Diabetes mellitus which may cause increased blood glucose levels (called 'hyperglycemia'): Symptoms may include weight loss, increased urination, increased thirst, and increased hunger. Type 1 diabetes will require replacement of insulin through injection. Tell your study doctor right away if you have any of these symptoms.
  - Underactive function of the pituitary gland (hypopituitarism): Hypopituitarism refers to decreased output of hormones from the pituitary gland in the brain and may be caused by inflammation of the pituitary gland (hypophysitis). Symptoms may include headaches, thirstiness, and trouble seeing or double vision, or irregular periods in women. These complications may be permanent and may require hormone replacement.
  - Inflammation of the heart muscle (myocarditis). Symptoms can include chest pain, rapid or abnormal heart beat, shortness of breath and swelling of your legs. Tell your study doctor right away if you experience any of these symptoms.
  - Blistering rash (pemphigoid): Blistering and break down of the skin, mouth, and other mucous membranes
  - Decrease in cells that help your blood clot (immune thrombocytopenia)
  - Weakness of the muscles (Myasthenia Gravis): Symptoms can include unusual weakness of legs, arms, or face, numbness or tingling in hands or feet. In rare situations, there is the potential for the inflammation of the nervous system to be severe and cause damage to the nerve cells or breakdown in the communication

between nerves and muscles. Tell your study doctor right away if you have problems swallowing, if you start to feel weak very quickly and you are having trouble breathing.

- Polymyositis: Inflammation of the multiple muscles or associated tissues, such as blood vessels that supply the muscles. Symptoms can include muscle weakness and aches, tired feeling when standing or walking, muscle pain and soreness that does not resolve after a few weeks.
- Encephalitis: Inflammation of the brain, which can be life-threatening. Symptoms can include mild flu-like symptoms, such as fever or headache or no symptoms at all. Sometimes flu-like symptoms can be more severe.

In addition to these side effects, frequently reported adverse effects include fatigue, nausea and vomiting, and loss of appetite.

In addition to the side effects described above, patients with different types of cancer may experience the side effects described here, based on drugs similar to durvalumab in clinical trials:

Other rare or less frequent events: inflammation of the membrane surrounding the heart, growths of tiny collections of inflammatory cells in different parts of the body, inflammation of the middle layer of the eye and other events involving the eye (e.g. inflammation of the cornea and optic nerves), inflammation of the brain or the membranes that cover the brain and spinal cord, hardening and tightening of the skin and connective tissues and loss of skin color), and hematological events (e.g., abnormal breakdown of the red blood cells), weakness of the muscles (Guillain-Barre syndrome), inflammation of the blood vessels, and rheumatological events (inflammatory disorder causing muscle pain and stiffness and autoimmune arthritis).

Inflammation of the pancreas (pancreatitis). Pancreatitis usually causes symptoms of persistent upper abdominal pain (sometimes made worse by eating and drinking), nausea, vomiting and general weakness. Pancreatitis usually settles with simple measures but it can be a serious condition and can be fatal. You should immediately tell your study doctor if you develop any of these symptoms. You may get an increase of lipase and amylase levels in a blood test (related to the pancreas) but not have any symptoms or feel unwell. Lipase and amylase are enzymes or protein markers that measure the function of your pancreas.

Allergic reactions: These can cause swelling of the face, lips and throat, breathing difficulties along with hives or nettle like rash. Some reactions can cause severe cause swelling, shortness of breath, fever, fatigue, nausea, kidney failure and confusion (cytokine release syndrome).

You may experience other infections like urinary tract infection, respiratory tract infection and sepsis.

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Reproductive Risks

Because of risks of fetal harm, women who are pregnant cannot participate in this study and women of child-bearing potential must avoid becoming pregnant while on study treatment. Women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) and not breastfeed a child prior to study entry and for the duration of study treatment up until 3 months after your last dose of durvalumab. It is important for you to tell the study doctor at once if you get pregnant or think that you might be pregnant while you are in the research study. If this happens, the study doctor will discuss with you what you should do. If you get pregnant, you will be asked to stop taking part in the study. You may be asked questions about your pregnancy and the baby.

Men with partners of child-bearing potential should use adequate contraception and agree not to donate sperm while you are receiving treatment with durvalumab and for up to 3 months after the last dose of durvalumab.

WILL I BENEFIT FROM PARTICIPATING IN THIS STUDY?

The benefits of SBRT plus chemoradiation and durvalumab are not fully known and you may not get any direct benefit from being in this research study. With our current knowledge and understanding this combination of study treatments **may** help subjects with locally-advanced NSCLC live longer without their disease getting worse. There is also the possibility that the combination of study treatments in this study (SBRT plus chemoradiation and durvalumab) may have fewer side effects from radiation compared to chemoradiation alone. This is because the volume or amount of lung tissue that will be exposed to radiation with a combination of SBRT and chemoradiation may be less than the amount of lung tissue treated with traditional chemoradiation. When a smaller volume of the lung is treated, there may be less risk of having side effects from the radiation.

Information from this study may help you and/or other people with your disease in the future.

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

You may choose not to participate in this study and receive routine care or the standard therapy for your cancer that would otherwise be offered to you by your doctor. This would typically consist of the same chemotherapy, radiation and durvalumab, but **would not** include SBRT. If you decide that you don't want any more active treatment, one of your options is called "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, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible. If you think you might prefer comfort care, please discuss this with your family, friends and your doctor. Your study doctor can discuss the alternatives and the risks and benefits of these alternatives with you. Please ask any questions you may have and take as much time as you need to make your decision. **If you choose not to take part in this study, that will not harm your relationship with your study doctor or with the study site**.

