NCI Community Oncology Research Program – Kansas City (NCORP-KC)

NRG ONCOLOGY

NRG LU002 Consent Form

Study Title for Study Participants:

Comparing Standard Treatment Alone to Radiation Therapy +/- Surgery With Standard Treatment for Patients With Limited Metastatic Non-Small Cell Lung Cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

NCI Protocol NRG-LU002, Maintenance Systemic Therapy Versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): Randomized Phase II/III Trial (18-MAY-2018)

What is the usual approach to treating non-small cell lung cancer?

You are being asked to take part in this research study because you have advanced non-small cell lung cancer and it has spread to other parts of the body. You have received treatment and your disease is currently stable. People who are not in a study usually continue treatment with chemotherapy or immunotherapy. There are several FDA-approved drugs that are commonly used as part of the usual treatment. For patients who receive the usual approach for non-small cell lung cancer, less than 5 out of 100 are free of cancer at five years.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above
- you may choose to take part in a different study, if one is available
- or you may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

Why is this study being done?

The purpose of this research study is to compare any good and bad effects of using the usual drug therapy plus radiation with or without surgery to treat the lung cancer and areas of metastasis (where the cancer has spread) compared with the usual drug therapy alone. Two types of radiation delivery will be used in this study. One type is called stereotactic body radiation therapy (SBRT) and will be used to treat areas of metastasis (parts of your body where the cancer has spread). SBRT uses special equipment to position a patient and precisely deliver radiation to

tumors in the body. The total dose of radiation is divided into smaller doses given over several days. This type of radiation therapy helps spare normal tissue. The second type is standard radiation therapy and may be used to treat your primary lung tumor if SBRT cannot be used.

Surgery also may be used to treat metastases or your primary lung tumor if you and your treating doctor decide this is a safe and better approach.

Radiation, surgery, and usual drug therapy have already been tested for safety; however, using them in combination is not part of the usual approach. Adding radiation with or without surgery to the usual drug therapy could shrink or remove your tumor(s) or prevent the tumor(s) from returning but it could also cause side effects. This study will allow the researchers to know whether this different approach is better, the same, or worse than the usual therapy alone approach. Ultimately, to be better, the study treatment should increase life by six months or more compared to chemotherapy alone.

There will be about 400 people taking part in this study.

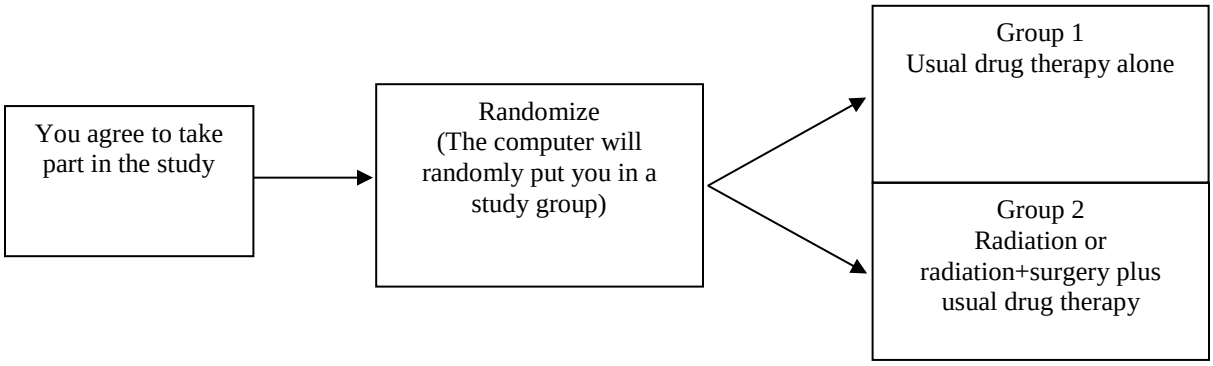
What are the study groups?

This study has two study groups:
Group 1 will receive the usual drug therapy alone.
Group 2 will receive radiation to the lung tumor and other areas in the body where the cancer has spread, and possibly undergo surgery, followed by the usual drug therapy.

For both Group 1 and Group 2, your physician will speak with you about the drug therapy options that are available for patients on this study, and together you will decide what is best for your cancer. The drug therapy options are docetaxel given through a vein (also called IV), gemcitabine given IV, pemetrexed alone or combined with pembrolizumab (immunotherapy) given IV, and pembrolizumab alone given IV.

A computer will by chance assign you to one of the treatment groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the other. It is twice as likely that you will be placed in the radiation (with or without surgery) plus usual drug therapy group (Group 2) because this study is designed to allow more patients to be treated in Group 2 since that Group will receive the non-standard treatment.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



If you are in Group 2 and are randomized to radiation (with or without surgery) plus usual drug therapy, you will need to stop drug therapy for 4-6 weeks while receiving radiation (or radiation with surgery). You will begin drug therapy again after you've completed the radiation/surgery.

How long will I be in this study?

If you are in Group 1, you will receive the usual drug therapy until it is no longer working or until you experience side effects that prevent you from being able to take it.

