ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Patient-Reported Outcomes following chemoradiotherapy for Locally Advanced Non-small Cell Lung Cancer**. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Nitin Ohri, MD. You can reach Dr. **Ohri** at:
Office Address: Albert Einstein College of Medicine, Department of Radiation Oncology
1300 Morris Park Avenue, Mazer 610
Bronx, NY 10461
Telephone #: 718 405 8550
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by **The Department of Radiation Oncology**

Why is this study being done?

The goal of this study is to measure patient-reported outcomes during and after concurrent chemoradiotherapy for locally-advanced non-small cell lung cancer. We also will compare a PET-based, dose painted, 4 week accelerated radiotherapy course, to a 6 week standard radiotherapy course. The 4 week radiation therapy course will use information from your PET scan to offer a more personalized treatment course.

Why am I being asked to participate?

You are being asked to participate in this study because you have been diagnoses with Non-Small Cell Lung Cancer and plan to be treated with chemotherapy and radiation therapy.

How many people will take part in the research study?

You will be one of about **50** people who will be participating in this study at Montefiore Medical Center.

How long will I take part in this research?

It will take you 4 to 6 weeks to complete the treatment portion of this research study. During this time, we will not ask you to make any extra visits to Montefiore Medical Center for this study. You will be expected to come to your standard appointments and treatment sessions already scheduled for you by your doctor. We will then continue to follow up with you per standard of care. During some clinic visits, you will be asked to complete a brief (under 5 minutes) questionnaire describing your symptoms.

What will happen if I participate in the study?

Before you take part in this study, you will have some tests and procedures to be sure you qualify for the study. All of these procedures are performed as part of standard care for patients with your disease. The study doctor will review the results of these tests and procedures. If you aren't eligible, the study doctor will tell you why. These will include:

- A Review of your medical history
- A physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Test your blood or urine for pregnancy, if you are a female able to become pregnant. Pregnant women cannot take part in this research study.
- Take a PET/CT
- Take a chest CT if your PET/CT was greater than 42 days away from the day you sign this consent.

If you decided to participate, at this first visit we will also give you some questionnaires to fill out about your **general health, well-being, and quality of life.**

If you are eligible for the study, you will be placed into a treatment group based on a randomization (similar to a coin flip). You will receive 6 weeks of standard radiotherapy or 4 weeks of radiotherapy using information from your PET scan to offer a more personalized radiation plan, where the dose delivered to each tumor or lymph node is based on PET activity in that region.

You will have a visit with your doctor once each week during treatment, which is standard practice for all patients treated in our department.

At these weekly visits we will:

- Review your medical history
- Perform a physical exam to check your height, weight, and vital signs
- Ask you about side effects or health problems since your last visit
- Give you a brief questionnaire to fill out (every other week).

We will then continue to follow up with you for this study for about 6 months after your treatment. At each of your follow up visits we will:

- Review your medical history
- Perform a physical exam to check your height, weight, and vital signs
- Ask you about side effects or health problems since your last visit
- Give you questionnaires to fill out.
- Take a PET/CT or a chest CT (every three months).

Information Banking (Future Use and Storage)

We will store information about you in a "bank", which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose, or treat disease, including genetic research. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS

_____ I consent to have my information used for future research studies.

_____ I do NOT consent to have my information used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

If you take part in this study, you or your insurance will need to pay for some or all of the cost of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment, as determined by the participating hospital or sponsoring company, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.

- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr. Nitin Ohri at 718-405-8550.

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- If you think you have become pregnant, contact your research study doctor immediately.
- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor's name and phone number.
- You may carry out all your normal daily activities.

Confidentiality

We will keep your information confidential. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a secure manner and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information will be kept as long as they are useful for this research.

The only people who can see your research records are:

- the research team and staff who work with them
- Groups that review research (such as the Einstein IRB, and the Office for Human Research Protections).

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Are there any risks to me?

Questionnaire
You may feel uncomfortable answering questions about your quality of life and overall well-being. You can choose not to answer any questions that make you feel uncomfortable.

Therapeutic Radiation Risks

You will be receiving radiation as part of the study treatment and will receive standard radiotherapy (6 weeks) or a shorter course of radiotherapy (4 weeks) that is personalized using information from your PET scan. We are studying the 4 week personalized radiotherapy course because we believe that will be at least as safe and effective as the standard course. However, it is possible that the 4 week treatment may be less effective than the standard 6 week course.

You may have side effects while on study that are **common with all radiation therapy treatment for lung cancer**. Some of the side effects include:

Common side effects:

- Difficulty, pain, or burning sensation when swallowing, which often is temporary
- Tiredness, which is temporary
- Tanning, redness of skin, and hair loss within the treatment area, which is temporary
- Skin in treatment area may remain permanently dry, and chest hair may not grow back
- Scarring in the lung, which sometimes causes collapse of the lung
- Fluid collection in the lung sac

Less common side effects:

- Cough and some difficulty in breathing (or shortness of breath) due to lung inflammation or scarring, which may be severe at times
- Irritation of the heart sac
- Irritation of the heart muscle
- Injury to the tube that carries food to your stomach
- Injury to the tube that carries oxygen to your lungs
- Bleeding from injury to the large blood vessels

Uncommon and Rare side effects:

- Inflammation of the spinal cord
- A second cancer caused by the radiation you receive

Risks to Women Who Are or May Become Pregnant

The effects of radiation and chemotherapy on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, may be harmful. Because of these unknown risks, women cannot take part in this study if they are:

- Pregnant
- Trying to become pregnant
- Breastfeeding or sharing breast milk

If you are a menopausal woman and have not had a menstrual period for the past 12 months or more, you will not need to have a pregnancy test. Also, you will not need to have a pregnancy test if you have had a hysterectomy (surgical removal of your uterus and/or ovaries). All other female subjects must have a negative pregnancy test before starting the study drug.

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below. You must use birth control for the duration of the study. Acceptable birth control methods for use in this study are:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants

- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

If you miss a period, or think you might be pregnant during the study, you must tell the study doctor immediately.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. While doctors hope that this schedule of radiotherapy and chemotherapy will be more useful against cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about the effectiveness of this approach as a treatment for cancer. This information could help future cancer patients.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time