A pilot randomized study of lymphocyte depletion and change in lymphocyte functionality during lung stereotactic body radiation therapy (SBRT) treatment by selectively reducing irradiation of circulating blood compared to standard of care control group

HSR IRB #: 21718

National Clinical Trial (NCT) Identified Number: NCT04273893

Version Date: 12 November 2021

Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Medical Record # _____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Key Information About This Research Study

Principal Investigator:	Krishni Wijesooriya, PhD University of Virginia Health System 200 Jefferson Park Avenue Charlottesville, VA 22908 Phone 434-094-5741 Kw5wx@virginia.edu
Sponsor:	National Institute of Health (NIH)

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What problem is this study trying to solve?

Lymphocytes are a type of white blood cell (WBC) found in your blood. During radiation treatment, moving blood is exposed to radiation. This may cause a decrease in the amount of lymphocytes. A researcher at UVA has created a system to predict the amount of the decrease in lymphocytes in patients with Non-Small Cell Lung Cancer (NSCLC). The predicted decrease of lymphocytes will be compared to the actual decrease in lymphocytes found in blood.

Researchers have found a way to give radiation that they think will result in a smaller decrease in lymphocytes after radiation. There will be two groups in this study, about half of the participants will have their radiation designed to decrease radiation to organs with a lot of blood and the other half will receive standard radiation therapy.

You are being asked to take part in this study because you have been diagnosed with NSCLC and will be receiving a type of radiation therapy called stereotactic body radiation therapy (SBRT) where high doses of radiation will be delivered to the tumor, while minimizing damage to healthy surrounding tissues.

Why would you want to take part in this study?
You might like to take part in this study because you may be assigned to the group that receives less radiation to your blood. If you are, it is possible that your lymphocytes will be less damaged during radiation and your immune system will be stronger than if you lost more lymphocytes during radiation. The radiation should kill the same amount of tumor cells and still avoid damage to your healthy surrounding tissues regardless of which group you're in.

Why would you NOT want to take part in this study? You might not want to take part in this study because you and your doctor cannot choose which group you are in. You may also not want to take part in this study because it requires blood draws that you would not normally have as part of your clinical care.

What will I have to do if I take part in this study?
If you take part in this study the following will be done:

- A review of your medical history and current medications
- A physical exam
- Vital signs and weight will be collected throughout the study
- Height will be collected at the beginning of the study
- Blood would be drawn to see the numbers of each type of white blood cell and to look at how well they're working
- The delivery of the SBRT radiation (given on 5 business days). The total amount of radiation you will receive will not be changed. What changes in this research is whether it is designed to avoid blood-rich areas in the body or given as without avoiding the blood-rich areas, as is currently standard, just as if you were not participating
- Follow up visits including: within 3 days after completing SBRT, 1 month after SBRT, 6 months following SBRT and every 6 months for the 1st year; then annually

What is the difference between being in this study and getting usual care?
If you decide to take part in this study, you will have blood samples collected solely for the purposes of this study. Depending if you are randomized to Group A or Group B, your radiation planning may also include the additional efforts to decrease radiation to your blood vessels in order to minimize effects on your lymphocytes.

What other treatments may I receive if I decide to not take part in this study?
The following alternative treatment is available to you if you decide not take part in this study:

- You could receive SBRT outside of the study according to standard clinical procedures

Up to 65 subjects will be enrolled on this study at UVA.

How long will this study take?

Your participation in this study will require 9 visits over 6 months. Each visit will last about 1-2 hours.

What will happen if you are in the study?

Your participation in this study will require study-specific tests that will be done at the same time as the standard treatment for your cancer (listed below as procedures for "clinical care"). The study tests are listed as being for "research" in the sections below.

SCREENING /RANDOMIZATION/BASELINE (Visit will last about 1-2 hours)

(within One-month prior to starting SBRT)

If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate. Many of these tests and procedures are often used as regular care for your disease and might be done even if you do not take part in the research study.

