Official Title: LCI-LUN-SBRT-002: Pilot study of SGRT alone vs. SGRT in combination with fiducials for breath hold SBRT treatments of the lung

NCT04060927

IRB-Approved Date: 07/26/2022

ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title:	**Levine Cancer Institute/ Pilot study of SGRT alone vs. SGRT in combination with fiducials for breath hold SBRT treatments of the lung**
Protocol Number:	**LCI-LUN-SBRT-002**
Principal Investigator: (Study Doctor)	**John H. Heinzerling, MD**
Telephone:	[redacted] **(24 Hours)** [redacted] **(24 Hours)**
Address:	**Levine Cancer Institute** [redacted]

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign and date your name at the end of this form. You cannot take part in this research study until you sign and date this form.

INTRODUCTION

Dr. John Heinzerling and his associates (the investigators) are asking you to participate in a pilot research study at Levine Cancer Institute (LCI) and Atrium Health to compare Stereotactic Body Radiation Therapy (SBRT) treatments done with free breathing approach and Surface Guided Radiation Therapy (SGRT), breath hold treatments using either SGRT alone or with fiducials (visible markers placed in tumor) for patients with presumed Non-Small Cell Lung Cancer (NSCLC) and lung metastases (cancer that has spread to the lungs).

You are being asked to take part in this study because you have Primary lung cancer (NSCLC) or lung metastases from another cancer and will be receiving SBRT.

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 decide on study participation. You have also been told that you have the option not to participate.

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You may discuss your decision with your friends and family. You can also discuss it with your healthcare 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). VISION RT is the company that is providing funds for this study.

Taking part in this study is entirely voluntary.

PURPOSE OF THE RESEARCH STUDY

Research studies are done to find out information about investigational treatments.

The purpose of this study is to look at the side effects to the lungs in subjects who receive SBRT study treatment while using different methods to prevent tumor movement when breathing during study treatment.

INFORMATION ABOUT THE STUDY

Stereotactic Body Radiation Therapy (**SBRT**) is a radiation therapy method for non-surgical management of different types of cancer. Radiotherapy is delivered from many different positions around the body, where the beams meet at the tumor. Therefore, the tumor receives a high dose of radiation and the tissues around it only receive a low dose. This lowers the risk of side effects. A potential problem with SBRT is that the tumor moves when breathing and can expose more lung to radiation and possibly increase the risk of toxicity (damage) to normal lung tissue. One method that has been used to help control the motion of the tumor involves having the subject hold their breath during the study treatment. This can be achieved by placing some visible markers (**fiducials**) in or around the tumor.

A newer technology called Surface Guided Radiation Therapy (SGRT) uses a machine to track motion and makes sure the subject is in the intended position to perform breath hold during study radiation treatments. This lessens the amount that the tumor moves during study treatment and the amount of lung exposed to radiation. At this time there is limited information on the use of SGRT for breath hold SBRT lung treatments and no comparison has been made with use of SGRT alone and with implanted fiducials.

There will be 45 subjects involved in the study. Three groups of subjects will be formed for this study (total number is 45). This study will compare those groups using:
1) SBRT+SGRT with free breathing
2) SBRT+SGRT with a breath hold (holding your breath at specific times during study treatment)
3) SBRT+SGRT with a breath hold and fiducials

You will be assigned to a group based on where you will receive study treatment and the timing of your biopsy.

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WHAT WILL HAPPEN DURING THE STUDY

Your participation may last up to approximately 6 years (72 months).

Before you begin the study (Baseline):

Before the study starts, you will be asked to sign and date this consent form. If you agree to participate in the study and sign and date the consent form, the study doctor will do some tests and procedures to find out if you can be in the study. These tests and procedures include:

- Medical History, Physical Examination, weight and Performance Status (scale used to assess how active you are)
- You will be asked how you are feeling, and any symptoms you might have before you start study treatment will be documented.
- You will be asked about any medication you use (prescription, over the counter, supplements).
- You will have a CT (Computerized Tomography) scan of your chest. A CT is special x-ray equipment that will be used to measure the tumor prior to study treatment.
- You will have Pulmonary Function Tests that are non-invasive tests that show how well your lungs are working.
- You will be asked to complete Quality of Life questionnaires to evaluate your symptoms and how the symptoms are impacting your life.
- If you are a woman who can have children, a blood pregnancy test will be done. The test results must be negative to be in the study.

During the study:

If the exams, tests, and procedures show that you can be in the study, and you choose to take part, you will need the following exams, tests, and procedures:

During SBRT study treatment

- Physical Examination, weight and Performance Status
- Medical history
- You will be asked how you are feeling, and any symptoms (side effects) you are experiencing will be documented

One month after completing SBRT study treatment:

- You will be asked how you are feeling, and any symptoms (side effects) you are experiencing will be documented
- Quality of Life questionnaire

Active follow-up visits every 3 months for 1 year (Year 1) from the last SBRT study treatment:

- Physical Examination, weight and Performance Status

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- Medical history
- You will be asked how you are feeling, and any symptoms (side effects) you are experiencing will be documented
- Chest CT
- Pulmonary Function Tests at 6 month visit only
- Quality of Life: questionnaires will be obtained at 3 month follow-up, at 6 month follow-up, and at 12 month follow-up

