ID: UMCC 2015.035

NCT02492867

A Pilot Study of Response-Driven Adaptive Radiation Therapy for Patients With Locally Advanced Non-Small Cell Lung Cancer

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: A Pilot Study of Response-Driven Adaptive Radiation Therapy for Patients with Locally Advanced Non-Small Cell Lung Cancer, UMCC 2015.035

1.2 Company or agency sponsoring the study:
The National Institutes of Health, The University of Michigan Department of Radiation Oncology

1.3 Names, degrees, and affiliations of the researchers conducting the study:
Principal Investigator
Shruti Jolly, MD Department of Radiation Oncology, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
Successful treatment of lung cancer with radiation therapy requires that the physicians determine exactly where the tumor is in your body and seek to limit any unnecessary radiation to normal parts of the body. This study is designed to apply functional imaging, Fluorodeoxyglucose–Positron Emission Tomography (FDG-PET) ("a PET scan") and Ventilation/Perfusion Single Photon Emission Computerized Tomography (V/Q SPECT) ("a perfusion scan"), before treatment and then again during treatment to see if this scanning helps predict how well the treatment works for your cancer and how well your lung functions during treatment. FDG-PET is a modern technology that uses small amounts of a radioactive glucose (FDG) to make images of your whole body and areas of active cancer. V/Q SPECT is an image mapping tool that helps assess how well your lungs are working. A Computerized Tomography (CT) will also be performed along with both of these procedures to help the researchers see clearly where your cancer or your healthy lung is located.

The researchers are also doing blood and urine tests in this study to look for markers to see if this helps them determine your risk of developing side effects from radiation to the lungs. The researchers hope by using these types of tests that they can have more information to help decrease the amount of toxicity patients have from this type of treatment. The researchers hope that this study will help them in the future to design radiation treatment plans that provide the best treatment for each individual patient.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?
Patients who have stage IIA-IIIB non-small cell lung cancer and considered unresectable or inoperable are eligible for this study. All patients must be age 18 or over. Pregnant women cannot participate in this study. Prisoners are excluded from this study.

3.2 How many people (subjects) are expected to take part in this study?
Fifty-five evaluable subjects are expected to take part in this research, and we may need to enroll up to seventy subjects to reach this goal. Approximately 40 subjects will be enrolled at the University of Michigan, and approximately 30 subjects will be enrolled at the VA Ann Arbor Healthcare System.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
After agreeing to participate in this study and signing this consent, you will have some pre-treatment procedures completed.

Within 6 weeks prior to the start of treatment, you must have a chest and upper abdomen CT and pulmonary function tests. You must also have a head CT or MRI within 6 weeks. Within 4 weeks prior to the start of treatment, you must have history, physical, and a baseline toxicity evaluation. Within 4 weeks prior to the start of treatment, you must have vitals and blood work completed, including blood counts and liver function tests, and have urine collected. These are all standard procedures for people with lung cancer being treated with radiation therapy.

Within 2 weeks prior to or after your treatment planning CT scan, you must also have an FDG-PET-CT scan and V/Q SPECT. This is used to help plan your radiation therapy. If any of these procedures have already been completed in the appropriate timeframes, they will not be repeated for this research. If your clinical FDG-PET/CT scan was completed more than 2 weeks' prior your treatment planning CT, another scan will be completed for updated tumor assessment. This will be used for research purposes and care.

For the V/Q SPECT, you will be required to lie on a table while the machine creates computer images of your lungs. This procedure will have 3 different parts. For the first part, you will be required to breathe into a radiotracer through a mouthpiece. A radiotracer is a radioactive chemical that can be seen on the images of your body. This tracer, called [^{99m}Tc] DTPA, is in aerosol form and is tasteless. You will be able to breath normally with this mouthpiece. Once the tracer has gotten into your system, you will be given a small amount of water to drink to clear your mouth and throat. This part of the procedure will last approximately 15-20 minutes. You will stay in the exact same place on the table for the second part of the procedure. You will then be injected with a different radiotracer. This second tracer is called [^{99m}Tc] MAA. It will be injected into a vein in your arm or leg. The second part of the procedure will last approximately 10 minutes. For the last part, you will have a CT scan done. This part of the procedure will last less than one minute.

For University of Michigan patients only, a portion of the tumor tissue collected at the biopsy at diagnosis will be analyzed for research purposes. No additional tissue will be collected for this study, beyond what is collected during your standard biopsy.