The study team may also want to have access to results of tests and procedures done before this study as part of your usual care. The research team may request copies of documents, which will become part of your study records, including the following:

- Your medical history
- Results from prior physical exams or laboratory tests
- Pathology reports
- Notes your clinicians may have made about your care

SCREENING: The following tests/procedures will be performed for clinical care (which means as part of your routine medical care). The study team will access these results from your medical record and use the information for research purposes:

- Demographic information (such as your age, race and sex), medical history and current medications will be reviewed
- Weight will be measured
- Physical Exam Vital signs (including blood pressure, heart rate, etc) will be collected
- Your ability to perform everyday tasks (performance status) will be reviewed
- Blood or urine pregnancy test (Women of Childbearing Potential Only)
- Planning/Chest CT scan with contrast (may be completed after confirmation you are eligible and within 8 weeks of SBRT delivery)

The following screening procedures will be performed for research:

- About 1 teaspoon of blood will be collected to do a clinical test (CBC with differential) to check your blood counts, including the numbers of each type of white blood cell

If these tests show you're eligible then you will be randomized (assigned to one of the study groups) and you will return to the clinic for SBRT according to standard of care timing.

RANDOMIZATION: This process takes place after all the results from Screening determine you are eligible. No separate additional visit is required.
You will be randomly assigned (like the flip of a coin) to 1 of 2 study treatment groups. You have an equal chance of being assigned to either of the groups. The dose to the tumor and frequency of the radiation will not be different between the groups. If you are in Group A, then your plan will be designed to avoid blood-rich organs even more than the standard of care requirements. If you are in Group B, then your plan will be designed just like if you weren't participating in the study. Your plan would still meet all standard of care requirements for radiation to the organs near your tumor. This additional effort to decrease radiation to blood-rich organs is not routinely done for standard of care because researchers don't know for sure if there is benefit to these further reductions.

GROUP A: Lung SBRT plans that meet standard of care WITH additional investigation planning steps to reduce exposure to blood vessels.

GROUP B: Lung SBRT plans that meet standard of care WITHOUT additional investigation planning steps to reduce exposure to blood vessels

BASELINE: The following procedures will be performed for research:

- Before you start SBRT, about 2-3 tablespoons of blood will be collected for research to see how many and what type of lymphocytes you have, as well as how well they are working. Additionally, the study team may ask you questions about how you are feeling.
- Height may be measured if it has not been previously recorded in you medical record
- COVID related questions

STUDY TREATMENT (5 DAYS) (Each visit will last about 1-1.5 hours)

SBRT is a type of radiation treatment that delivers precise high doses of radiation to cancer cells. Regardless of whether you are assigned to Group A or Group B, the total dose of radiation you will receive will be the same. Both groups will have 5 days of radiation treatment that must be completed within 10 days of starting treatment.

The following tests/procedures will be performed for clinical care. The study team will access these results from your medical record and use the information for research purposes:

- Weight

END OF SBRT (WITHIN 3-5 DAYS of END of SBRT) (Visit will last 30 minutes-1 hour):

The following tests/procedures will be performed for clinical care. The study team will access these results from your medical record and use the information for research purposes:

- Review of current medications
- Physical Exam
- Vital signs (including blood pressure, heart rate, etc)
- Weight
- Your ability to perform everyday tasks (performance status) will be reviewed
- Review of how you are feeling

The following will be performed for research purposes:

- About 1 teaspoon of blood will be drawn to do a CBC with differential (to see the numbers of each type of white blood cell)
- asked COVID related questions

1 MONTH FOLLOW UP (1 MONTH AFTER SBRT) (Visit will last 30 minutes-1 hour):

The following will be performed for research purposes:

- About 1 teaspoon of blood will be drawn to do a CBC with differential (to see the numbers of each type of white blood cell)
- About 2-3 tablespoons of blood will be collected for research to see how many and what type of lymphocytes you have, as well as how well they are working

3 MONTH FOLLOW UP (3 MONTH AFTER SBRT) (Visit will last 30 minutes-1 hour):

The following tests/procedures will be performed for clinical care. The study team will access these results from your medical record and use the information for research purposes:

- Review of current medications
- Physical Exam
- Weight
- Your ability to perform everyday tasks (performance status) will be reviewed
- Review of how you are feeling
- Chest CT (if required by your doctor)

The following will be performed for research purposes:

- COVID related questions

6 MONTH FOLLOW UP (6 MONTHS AFTER SBRT) (Visit will last 30 minutes-1 hour):

The following tests/procedures will be performed for clinical care. The study team will access these results from your medical record and use the information for research purposes:

- Review of current medications
- Weight
- Your ability to perform everyday tasks (performance status) will be reviewed

Review of how you are feeling

The following will be performed for research purposes:

- About 1 teaspoon of blood will be drawn to do a CBC with differential (to see the numbers of each type of white blood cell)
- Asked COVID related questions

ANNUAL FOLLOW UP **(Visit will last 10-15 minutes):**

About once a year the study team will contact you by phone, email, or just by looking at your UVA medical record to find out how you are doing and the status of your disease.

