The Role of Adaptive Radiation Planning in Patients with Non-Small Cell Lung Cancer on Radiation Induced Toxicity

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RUTGERS HEALTH
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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Evaluating the Effect of Adaptive Radiation Planning in Patients with Non-Small Cell Lung Cancer on Radiation Induced Toxicity

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STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The purpose of the research is to investigate whether establishing set intervals for patients to receive adaptive radiation planning (re-simulating and contouring), will impact radiation-induced side effects in patients receiving chemoradiation for non-small cell lung cancer (NSCLC). "Adaptive planning" is the process by which your radiation oncologist and radiation team will have you re-simulated at different points during your treatment process in order to adjust or adapt, the radiation plan in response to how your tumor is responding. The overall goal is to spare the amount of healthy lung tissue receiving radiation as your tumor shrinks during radiation therapy.

If you take part in the research, you will be asked to receive three computed tomography (CT) scan simulations scans at days 1, 15, and 29 of treatment to assess changes in your tumor so your radiation team can plan accordingly. You will then receive standard of care immunotherapy with your medical oncologist. Your time in the study will include the duration of chemoradiation treatment (6 weeks) plus 23-25 months on follow-up.

No foreseeable risks of harm are expected other than potential inconvenience for the patient with additional time spent in doctors' offices and possible benefits of taking part may be a reduction in side effects associated with radiation treatment. Typically patients receive 1 simulation prior to therapy, but often times the radiation oncologist will ask the patient to go for another simulation if the treating physician believes that changing the radiation plan will benefit the patient. The small amount of extra radiation, from the resimulation process is less than 1/1000th of the dose of planned radiation therapy and will not affect lung or other organ functioning.

An alternative to taking part in the research study would be to receive standard treatment for your disease without the research component.

Participating Sites:	
Jack & Sheryl Morris Cancer Center 165 Somerset Street, New Brunswick, NJ 08901 Telephone Number: 732-235-2465 **Principal Investigator:** Salma Jabbour, MD	

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. Salma Jabbour is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Jabbour may be reached at the address provided at the top of this consent form. The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
The standard treatment for your type of cancer is chemotherapy and radiation for 6 weeks, followed by immunotherapy. Prior to the radiation treatment, each patient goes through a process known as simulation. During simulation, you will be positioned on the treatment table in a manner than can be reproduced for each time you receive treatment. The purpose of simulation is to make sure that the radiation is reaching the tumor exactly at the same spot throughout each treatment. Next, your radiation oncologist, along with a specialized team will create your treatment plan, ensuring that they can deliver the radiation to your tumor with minimal risk to your lungs and heart; however, there is still a risk of side effects such as inflammation in the surrounding areas.

The plan that radiation oncologist assigns generally remains the same throughout the entire course of treatment. However, we know that a patient's tumor has the potential to shrink even after the first dose of radiation, therefore, disregarding the measurements calculated in the patient's treatment plan. As a result, patients often receive radiation to areas of healthy tissue. Currently, there is no standard method to assess whether a patient's treatment plan should be adjusted if the radiation oncologist sees tumor shrinkage. This study is proposing a standardized method of **Adaptive Radiation Planning**, which involves an individualized re-designing of your treatment plan at set intervals. The purpose of this study is to see whether establishing set time points through adaptive radiation planning, regardless of whether the physician notices a significant decrease in tumor size, will reduce some of the side effects associated with radiation treatment and immunotherapy.

Who may take part in this study and who may not?
You may participate in this study if you are 18 years of age with inoperable stage II, stage III or oligometastatic stage IV non-small small cell lung cancer. Additionally, you may partake in this study if:

1. Your treatment plan includes chemoradiation for 6 weeks and planned immunotherapy as per your treating physician.
2. Your physician deems you in good health to receive this treatment.
3. You have read and signed this consent form.

You may NOT participate in this study if:

1. You are unable to keep your doctor's appointments.
2. You have a condition or medicine that might interfere with your ability to receive chemoradiation.
3. You had prior treatment for your lung cancer.
4. Pregnant or breastfeeding, or expecting to conceive or father children within the projected duration of the study period.