Blood and urine will be collected. For the research blood draw, the researchers will be checking for proteins in your blood, to correlate with your treatment side effects. For this test, you will need to have four tubes of blood drawn for a total of 40 ml. This will be similar to 3 tablespoonful's. Urine will be used for analysis of RNA, DNA, protein, and other biomarkers. You will have blood and urine collected 4 weeks prior to starting radiation. It will be repeated Day 1 (1 hour post radiation), Day 2 (prior to radiation), Day 5 (prior to radiation and 1 hour post radiation), thereafter weekly while you are receiving radiation, and during follow-up at months 1, 3, every 3 months through 12 months, then every 6 months through 36 months, and then annually for years 4 and 5 post treatment. The exact number of weeks of radiation therapy you will receive will be determined by your doctor. After approximately two-thirds of your radiation treatment has been completed, you will have another FDG-PET/CT scan, a V/Q SPECT scan, and a re-planning CT Simulation scan. Following the mid-treatment scans, a radiation treatment break of one day will be permitted in the

event that additional time is needed for treatment planning and QA. These are all being done only because of this research study.

You will complete Quality of Life questionnaires 4 weeks prior to starting treatment, again during the third week of treatment, and also the last week of treatment.

The researchers hope the active tumor will be smaller on these scans than the previous ones, so the treatment fields can be shrunk accordingly. By doing so, the radiation dose to the tumor and your total radiation dose can be increased while the probability of normal tissue toxicity of the lung remains the same. In the event the tumor is not smaller, the information we learn during the scan will also be used to adjust your treatment plan. Similarly, the V/Q SPECT will be used to measure the function of the lung and may also impact how the radiation is delivered near the end of treatment in order to try to decrease the risk of long term damage to the lung.

During the study, you will have 2 total V/Q SPECT scans for the purposes of this research protocol. Each V/Q SPECT will last approximately 45 minutes. You will also have 2 FDG-PET/CT scans. These scans are used routinely for lung cancer patients, but it is not standard of care for patients to have this type of scan during their radiation treatment. Each FDG-PET/CT study will generally take about 2 hours. You will be injected with the radiotracer and then wait about 1 hour before the PET/CT scans begins. The scan itself will last less than 30 minutes. The amount of radiation you will receive from all of the scans will be a small fraction of the dose of radiation you will receive for the treatment of your lung cancer.

You will receive 30 daily radiation treatments along with chemotherapy.

You will receive chemotherapy while on study and the drugs you will receive are Carboplatin and Paclitaxel. You will receive one chemotherapy treatment a week for six weeks during radiation treatment. Following radiation, you will receive one chemotherapy dose every three weeks for three additional cycles or one immunotherapy dose every two weeks for an additional twenty-six cycles. The standard risks of Carboplatin and Paclitaxel or Durvalumab will be discussed with your physician. The decision to receive chemotherapy or immunotherapy will be at the discretion of the medical oncologist.

After you finish your radiation treatment, you will continue to be followed on a regular basis. You will be seen in the clinic about 1 month following your radiation. At the visit, you will have a physical exam, CT, and have research blood and urine collected. You will be scheduled to be seen 3, 6, 9, 12, 18, 24, 30, 36, 48, and 60 months (5 years) after you finish treatment. You would be scheduled for follow-up at these time points whether or not you take part in this research and they are considered a part of your standard care. At each time point, you will have a clinic visit and research blood and urine collected. At 3 and 12 months, you will have pulmonary function tests. A chest CT will be done at 6 months, every 6 months through 36 months, and then annually for years 4 and 5. You will complete a Quality of Life questionnaire at each follow-up visit.

If you participate in an additional lung study with similar sample collection, only one set of samples will be collected. You will not be double-drawn if you are on two studies.

4.2 How much of my time will be needed to take part in this study?

You will have the pre-treatment study procedures within about six weeks prior to your radiation treatment. The duration of your radiation treatment and chemotherapy will be around 6 weeks for a total of 30 daily radiation treatments.

After you complete your treatment, you will be clinically followed for five years and the information collected will also be used for purposes of this research. All of these visits are a part of standard of care. The only extra time needed strictly for research is the time needed for the V/Q SPECT scan prior to treatment, the PET scan and V/Q SPECT scan during the treatment, which the total combined time will be about three hours. The re-planning CT Simulation will take about 60 minutes. Each questionnaire will take about 8 minutes to complete.