Study Schedule

	Screening and Baseline [1]	SBRT (5 clinic days)	End of SBRT within 3-5 days	1 month after SBRT	3 months after SBRT	6 months after SBRT	Annual
Informed Consent	X						
Review study eligibility	X						
Demographics	X						
Medical History	X						
Randomization	X[2]						
Review of current medications	X		X		X	X	
Physical Exam	X		X		X		
Vital signs	X		X		X		
Height	X						
Weight	X		X[3]		X[3]	X[3]	
Performance Status	X		X			X	
Pregnancy test (if applicable)	X						
CBC with Diff.	X		X	X		X	X[3]
Research Blood Samples	X			X			
COVID Questions	X		X		X	X	
Chest CT	X[3]				X[3]		
Review of Medical Record	X		X	X	X	X	X
Adverse event review and evaluation			X		X	X	
SBRT		X					

[1] All screening procedures should occur within one month before SBRT treatment start time.
[2] These procedures should be completed after the confirmation of eligibility and within 5 days of the treatment planning
[3] Only performed and recorded if required by the doctor as a part of your clinical care

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- You must come to each study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

Blood Testing

Approximately 1 teaspoon (5ml) of blood will be drawn from you 5 times through the course of 6 months. This test is collected to see the numbers of each type of white blood cell.

In addition, 2-3 tablespoons (40ml) of blood will be drawn from you at two time points through the course of 6 months. This test is performed to see how many and what type of lymphocytes you have as well as how well they are working.

Approximately 1 teaspoon (5ml) may be collected once before starting treatment to conduct a pregnancy test if you are a female who is able to have children.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

Collection of Samples and Health Information Specimen Banking

What Sort of Research Will Be Done On Your Sample(s)?

With your approval, your research blood samples will be coded and stored in Dr. Lawrence Lum's Tissue Bank for Future Cell Therapy Studies biorepository in Dr. Lum's lab in UVA. These samples will be used to look at the amounts of different types of lymphocytes in your blood and how well they are working before SBRT, just afterward, 4 weeks later and 6 months later.

If any sample is leftover after the planned research for this study, this blood could be used for future research on the causes of cancer, its complications, to improve treatment, and to study other conditions for which individuals with cancer are at increased risk.

You may withdraw consent to have your specimens stored for future research in Dr. Lum's bank at any time. To do this you should contact the Principal Investigator listed at the top of this form.

You are being asked to provide samples of your blood to be used for research. Along with specimens, researchers may need to collect some health information about you. Combining information from the specimen with information from your health records may be useful for this research. For this research, the following types of information could be included: diagnosis, treatment results of the labs and recurrence.

In addition, if you agree, specimens collected for research will be added to a research specimen bank. The purpose of a specimen bank is to process, and store samples until researchers need them for future research. The long term goals of the samples collected in this bank will be mainly used for research on future cell therapy studies. It is not possible to list every research project that will include the samples because we cannot predict all of the research questions that will be important over the coming years. As we learn more, new research questions and new types of research may be done.

What will you have to do to give samples for research?
Your research doctor will obtain blood samples from you for testing. This will be collected at baseline (before treatment) and 4 weeks after treatment.

After the tests for your medical care are completed, there may be samples left over. Normally, these leftover samples would be thrown away. We are asking you to allow us to collect this leftover material specimen banking.

How Will Your Sample(s) Be Labeled?
Dr. Lawrence Lum will be responsible for storing your sample and for protecting your privacy.

Your sample(s) will not be labeled with your name or other information that would identify you directly. Instead, it will have a unique code that allows for it to be linked to some of your health information. This link means that your specimen can be identified but only indirectly. We can find out if we need to know which sample is yours in the event you wish the sample to be removed at a later date.

How Will Your Sample(s) Be Stored and Labeled for Specimen Banking?
Dr. Lawrence Lum will be responsible for storing your sample and for protecting your privacy.