If you are in Group 2, you will receive radiation for between 2 and 4 weeks. If you have surgery, it will be scheduled in coordination with radiation and should be performed within 6 weeks of randomization. You will start usual therapy two weeks after you complete radiation. If surgery is the last treatment you receive, you will start usual drug therapy three weeks after surgery. You will receive that drug therapy until it is no longer working or until you experience side effects that prevent you from being able to take it.

For both groups, after you stop the usual therapy your doctor will continue to watch you for side effects and follow your condition every 3 months for the first 2 years, every 6 months for the next 3 years, and then yearly afterwards or as indicated by your doctor.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have for this study are part of the usual approach for your cancer. However, there are some extra tests and procedures that you will need to have if you take part in this study.

Quality of Life Study

You will be asked to fill out three different forms with questions about your physical and emotional well-being and your tobacco use. Researchers will use this information to better understand how patients feel during treatments and what effects the treatments are having.

You will be asked to fill out these forms at 6 times:

- Before you receive treatment on this study

- During months 1, 3, 6, 9 and 12 of treatment

Each form will take between 5 and 10 minutes to complete. The forms will ask about things like your pain level, your energy level, your own health concerns, and your smoking habits. You may feel uncomfortable answering some of the questions, and you can skip any you do not want to answer.

Neither you nor your health care plan/insurance carrier will be billed for your participation in this quality of life study.

If you do not speak English or a language in which the forms are available, you will not be asked to complete the forms.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- The study treatment (radiation with or without surgery plus usual drug therapy) may not be better, and could possibly be worse, than the usual approach for your cancer.
- If you are in Group 2, it is possible your cancer could get worse and/or other spread to other areas during the time before the start of radiation therapy when no drug therapy or radiation is given.

The radiation therapy and usual therapy drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the radiation and usual drug therapy. If this happens, you may not be able to finish radiation and/or further drug therapy.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects of the usual drugs given for this type of cancer. These tables show the side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects of Docetaxel

COMMON, SOME MAY BE SERIOUS In 100 people receiving Docetaxel, more than 20 and up to 100 may have:
• Swelling of the body • Hair loss • Change in nails • Rash, itching • Vomiting, diarrhea, nausea, constipation • Sores in mouth which may cause difficulty swallowing • Infection, especially when white blood cell count is low • Anemia which may require blood transfusions • Bruising, bleeding • Tiredness • Numbness and tingling of the arms and legs • Fever • Absence of menstrual period • Swelling and redness of the arms, leg or face • Pain • Watering, itchy eyes
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Docetaxel, from 4 to 20 may have:
• Severe skin rash with blisters and peeling which can involve inside of mouth and other parts of the body • Belly pain • Kidney damage which may require dialysis • Blood clot which may cause swelling, pain, shortness of breath • Abnormal heart rate • Shortness of breath, wheezing • Chest pain
RARE, AND SERIOUS In 100 people receiving Docetaxel, 3 or fewer may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Cancer of bone marrow (leukemia) caused by chemotherapy

Patients should be aware that Docetaxel may cause them to become intoxicated from the alcohol it contains. Patients should avoid driving, operating machinery, or performing other activities that are dangerous within one to two hours after the infusion of Docetaxel. In addition, some medications, such as pain relievers and sleep aids, may interact with the alcohol in the Docetaxel infusion and worsen the intoxicating effects.

Possible Side Effects of Pemetrexed

COMMON, SOME MAY BE SERIOUS In 100 people receiving Pemetrexed, more than 20 and up to 100 may have:
• Anemia which may cause tiredness, or may require blood transfusions • Constipation, nausea, vomiting, loss of appetite • Sores in mouth which may cause difficulty swallowing • Tiredness • Bruising, bleeding • Infection, especially when white blood cell count is low • Peeling of skin

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Pemetrexed, from 4 to 20 may have:
• Diarrhea • Swelling and redness of the area of radiation • Kidney damage which may cause swelling, may require dialysis • Liver damage which may cause yellowing of eyes and skin • Damage to the lungs which may cause shortness of breath • Scarring of the lungs • Itching • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body

RARE, AND SERIOUS In 100 people receiving Pemetrexed, 3 or fewer may have:
• Blockage of the bowels • Numbness and tingling of the arms and legs • Hair loss • Blood clot which may cause swelling, pain

Possible Side Effects of Gemcitabine

COMMON, SOME MAY BE SERIOUS In 100 people receiving Gemcitabine, more than 20 and up to 100 may have:
• Flu-like symptoms of muscle pain, fever, headache, chills and fatigue • Nausea, vomiting • Rash • Hair loss • Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may require a blood transfusion • Muscle weakness • Blood in urine • Feeling of "pins and needles" in arms and legs • Numbness and tingling of the arms and legs • Tiredness • Difficulty sleeping • Swelling of arms, legs
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Gemcitabine, from 4 to 20 may have:
• Swelling and redness of the area of radiation • Blisters on the skin • Diarrhea, constipation • Sores in mouth which may cause difficulty swallowing • Liver damage which may cause yellowing of eyes and skin, swelling • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Scarring of the lungs • Shortness of breath • Fluid in the organs which may cause low blood pressure, shortness of breath, swelling of ankles • Brain damage, Reversible Posterior Leukoencephalopathy Syndrome, which may cause headache, seizure, blindness
RARE, AND SERIOUS In 100 people receiving Gemcitabine, 3 or fewer may have:
• Severe blood Infection • Anemia, kidney problems which may require dialysis • Blood clot • Blockage of the airway which may cause cough