Why have I been asked to take part in this study?
You are being asked to take part in this study because you have non-small cell lung cancer. Your treatment includes chemotherapy together with radiation.

How long will the study take and how many subjects will take part?
Approximately 53 patients will participate in this study at the Rutgers Cancer Institute Radiation Oncology Clinic at the Robert Wood Johnson University Hospital. Each patient will be enrolled in the study for a period of 2 years, including the 6-week course of chemoradiation and subsequent follow-up appointments.

What will I be asked to do if I take part in this study?
Before you begin study treatment:
You will have some exams, tests and procedures to find out if you can take part in this study. Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, your doctor will do some extra testing as part of the study. The testing that you will need to have if you take part in this study is discussed below. If some of these have been done recently they may not need to be repeated, this will be up to the study doctor.

- Your age and race/ethnicity will be recorded
- You will be asked about your medical history and any medications you are currently taking, both prescription and over the counter.
- You will have a complete physical examination, with your physician or physician's assistant, including measurement of your vital signs (breathing rate, blood pressure, temperature, and heart rate), height, and weight.
- You will receive an evaluation of your ability to carry out daily activities
- You may meet with a cardiologist and receive several cardiac tests (optional).
- You will undergo a computed tomography (CT) scan, a scan that uses x-rays to look at one part of your body. It may be done with or without intravenous (IV) contrast. IV contrast means that dye is injected into your vein to increase the differences between normal and abnormal tissue. This allows physicians to better visualize the internal structures in your body, including your tumor. However, it is up to the physician's clinical judgment to decide whether the patient will receive a CT scan with or without contrast. All patients undergoing treatment for radiation therapy receive this test; this test is not just for research purposes.

If you do not meet the eligibility requirements, you cannot take part in this study. The study doctor will inform you of other options that are available to you. If the tests, exams, procedures show that you can be in the study, you will be registered.

- Closer to the start of treatment, you will undergo another CT scan simulation with IV contrast unless there are contraindications suggesting IV contrast is safe. All patients undergoing treatment for radiation therapy receive this as well test as per routine radiation planning. This CT scan is known as simulation, and will allow the physician to begin creating a treatment plan for you. The process of the first simulation will take approximately 1.5 hours.

During Treatment:
All study participants will receive a 6-week course of chemoradiation, as planned by the Principal Investigator, Dr. Jabbour. The choice of chemotherapy will be chosen by your medical oncologist and will be recorded for research purposes.

- Patients will receive chemotherapy as per routine care
- Patients will receive standard of care radiation treatment at a specified dose Monday through Friday for 6-weeks in a row.
- On about **Day 15** of treatment, you will undergo a second CT scan simulation without IV contrast. This will take approximately 20 minutes. Your physician will use this CT scan to re-evaluate your

treatment plan, if needed. Additional information such as side effects will be collected from you at this time

- NOTE: You WILL receive radiation treatment as planned on day 15. This scan is used to determine if a new radiation plan will help reduce radiation doses to your organs.

- On about **Day 29**, of treatment you will undergo a second CT scan simulation without IV contrast. This will take approximately 20 minutes. Your physician will use this CT scan to re-evaluate your treatment plan, if needed. Additional information such as side effects will be collected from you at this time.
    - NOTE: You WILL receive radiation treatment as planned on day 29. This scan is used to determine if a new radiation plan will help reduce radiation doses to your organs.

After Treatment:

- Following treatment, you will be able to meet with your medical oncologist to undergo planned immunotherapy and will be monitored for immune related side effects.
- 3-10 weeks following the completion of your chemoradiation treatment, you will follow up with your treating radiation oncologist.
    - At this time, you will receive the following tests: a CT scan assessing your tumor.
    - Your treating physician may recommend you to visit a cardiologist for heart function tests.
    - You will be asked about any side effects you are experiencing related to your treatment.

You will follow up will your radiation oncologist every 6 months approximately 2 years (23-25 months), to assess your health.

- You will undergo a CT scan with IV contrast with a Positron emission tomography-computered tomography scan (PET/CT), as permitted by insurance carriers. A PET/CT scan is a type of imaging technique, similar to a CT scan, but it can generate colored imaged of your tumor.
- You will be asked about your side effects relating to radiation.