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WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You will not receive payment for taking part in this study. You and/or your health plan/insurance will need to pay for all routine care procedures and treatment. You may have to pay for these costs if they are not covered by your insurance company. The Stereotactic Body Radiation Therapy (SBRT) will be billed at the same cost as standard radiation. Durvalumab will be provided by AstraZeneca at no cost to you.

You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

In the event that you are injured as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You will be responsible for deductibles, co-payments, and co-insurance. There are no plans to pay or give you other compensation for the injury. You do not waive any legal rights by signing this consent form.

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

For insurance or other payment reporting purposes, we may need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because we may have to check to see if you receive Medicare and if you do, report the payment we make to Medicare.

In no way does signing and dating this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

WHAT IF I WANT TO QUIT THE STUDY LATER ON?

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.

If you stop taking part in the study, any specimens which may have already been collected and processed will remain de-identified and part of the study. Any specimens which may have been collected, but have not yet been processed may be destroyed upon your written request. No specimens will be returned to you. Information contributed to the study will remain in the study even if you choose to withdraw. Tell your study doctor if you are thinking about stopping the study treatment. He/she will help you stop safely. If you choose to withdraw from the study, please notify the study doctor in writing at the address on page 1 of this consent form.

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The study doctor may choose to involuntarily withdraw you from the study for any reason, including if you are unable to adhere to the study schedule or requirements.

We will tell you about any new medical findings that may affect your willingness to continue in the study.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by the Levine Cancer Institute, by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

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AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

If you wish to participate in this research study, you

_____

Printed Name of Research Subject

must sign this Authorization. By signing this Authorization, you give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:

LCI-LUN-NSC-SBRT-001: PHASE II PROSPECTIVE TRIAL OF PRIMARY LUNG TUMOR STEREOTACTIC BODY RADIATION THERAPY FOLLOWED BY CONCURRENT MEDIASTINAL CHEMORADIATION AND ADJUVANT IMMUNOTHERAPY FOR LOCALLY-ADVANCED NON-SMALL CELL LUNG CANCER

The protected health information that we may use or disclose (release) for this research may include all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

The health information listed above may be used by and/or disclosed (released) to:

- Study investigator and research staff
- Study sponsor and/or its associated companies
- Regulatory or other governmental authorities of the United States or other countries based on this study
- Other persons or agents authorized by the study sponsor
- Atrium Health employees
- Other persons or agencies as required by law or allowed by federal regulations
- Advarra Institutional Review Board (Advarra IRB) or Data Safety and Monitoring Boards.

Atrium Health is required by law to protect your protected health information. By signing this Authorization, you authorize Atrium Health to use and/or disclose (release) your protected health information for this research study. Those persons who receive your protected health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your protected health information with others without your permission, if permitted by laws governing them. Your protected health information may then no longer be protected by the Privacy Rule.

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Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment through this study. However, Atrium Health may not condition (withhold or refuse) your other Atrium Health providers treating you on whether you sign this Authorization. You may change your mind and withdraw (take back) this Authorization at any time, except to the extent that Atrium Health or the Sponsor has already used or disclosed your protected health information based on this Authorization. To withdraw this Authorization, you must write to the Study Doctor at the address listed on the first page of this form

No publication or public presentation about the research described above will reveal your identity without another Authorization from you. If all protected health information that does or can identify you is removed, the remaining information will no longer be subject to this Authorization or federal rules (such as the Privacy Rule) and may be used or disclosed for other purposes.

When the research for which the use or disclosure is made involves treatment and is conducted by Atrium Health: To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete.

At the conclusion of the research study and at your request, you generally will have access to your protected health information. Access to your protected health information in a medical record is described in the Notice of Privacy Practices provided to you by Atrium Health.

When conducting research, the data and results may be used or disclosed for further treatment outcomes research or to research a secondary result. This Authorization will remain in effect after the end of the current study, and any future related secondary study unless it is revoked by you in writing as described above.

_____

Signature of Research Subject or Research Subject's Legally Authorized Representative

_____

Printed name of Research Subject or Research Subject's Legally Authorized Representative

_____

Date

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FINANCIAL DISCLOSURE

None of the doctors asking you to participate in this study has received or will receive money or other benefits for personal use from Levine Cancer Institute for their involvement in this study.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff at Atrium Health, listed on the first page of this form, with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
- [redacted]
- Advarra IRB
- [redacted]
- [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the study subject adviser: Pro00021247.

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.

Affix Participant Barcode Label Here

STORAGE OF BLOOD SPECIMENS FOR FUTURE STUDIES

The study doctor and study associates (the investigators) are asking you to allow your blood and tissue to be collected, tested, and/or banked (stored) for the purposes of research. All information for the main study's informed consent form still applies to this part of the informed consent. Your study doctor would like to store your blood and tissue samples collected for research for future, currently unplanned research. Regardless of your decision to allow storage of your blood and tissue samples for future research, you may still participate in the main study, if you choose to.

If you agree to donate samples, they will be stored at the Levine Cancer Institute Biospecimen Repository in [redacted] a place where human samples are securely stored and where any of your remaining samples will be stored.

If you decide, at a later date to withdraw your consent for any reason, you have the option not to allow Levine Cancer Institute to use your blood or tissue samples collected for testing by contacting the study doctor at the telephone number or address listed on the first page of this form. Blood and tissue samples will be destroyed only if they have not already been tested.

1. Do you give permission to have your blood and tissue samples collected for research to be stored for future research? Please enter your initials in the line following your selection below:

Yes_____ **No**_____
Initials **Initials**

Affix Participant Barcode Label Here

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____ ____/____/____ _____
Signature of Impartial Witness Date Time

_____
Printed Name of Impartial Witness

Affix Participant Barcode Label Here