This research specimen bank is located at the University of Virginia under the leadership of Dr. Lawrence Lum. There is no set limit to the number of people who will provide samples to this bank.

Your sample(s) will not be labeled with your name or other information that would identify you directly. Instead, it will have a unique code that allows for it to be linked to some of your health information. This link means that your specimen can be identified but only indirectly. We can find out if we need to know which sample is yours in the event you wish the sample to be removed from the bank later.

Some of the people who receive your information may not have to follow the privacy laws and may share or release your information because they do not have to follow the privacy laws.

What Are the Benefits To Donating Your Sample(s) for Specimen Banking?
It is very unlikely that any future research (specimen banking) performed using your specimen(s) would benefit you directly, but it may provide important medical knowledge that could help other patients with your medical condition or other medical problems in the future.

What Are The Risks of Donating Your Sample(s) For This Study?
Risks to Privacy from Specimen Banking:
The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. One of the risks to you is the release of information from your health records. The University of Virginia will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot *guarantee* it will be safe. To further safeguard your privacy, information obtained from future research will not be placed in your medical record.

There are certain risks of having health information given to other people by mistake. In the unlikely event that this happens, it could cause discrimination or mental harm to you or your family members if others were to see this information. The results could be that you may not be able to get or keep certain kinds of insurance. It could also hurt family relationships.

Will You Find Out the Results of the Research on Your Sample(s) for Specimen Banking?
Neither you, your health care provider**,** nor anyone in your family, will receive the results of any research done on your sample(s). The results will not be put in your health records. Therefore, results from any research done on your sample(s) will not affect your medical care. This helps protect you and other members of your family from harm that might be caused by this information.

What If You Change Your Mind About Donating Your Sample(s) for Specimen Banking?
If you decide now that your sample(s) can be kept for genetic research and/or specimen banking, and later change your mind, you can simply withdraw the sample(s) at that time. To

withdraw you will need to write to the Principal Investigator listed on the first page of this form. We will then destroy any of your tissue that has not already been used. However, if your sample has been used in genetic research, the information that we have learned will remain in the study, even if you withdraw. Unless you withdraw from the study, permission for researchers to use your tissue and to use and share your private health information for this study will never end.

Will You Be Paid For Donating Your Sample(s) for Genetic Research and /or Specimen Banking?

You will not be paid to donate your sample(s) for genetic research and /or specimen banking.

Will Donating Your Sample(s) Cost You Any Money?

There is no cost to you to have your samples collected or used for specimen banking.

Specimen Banking Options:

You do not have to participate and agree for specimens to be collected for specimen banking in order to be in the main part of this study. No matter what you decide to do, your decision will not affect your medical care. You can tell us your choice by placing your initials in one of the options below:

SPECIMEN BANKING:

Please indicate your choice by placing your initials below (if applicable):

___ YES **Your sample(s) may be saved for future research and stored in a specimen bank.**

___ NO **Your sample(s) may not be saved for future research and stored in a specimen bank.**

What are the risks of being in this study?

The risks are the same between the two groups since the amount of radiation and the frequency of radiation is not changed. The optimization group MAY reduce the risk/severity of lymphopenia (decrease in white blood cells). Similarly, the risks of receiving SBRT as part of this study or as part of clinical care are no different. Precautions are taken to minimize radiation to organs near your tumor and that does not change when you participate in this study. The only other procedures specific to research completed as part of this study are the blood draws to look at the number of many types of your white blood cells, and how well each type of your lymphocytes are working.

Risks of SBRT as administered at UVA (both Group A and Group B)
Likely:

- Fatigue (tiredness) for no apparent reason, which is temporary
- The skin in the treatment area may become reddened and/or dry, and chest hair may not grow back

Likely and Serious:
A common effect of this treatment in previous studies was eventual collapse of a portion of the treated lung; this collapse generally affects a limited portion of the lung, but the collapse appears to be permanent. Efforts will be made to reduce this risk and limit its effect. If collapse of a portion of the treated lung occurs, the patient will have shortness of breath at rest or during exercise, may need to receive oxygen, and/or may have chest wall pain. Some patients may need oxygen therapy permanently. A collapse of a portion of the lung may be life threatening

Less Likely:

- Cough
- Difficulty breathing
- Fever
- Chest wall discomfort

Less Likely and Serious

- Irritation of the lining around the heart, which can cause chest pain, shortness of breath and irregular or rapid heartbeat; rarely, this can require surgery to correct
- Irritation and/or damage to the muscle of the heart; rarely, this can cause a heart attack, heart failure and/or death
- Irritation and/or damage to the spinal cord (the major nerve within the spine), which can lead to weakness, tingling or numbness of the lower body and legs; very rarely, this can lead to inability to move or control the lower half of the body
- Narrowing of the esophagus (tube to the stomach)
- Irritation of the large blood vessels surrounding the heart; rarely, this can cause bleeding (coughing up blood) and/or death

Risks of having SBRT that is optimized: There are no known risks associated with the optimization.

Risks of having your blood drawn:
Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare)

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you.

Pregnancy and Contraception

The radiation used in this study can harm an unborn or nursing baby. Therefore, you cannot be in this study if you are pregnant or nursing a baby. A pregnancy blood test will be done within two weeks of registration of this study if you are a woman able to become pregnant. You MUST NOT become pregnant prior to study entry and through the completion of SBRT.

You and your partner must use an approved form of birth control during this study. Examples of birth control you may use are:

- Intra-uterine device (IUD)
- Cervical cap with spermicide
- Abstinence (no heterosexual activity)
- Diaphragm with
- Condom with spermicide

Ask your doctor for more details about the proper birth control method for you. If you become pregnant during this study, you must tell your doctor right away. Your doctor will discuss your treatment and the effect on the pregnancy.

If your partner becomes pregnant during this study, you must tell your doctor right away.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. It is possible that if you are assigned to Group A, the radiation may not damage your lymphocytes as much as it would if you are assigned to Group B (or if you receive standard SBRT at UVA outside of this study). However, we don't know for sure and that is what this study is trying to better understand and figure out.

Information researchers collect from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Standard of care SBRT treatment

If you are an employee of UVa your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will be paid $50 by gift card after finishing all tests/procedures through the 1 month after SBRT follow up visit.

By agreeing to be in this study, you are donating your blood and giving up any property rights you may have to it. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance:

- Collection of blood for CBC (to see changes in your lymphocyte counts) and for research to understand more about how well your lymphocytes are working
- CBC with differential testing
- Research blood testing

You and/or your insurance company must pay for the SBRT treatment and any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the Radiation Oncology group can take you out of the study. Some of the reasons for doing so may include

a) Your study physician is concerned about your health
b) Your disease gets worse
c) The side effects of the treatment are too dangerous for you
d) New information shows the treatment will not work or is not safe for you
e) You do not follow your doctor's instructions
f) The study sponsor closes the study for safety, administrative or other reasons

If you decide to stop being in the study, we will ask you to let the Radiation Oncology staff team at UVA know.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA), if the study is regulated by the FDA
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

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.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVa will not use it in the following cases.

- You have agreed in writing to allow UVa to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

Please contact the Principal Investigator listed earlier in this form to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Krishni Wijesooriya, PhD
University of Virginia Health System
200 Jefferson Park Avenue
Charlottesville, VA 22908
Telephone: (434)094-5741

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: (434)924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the IRB approved Short Form or full consent written in the language they can understand. A modification to add signature lines for interpreter also required.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Signature of Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Interpreter

By signing below you confirm that the study has been fully explained in a language the person understood and that all of their questions have been answered.

_____	_____	_____
INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE

If an interpreter was used via an outside phone service such as Cyracom, enter the interpreters ID# on the signature line above and document in the consenting process note that an outside interpreter via phone service was used to obtain consent/assent.

Notification of My Health Care Provider

Your health care provider will be notified of your participation in this study.

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.
The follow up information will be collected by the Department of Radiation Oncology at UVA

- Obtaining information from my medical records
- In person follow up visit (physicians may still ask how you are feeling and to review current medications)

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Signature From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Signature

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING SIGNATURE (SIGNATURE)	PERSON OBTAINING SIGNATURE (PRINT)	DATE

Interpreter

By signing below you confirm that the information regarding Leaving the Study Early has been fully explained in a language the person understood and that all of their questions have been answered.

_____	_____	_____
INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE

If an interpreter was used via an outside phone service such as Cyracom, enter the interpreters ID# on the signature line above and document in the consenting process note that an outside interpreter via phone service was used to obtain consent/assent.