Overall, your time in the study will include the duration of chemoradiation treatment (6 weeks) plus 23-25 months on follow-up.

What are the risks of harm or discomforts I might experience if I take part in this study?
No foreseeable risks of harm will be expected as a result of the adaptive planning other than patient inconvenience with additional time spent in doctors' offices. There is minimal risk regarding the additional CT scans on lung and other organ functioning.

The risks of this trial are related to receiving radiation therapy in general, which will be discusses in detail with your treating physician and are listed below. There is also a risk that adaptive planning will not be superior to standard of care radiation therapy. Since you will still be receiving the same dosing as standard of care, there is minimal risk that adaptive planning will not be as good as standard of care, but it is still a possibility.

Possible General Side Effects of Lung Radiation Include:
Common, Some may be serious (5% of people who receive radiation, may have):

- Swelling and redness, tanning, thickening, numbness, or peeling of the skin in the area of radiation
- Difficulty and/or pain with swallowing
- Hair loss in the treatment area, may be permanent
- Shortness of breath
- Cough with or without increased phlegm production
- Tiredness
- Pain in chest wall

Less Common, Some may be serious (5% or less of people who receive may have):

- Inflammation of the lung that may cause difficulty breathing and can be life-threatening
- Narrowing of the throat which may cause vomiting, difficulty swallowing
- Scarring in the lung
- Lung collapse
- Fluid around lungs
- Bleeding from the lungs which may cause coughing up blood
- Fever
- Narrowing of the esophagus

Reproductive Risks of Harm for General Radiation Treatment

Both males and females will be included in this study. If you are pregnant, you cannot participate in this study. You should not become pregnant or father a baby while participating in this study because the drugs in this study can be associated with unknown risks that could affect you or an unborn baby.

All subjects and their spouses or partners must use an effective birth control method. Some examples of birth control are the following: have had a prior history of surgically-induced sterility (i.e., tubes tied, vasectomy), avoiding any activity that could cause you to become pregnant (no sexual intercourse), or using birth control pills, IUD, condom, or double-barrier contraception diaphragm with spermicidal jelly, transdermal (through your skin) or injectable contraceptives. Whether you are a man or woman, you must practice birth control during the study and for at least three months after you receive the last dose of the study drug. Before entering the study, you and the study doctor must agree on the birth control method you will use during the entire study. A counselor and more information about preventing pregnancy will be made available to you if you have any questions.

FEMALES

If you are capable of becoming pregnant, a pregnancy test (using a urine and/or blood sample) will be done and the results must be negative before you are permitted to enroll in this study. A repeat pregnancy test must be done if you miss any periods or your periods becomes irregular.
If you are currently breast-feeding a child and agree to participate in this study, you must stop breast feeding before receiving the first dose of study drug. You must agree to discontinue breast-feeding for the entire time you are participating in the study to prevent any potential health risk or injury to the child.
If you become pregnant while in this study or within 12 weeks during your treatment, you must tell the study doctor as soon as possible. The study doctor will advise you of the possible risks to your unborn child and options available to you. Because of the possible risks to an unborn child, the treatment will be stopped. You may be asked to receive medical follow-up services for yourself during the pregnancy and for the baby after birth. You may be asked to provide more information about the pregnancy and its outcome.

MALES

Male subjects must be surgically sterile or agree to use an acceptable method of contraception. You should make certain that you use adequate birth control measures to protect your spouse/female sexual partner(s), who may be capable of becoming pregnant. You should also make certain that you inform your spouse/female sexual partner(s), who are capable of becoming pregnant, about the risk of harm to an unborn child posed by this drug so that they can take their own contraceptive measures. Male participants should immediately inform the study doctor if your partner becomes pregnant during the study, within 12 weeks after your last dose of the study drug. You should not take any over-the-counter medicines, herbal products, vitamins or food supplements while taking part in this study, unless you tell the study doctor and get permission from the study doctor to go on taking these medicines. You will follow the instructions of the study doctor about the use of any of these products. You should also tell the study doctor about all medicines that other doctors may have prescribed for you to take.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be a reduction in side effects associated with radiation treatment. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
You do not need to participate in this study. If you choose not to participate in this study, you will be able to receive standard of care chemoradiation. Instead of being in this study, you can:

- Choose to have the usual approach described above (see page 2).
- Take part in another study
- Receive no therapy specific to your cancer

Talk to your doctor about your choices before you decide if you will take part in this study. You are under no obligation to take part in this research study. If you decide that you do not wish to take part in this study, you are free to leave the study at any time.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Will there be any cost to me to take part in this study?
You and/or your insurance company will be billed for the costs of your treatment that are considered standard of care (for example, doctor/ Advanced Practice Nurse (APN) visits, nursing care to administer the treatments, routine lab tests, restaging scans, etc.) as you would have received these services even if you were not participating in this study. Please note that restaging scans are different from replanning scans and are a part of standard of care treatment. You will be responsible for any co-payments due for office visits, co-insurances and deductibles due on any tests and/or procedures that are required and considered standard care. If patients receive optional cardiology consult, the treating physician will work with the patient to ensure cardiology consult is in network. If patient chooses a cardiologist out of network, it will be the patient's responsibility to cover the cost.

Will I be paid to take part in this study?
You will not be paid to for your participation in this research study.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Your personal information may be given out if required by law. Information about your cancer and treatment will be collected from your medical record for the study. The information will be with a study identification number and stored in a secured electronic file. The electronic file is password protected and accessible only to authorized study personnel. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen to my information collected for this research after the study is over?
At the completion of the study, all information collected for research purposes will be discarded in accordance with HIPAA guidelines.

What will happen if I am injured during this study?
Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which were discussed in the Risk and Discomforts section of this consent form. In addition, it is possible that during the course of this study, new adverse effects of radiation and additional CT scan simulation that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled. You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Salma Jabbour, with the address provided in this consent form. If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I contact if I have questions?
If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the Principal Investigator:

Salma Jabbour, MD
Rutgers Cancer Institute
195 Little Albany Street
New Brunswick, NJ 08903
Telephone: (732) 235-2465

If you have any questions about your rights as a research subject, you can call:

IRB Director
New Brunswick/Piscataway Health Science IRB
335 George St.,
Liberty Plaza Ste. 3100,
New Brunswick, NJ 08901,
Tel: (732)235-9806

OR

Rutgers Human Subjects Protection Program
65 Bergen St., Suite 507
Newark, NJ 07107.
Tel: (973) 972-1149,
Email: humansubjects@ored.rutgers.edu

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described

here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?
If you choose to be in this study, the study doctor will get your personal and medical information. This information may include:

- All information in a medical record
- Radiology records or images (MRI, CT, PET scans)
- Medical history
- Results of physical examinations
- Information regarding the dose of radiation, lung volumes, and other related values
- Laboratory/ diagnostic tests or imaging (including: MRI, CT)
- EKG and/or other cardiac tests
- Pathology reports, specimen(s) or slide(s)
- Current and past medication or therapies
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Information regarding any side effects you may experience while on study
- Information regarding cancer status

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved In The Study
- Rutgers Cancer Institute
- University Hospital or Robert Wood University Hospital personnel to communicate information necessary for health care operations;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision.

Salma Jabbour, MD
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195 Little Albany Street
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How Long Will My Permission Last?
There is no set date when your permission will end. Your health information may be studied for many years.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

FOR NON-ENGLISH SPEAKING SUBJECTS:

Signature of Reader/Translator If the Subject Does Not Read English Well:

The person who has signed the short form, _____, does not read English well. You read English well and are fluent in _____ (*name of the language)*, a language that the subject (his/her parent(s)/legal guardian) understands well. You understand the content of this consent form and you have translated for the subject (his/her parent(s)/legal guardian) the entire content of this form. To the best of your knowledge, the subject (his/her parent(s)/legal guardian) understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and these questions have been answered (his/her parent(s)/legal guardian).

Reader/Translator Name:_____

Reader/Translator Signature:_____ Date:_____

Witness Name:_____

Witness Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:
To the best of your ability, you have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____