4.3 When will my participation in the study be over?

After you complete your treatment, you will be followed for up to five years.

4.4 What will happen with my information and/or biospecimens used in this study?
Your biospecimens and collected information may be shared with NIH and the University of Michigan Department of Radiation Oncology. With appropriate permissions, your samples and collected information may also be shared with other researchers, here, around the world, and with companies. Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Risks Associated with Radiation Therapy to the Chest:
Listed below are toxicities that a patient could experience by receiving standard radiation to the lung. Because you may receive an intensified form of radiation by participating in this study (in combination with chemotherapy), there may be side effects other than those listed below that we cannot predict.

Very Likely (> 10% of patients)
Difficulty, pain, or burning sensation when swallowing, which is temporary
Fatigue, 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
Decrease in blood counts while undergoing treatment that may result in bleeding and bruising easily
Scarring in radiated normal tissue, particularly in the lung

Less Likely, But Serious (< 10% of patients)
Cough and some difficulty in breathing (or shortness of breath) due to lung inflammation or scarring, which may be severe at times (Radiation Pneumonitis)
Coughing up blood
Irritation of the heart sac (Pericarditis)
Irritation of the heart muscle (Myocarditis)
Esophageal Injury

Very Unlikely (< 1% of patients)
Inflammation of the spinal cord (Transverse Myelitis)
A second cancer caused by radiation
Permanent damage to the lung tissue
Death

Risks Associated with Paclitaxel:
Very Likely (> 10% of patients)
Loss of hair, lower blood counts which can lead to a risk of infection and bleeding, gastrointestinal discomforts, skin redness or rash, fatigue

Less Likely (< 10% of patients)
Nausea and/or vomiting, diarrhea, anemia, headaches, blurred vision, skin or nail darkening, aches and pains in muscle and joints, swelling, mouth sores, low pulse, low blood pressure, tingling, numbness, burning pain in hands and feet.

Less Likely, But Serious (< 1% of patients)
Irregular heartbeat and heart palpitations, seizures, severe allergic reactions, non-itching lesions in mouth and/or

mucous membranes, fever, temporary changes in blood tests that measure liver function, temporary "blind spots" in vision, severe rash called Steven-Johnson syndrome which can cause fever and red sores in your mouth and eyes.

Risks Associated with Carboplatin:

Very Likely (> 10% of patients)

Lower blood counts which can lead to a risk of infection and bleeding, nausea and/or vomiting, fatigue, loss of hair

Less Likely (< 10% of patients)

Weakness, loss of strength, pain, mouth sores, tingling, numbness, burning pain in hands and feet,

Less Likely, But Serious (< 1% of patients)

Allergic reactions, cardiovascular changes, respiratory changes, temporary changes in blood tests which measure kidney and liver function, blurred vision, hearing loss

While these side effects may occur during standard chest radiation therapy and chemotherapy, participating in the study could place you at higher risk for the known or expected side effects listed above. Because you may receive more intensified radiation therapy, and will also get chemotherapy, there may be side effects that the researchers cannot predict. You should discuss these with the researcher and/or your regular doctor. Your physician will see you weekly while you are on treatment to monitor any side effects and will continue to see you following treatment on a regular basis. Your doctor will treat you for any side effects as is medically appropriate. Other drugs will be given to make side effects less serious and uncomfortable. Many side effects will go away shortly after the radiation therapy or chemotherapy is stopped, but in some cases side effects can be serious and long-lasting or permanent.

Risks Associated with Durvalumab:

Likely (These side effects occur in approximately 10% or more of people receiving durvalumab):

- Diarrhea
- Rash / dry itchy skin
- Liver problems – Increases in the blood level of substances called enzymes found within your liver cells may occur. The enzyme changes are unlikely to make you feel unwell. However, if these blood enzyme levels become very high, your study doctor may need to stop the study medication. A person may develop inflammation of the liver called hepatitis; however, this is uncommon. Signs and symptoms of this include yellowing of the skin or whites of the eyes, dark urine, severe nausea and vomiting, pain in the upper right side of your abdomen, skin itchiness, not feeling hungry, and bleeding or bruising more easily than normal.
- Fatigue; feeling tired
- Nausea
- Vomiting
- Decreased appetite
- Shortness of breath
- Cough
- Fever
- Pain in muscles and joints.