Active follow-up visits every 6 months for 1 year after Year 1 follow-up has been completed (Year 2):

- Chest CT (totaling at least 24 months of scans from start of trial; the last scan required must have been done at least 24 months from enrollment into the trial)
- Contact by phone (if you are not being seen in the clinic for a routine visit) to check on your health status

Yearly long-term follow-up visits after Year 2 follow-up has been completed, up to approximately 6 years after completion of the last SBRT study treatment. The length of your participation will depend on when you are enrolled into the study:

- Contact by phone (if you are not being seen in the clinic for a routine visit) to check on your health status

YOUR ROLE IN THE STUDY

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research subject when you are deciding to take part. Your responsibilities as a study subject include the following:

- Tell the truth about your medical history and current conditions
- Tell the study doctor if you have been in a research study in the last 30 days or are in another research study now
- Tell the study doctor about any problems you have during the study

RISKS OF THE STUDY

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 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.

Risks of Radiation Therapy

The side effects of radiation can be either **early** (which occur during or shortly after radiation treatment and usually go away after the completion of therapy) or **late** (which occur several weeks,

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months or years after the completion of radiation.) The most common known side effects of radiation therapy are listed below.

Possible <u>early</u> side effects:

- Skin changes which may include:
  - dryness
  - redness
  - burning
  - swelling, or;
  - peeling of the skin
- Decrease in weight, loss of appetite, nausea, and fatigue.
- Irritation of the esophagus causing pain when swallowing
- Swelling/inflammation of the lungs causing pain, fever, cough, or shortness of breath or difficulty breathing
- Rare: Ulcerations (sores) of the skin in the area treated with radiation

Possible <u>late</u> 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

CT Scan Risks

A CT scan is a computerized x-ray picture of your internal organs. You may feel some discomfort or anxiety when lying inside of the CT scanner. The contrast material (dye) that is injected into your body may cause you to get a metallic taste in your mouth and to feel warm. Rarely, it causes nausea and vomiting. The dye can also cause damage to the kidneys, which may lead to kidney failure. This is a concern if you have poor kidney function. Rarely, the dye can cause a life threatening reaction.

Reproductive Risks

Women Who Can Get Pregnant or Are Breastfeeding

You may not take part in this study if you are breastfeeding, are pregnant, think that you may be pregnant, or are trying to get pregnant. If you are pregnant or breastfeeding, there may be risks to you and the baby that are not known at this time.

You must avoid getting pregnant in order to take part in this research study. You should not have sexual intercourse or you should use a method of birth control that is acceptable to you, the study doctor, and the sponsor from the time of informed consent until 5 days after the last SBRT study treatment.

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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 study treatments. You may also be asked questions about your pregnancy and the baby.

Men
Non-sterilized men with female partners of child-bearing potential must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and until 5 days after the last SBRT study treatment.

Unknown Risks

You might have side effects or discomforts that are not listed in this form. Some side effects may not be known yet. New ones could happen to you. Tell the study doctor or study staff right away if you have any problems.

ALTERNATIVES TO BEING IN THE STUDY

You do not need to take part in this research study. Your study doctor can discuss the alternatives and the risks and benefits of these alternatives with you.

POTENTIAL BENEFITS OF BEING IN THE STUDY

Taking part in this study may or may not improve the symptoms of your condition. There may be no benefit to you and your condition may not improve. While you are in this study, your study doctor will follow your condition closely. By taking part in the study, you may help future patients.

COSTS OF BEING IN THE STUDY

You or your insurance company will be charged for routine medical care and/or hospitalization in the usual manner. You may have to pay for these costs if they are not covered by your insurance company. The Stereotactic Body Radiation Therapy (SBRT) is not covered by the study and will be billed at the same cost as standard radiation. You may wish to discuss coverage with your insurance company before agreeing to participate in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

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YOUR PAYMENT FOR BEING IN THE STUDY

You will not be paid for being in this study. You will also not be paid or reimbursed for time and transportation costs for traveling to and from the clinic.

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 the company (Vision RT). However, Vision RT will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the study doctor or study staff is associated.

COMPENSATION FOR INJURY

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 the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

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

CONFIDENTIALITY

The records of this study will be kept private. If any report about this research is published, we will not include any information that will make it possible to identify you. However, there is some risk that de-identified data might be re-identified. Also, your record for this study may be reviewed and/or photocopied by the Sponsor, by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies.

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 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:

"Pilot study of SGRT alone vs. SGRT in combination with fiducials for breath hold SBRT treatments of the lung".

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 (Levine Cancer Institute)
- 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
- Data coordinating centers that will receive and process PHI; and/or;
- 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.

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.

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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 the you in writing as described above.

_____

Printed name of Research Subject

_____

Signature of Research Subject

_____

Date

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WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

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

Please reference the following number when contacting the Study Subject Adviser: **Pro00036616**

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.

BEING A STUDY VOLUNTEER AND WITHDRAWING FROM THE STUDY

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.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.

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- You need additional medicine.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop. Once you have stopped the study you will not participate in any study related procedures, including data collection.

NEW INFORMATION ABOUT THE STUDY

You will be told about any new information found during the study that may affect whether you want to continue to take part.

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

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