Less Likely (These side effects occur in approximately 1-9% of people receiving durvalumab):

- Inflammation in the lungs (pneumonitis) – Symptoms may include, but are not limited to, a new or worsening cough, and shortness of breath possibly with fever. Pneumonitis can be fatal. Tell your study doctor right away if you have any of these symptoms as it may need to be treated urgently.
- Low thyroid (hypothyroidism) – This is when the thyroid gland produces less thyroid hormone than it should which causes the metabolism to run too slow. Symptoms may include, but are not limited to, fatigue, increased

sensitivity to cold, constipation, dry skin, unexplained weight gain, puffy face, muscle weakness, slow heart rate, thinning hair, and impaired memory. The condition can be treated with replacement thyroid hormone.

• High thyroid (hyperthyroidism) – This is when the thyroid gland produces too much thyroid hormone. Symptoms include anxiety or nervousness, weight loss, frequent and loose bowel movements, breathlessness, feeling hot, and possibly having heart palpitations. Depending on the severity of the symptoms, treatment may include just monitoring the symptoms, treating the symptoms themselves, and/or giving medicine to block the thyroid hormone.

• Kidney problems – You may have an increase of creatinine levels in a blood test (creatinine is a protein marker that measures kidney function) but not have any symptoms or feel unwell. Less commonly a person may experience nephritis which is an inflammation of the kidneys that stops the kidneys from working properly.

• Nervous system problems – Symptoms can include unusual weakness of legs, arms, or face, numbness or tingling in hands or feet. In rare situations there is the potential for the inflammation of the nervous system to be severe. Tell your study doctor right away if you have problems swallowing, if you start to feel weak very quickly, and you are having trouble breathing.

• Infusion related reactions – Reactions may occur during or after the infusion of study medication. The reaction may cause fever or chills and a change in blood pressure or difficulty in breathing which might be serious. Tell your study doctor right away if you experience any of these symptoms even if it has been several days after the infusion has been completed.

• Inflammation of the intestine (colitis) – It may cause abdominal pain and diarrhea with or without blood. Fever may be present. It may require you to receive additional fluids. If left untreated, this may lead to a tear in the wall of the intestine which can be serious and life threatening. Tell your study doctor right away if you have any of these symptoms.

Rare but Serious (These side effects occur in less than 1% of people receiving durvalumab):

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

• Type 1 diabetes mellitus which may cause increased blood glucose levels (called 'hyperglycemia') – Symptoms may include weight loss, increased urination, increased thirst, and increased hunger. Type 1 diabetes will require replacement of insulin through injection. Tell your study doctor right away if you have any of these symptoms.

• Problems with your adrenal glands (adrenal insufficiency) – May cause stomach pains, vomiting, muscle weakness and fatigue, depression, low blood pressure, weight loss, kidney problems, nausea, and changes in mood and personality. These complications may be permanent and may require hormone replacement.

• Allergic reactions – These can cause swelling of the face, lips and throat, breathing difficulties along with hives or nettle-like rash. You should immediately tell your study doctor if you develop any of these symptoms.

• Problems with the pituitary gland (hypopituitarism) – Hypopituitarism refers to decreased output of hormones from the pituitary gland in the brain and may be caused by inflammation of the pituitary gland (hypophysitis). Symptoms may include headaches, thirstiness, and trouble seeing or double vision, leakage of breast milk or irregular periods in women. These complications may be permanent and may require hormone replacement.

• Inflammation of the heart (myocarditis) – In rare cases, myocarditis has been reported. Symptoms may include irregular heart rhythm, chest pain, increasing shortness of breath during regular activities, and decrease in the hearts ability to pump blood. Myocarditis can be life threatening. Tell your doctor if you have or have had any heart problems in the past.

• Inflammation of the skin – In rare cases, severe dermatitis has been reported to show as Stevens-Johnson syndrome, toxic epidermal necrolysis or rashes complicated by cell injury or cell death, blisters or hemorrhaging. These events can be life-threatening.

• People with previous history of bleeding and/or who are taking anticoagulant medications or "blood thinners" may have a higher risk of bleeding while on durvalumab. Tell your doctor if you are taking any of these medications. Your doctor may need to monitor you for any bleeding more closely than usual.

Other rare but serious side effects include inflammation of the sac around the heart called pericarditis (symptoms that may include irregular heart rhythm, chest pain, increasing shortness of breath during regular activities) and a form of eye inflammation called uveitis that affects the middle layer of tissue in the eye wall (uvea) (symptoms include eye redness, pain and blurred vision). Uveitis can be serious, leading to permanent vision loss. Tell your doctor if you are having any of these symptoms. Early diagnosis and treatment are important to prevent the complications of uveitis. It is possible that an inflammatory or immune system reaction could occur in nearly all organs of the body which may require more frequent monitoring and may require treatment.

For more information about risks and side effects, ask your study doctor.

Study Procedure Risks:

There is an unlikely risk that the outcome of the study therapy could be worse than standard therapy since the use of FDG-PET/CT-adapted radiation therapy with targeted therapy is experimental.

Radioactivity

During the course of this study, you will be exposed to radiation from the PET radiotracer [18F]FDG, and from the CT portion of the PET/CT scanner. The biological effect of radiation in humans is measured in terms of Sieverts (Sv) or mSv (1/1000 Sv), which is a unit of uniform whole body exposure. The total radiation you will be exposed to from this research project will be approximately 42 mSv from internal and external exposures for the PET/CT scans, and the SPECT V/Q scans. The effects on the body of this radiation exposure will be added to your overall lifetime radiation risk. Your life-time radiation risk includes the background radiation you are exposed to naturally like everyone else living on this planet, which is on the average 3 mSv per year; the maximum radiation you will be exposed to in this study is about 14 times this average yearly background radiation. In terms of radiation a person may get exposed to during medical care, the maximum amount you could receive in this study is less than the radiation received in 6 routine X-ray CT scans (CAT scan) of the chest. The US Federal Government requires that the annual amount of radiation exposure of radiation workers does not exceed 50 mSv per year; the radiation you will be exposed to in this study is 84% of this amount.

Your lifetime radiation risk also includes any radiation you may have received in the past for diagnosis or treatment, and any such radiation you may be exposed to in the future. Please inform the investigators if you have had any major radiation exposure in the past, particularly in the past year, such as medical treatment with X-rays or radioactivity, or diagnostic X-rays, CT-scans or nuclear medicine scans.

No PET studies will be performed on pregnant, nursing, or potentially pregnant women, as determined by pregnancy testing within 48 hours prior to PET the scanning session.

To reduce the risk of external radiation exposure we take as short of a picture as possible to define the size and shape of your body. To reduce the risk of internal radiation exposure we inject as little radioactivity as possible.

V/Q SPECT: These scans are an established diagnostic test and are conventionally performed for evaluation of pulmonary embolism (a blood clot in the lung) and involve only minimal risk. There is a very small amount of radiation you will receive from these scans. The radiation dose from these scans are insignificant in comparison to the dose you will receive as therapy for your lung cancer (less than 1/1000th of your treatment dose). You may

experience some bruising, swelling, or infection at the site of the injection of the radiotracers. Rarely, some patients may experience a severe allergic reaction to the radiotracers.

FDG-PET/CT scans: The risks associated with an FDG-PET/CT scan are minimal. FDG is considered safe, and there has not been a report of an adverse event with this type of use. This scan is an established diagnostic test and is often performed for detecting, staging and monitoring many kinds of cancers. Despite this information there is still a possibility of a rare allergic reaction, such as hives or difficulty breathing. There is a risk of discomfort, bruising, bleeding, fainting or infection with the placement or removal of the needle used for drawing blood and injecting the FDG. Some persons may find it uncomfortable to lie still on their back for 30 minutes. Rarely, some patients may experience a severe allergic reaction to the radiotracers.

Adaptive Therapy: There is a rare risk that the outcome of the therapy could be worse for the subject. The use of PET scan results during therapy is experimental and could present a situation where there are false negative areas of the tumor, so, the possibility exists that the tumor volume to be modified could be completed to under dose part of the tumor. In this case, that part of the tumor would still be treated with a radiation dose which is within the standard range that you would receive even if you were not on the study.

Research Blood Draw: The risks involved with having blood drawn for this test are the same as those with any blood draw. You may experience some bruising, swelling, infection at the site of the blood draw, pain, and, rarely, lightheadedness.

Reproductive Risks:

If there is ANY chance that you can get pregnant, you must either agree to not have vaginal intercourse or you must use TWO types of birth control (one from each list below) AT THE SAME TIME all during treatment (including during temporary breaks from treatment), and for 90 days after treatment has stopped. You must talk to the doctor before changing any birth control methods you have already agreed to use.

Primary forms:
- tubal sterilization (tubes tied)
- partner's vasectomy
- intrauterine device

Secondary forms:
- male latex condom with or without spermicide
- diaphragm with spermicide
- cervical cap with spermicide
- vaginal sponge with spermicide

Any birth control method can fail. The reports of birth control failing are more frequent for female patients who use only a single form of birth control. Using two forms of birth control at the same time greatly reduces the chance of pregnancy.

MEN

All men must use an acceptable form of birth control while taking part in the study because the effects on sperm are not known. Acceptable forms of birth control are male latex condom (with or without spermicide) or vasectomy. Men should not donate sperm or semen while taking part in the study because the effects on sperm are not known.

Genetic Information Nondiscrimination Act (GINA):

The federal Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under this law:

- Health insurance companies and group health plans may not request your genetic information that we obtain from this research
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums

- Employers with 15 or more employees may not use your genetic information that we obtain from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

GINA does not apply to the following groups; however, these groups have policies in place that provide similar protections against discrimination:

- Members of the US Military receiving care through Tricare
- Veterans receiving care through the Veteran's Administration (VA)
- The Indian Health Service

Federal employees receiving care through the Federal Employees Health Benefits Plans

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. It is possible that you may have better control of your cancer and have longer survival by taking part in this research instead of getting standard treatment, but this is not guaranteed. The researchers will use the information learned from this study to help with treating patients with lung cancer.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
If you do not take part in this study, you will continue to receive the same treatment that you would receive if you were not on the study. There will be no penalty to you by not participating in this research.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
Although there is no specific known risk to leaving the study early, it is in your best interest to discuss your decision to leave the study with the researchers at the time that you decide to leave to make sure that you are not at any specific risk.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, call Dr. Jolly immediately, at telephone 734-936-4302. The doctor will either treat you or send you to another doctor for treatment.

You will get free medical care at the UMHS hospitalization or ER visits directly caused by the study drug, device, or procedure. The UMHS and the study doctor are responsible for determining whether your condition was the result of your participation in the study.

The UMHS will pay for your treatment only if the need for treatment has been caused by the study drug, device or procedure. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will not get paid for taking part in this research.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?
Information collected about you will be put in a research records. This record will show your name and will have codes that will allow the information to be linked to you. This research record will be stored in a secure, non-public area of the Department of Radiation Oncology. Any electronic research data will be kept in a password protected database. The researchers will keep your records confidential to the fullest extent provided by local, state, and federal laws. No one will see your research record other than people who have a right to see it like the study investigators and their research staff. You will not be identified in any reports on this study.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

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.

9.3 What happens to information about me after the study is over or if I cancel my permission?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- 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:	Shruti Jolly, MD
Mailing Address:	UM Department of Radiation Oncology B2C490 University Hospital SPC 5010 Ann Arbor, MI 48109-5010
Telephone:	734-936-4302

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- Other (specify):_____

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

For use only if required by sponsor:

Date of Birth (mm/dd/yy): _____

ID Number: _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

UMCC # 2015.035

PERSONAL CENSUS FORM

Name _____ Date _____

The National Cancer Institute requires that The University of Michigan Comprehensive Cancer Center report race and ethnicity information about people who participate in clinical research to ensure that all populations are offered the opportunity to participate.

☐ Check here if you do not wish to provide some or all of the information below.

1. What race do you consider yourself to be? (Please select *one or more*)
   - ☐ American Indian/Alaska Native[a]
   - ☐ Asian[b]
   - ☐ Black or African American[c]
   - ☐ Native Hawaiian or Other Pacific Islander[d]
   - ☐ White[e]
   - ☐ More than one race[f]

2. Do you consider yourself to be Hispanic[g]? ☐ Yes ☐ No

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[a] American Indian or Alaska Native- A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

[b] Asian- A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam.

[c] Black or African American- A person having origins in any of the black racial groups of Africa. (Terms such as “Haitian” or “Negro” are sometimes used in addition to “Black” or “African American.”)

[d] Native Hawaiian or Other Pacific Islander- A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

[e] White- A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

[f] More than one race- (It is preferred that this be selected in addition to the selection of the specific races listed above, but this may also be solely selected.)

[g] Hispanic or Latino- A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race. The term “Spanish origin” is sometimes used in addition to “Hispanic” or “Latino.”