Possible Side Effects of Pembrolizumab

Risk Profile for MK-3475

COMMON, SOME MAY BE SERIOUS

In 100 people receiving MK-3475 (pembrolizumab), more than 20 and up to 100 may have:

- Tiredness

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving MK-3475 (pembrolizumab), from 4 to 20 may have:

- Nausea
- Infection
- Loss of appetite
- Pain in back
- Joint stiffness
- Cough
- Swelling and redness of the skin

MK-3475 (pembrolizumab) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:

- Anemia which may require blood transfusion
- Pain in lymph nodes
- Blood clot which may cause bleeding, confusion, paralysis, seizures and blindness
- Hormone gland problems (especially the thyroid, pituitary and adrenal glands, and pancreas). Signs and symptoms may include: headaches that will not go away or unusual headaches, extreme tiredness or changes in mood or behavior; decreased sex drive; weight loss or weight gain; excessive thirst or urine; dizziness or fainting
- Intestinal problems (colitis) that can rarely lead to tears or holes in your intestine. Signs and symptoms of colitis may include: diarrhea or increase in bowel movements, blood in your stools or dark, tarry, sticky stools, severe belly pain or tenderness
- Diarrhea
- Sores in the mouth which may cause difficulty swallowing
- Pain in belly
- Sores in the bowels
- Chills, fever
- Liver problems (hepatitis) which can cause liver failure. Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes, severe nausea or vomiting; drowsiness; pain in the right upper belly
- Pain or swelling of the joints
- Problem of the muscle, including swelling, which can cause muscle pain and severe muscle weakness sometimes with dark urine
- Fluid in the joints
- Pain in chest
- Lung problems (pneumonitis and other conditions). Symptoms may include: new or worsening cough, chest pain, shortness of breath.
- Skin: itching; acne; rash (can be severe); blisters and peeling on the skin, mouth; skin changes; hives

RARE, AND SERIOUS In 100 people receiving MK-3475 (pembrolizumab), 3 or fewer may have:
• Feeling of "pins and needles" in arms and legs • Redness, pain or peeling of palms and soles MK-3475 (pembrolizumab) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to: • Heart problems including swelling and heart failure. Symptoms and signs of heart problems may include: Shortness of breath, swelling of the ankles and body. • Swelling and redness of the eye • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Reaction during or following a drug infusion which may cause fever, chills, rash • Damage to organs in the body when donor cells attack host organs which may cause yellowing of eyes and skin, itchy dry skin • Damage to organs in the body when the body produces too many white cells • A condition with high blood sugar which leads to tiredness, frequent urination, excessive thirst, headache, nausea and vomiting, and can result in a coma • Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs. • Swelling of the brain (encephalitis/meningitis) which may cause headache, confusion, sleepiness, seizures, and stiff neck • Kidney problems, including nephritis and kidney failure requiring dialysis. Signs of kidney problems may include: decrease in the amount of urine, blood in your urine, ankle swelling. • Swelling or tenderness of blood vessels

You may also experience the additional risks specific to the area of the body where you receive the radiation.

Possible Side Effects of Radiation Therapy to the **LUNG**

COMMON, SOME MAY BE SERIOUS

In 100 people receiving lung radiation, more than 20 and up to 100 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
- Diarrhea, nausea
- Anemia, which may require blood transfusion
- Infection, especially when white blood cell count is low
- Bleeding, bruising
- Rib pain, increased risk of rib fracture

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving lung radiation, from 4 to 20 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
- Pain in chest wall

RARE, AND SERIOUS

In 100 people receiving lung radiation, 3 or fewer may have:

- Abnormal opening in internal organs which may cause pain and bleeding
- Irritation of the heart causing heart failure, heart attack, chest pain, abnormal heartbeat, shortness of breath, swelling of ankles, cough or tiredness
- Transverse myelitis – irritation of the spinal cord causing weakness, tingling or numbness of the lower body and legs, or paralysis of the lower half of the body
- Brachial plexopathy – irritation of the nerves controlling the arm, causing weakness or paralysis
- Bleeding from the airway (windpipe)
- Narrowing of the airway causing shortness of breath
- Death
- Lung damage, may be life threatening
- Damage to the large blood vessels surrounding the heart, which could cause coughing up of blood and possibly death
- Sores and skin damage causing bleeding and severe pain and may lead to an open wound

Possible Side Effects of Radiation Therapy to the **HEAD AND NECK**

COMMON, SOME MAY BE SERIOUS In 100 people receiving head and neck radiation, more than 20 and up to 100 may have:
• Sores in the mouth and throat which may be painful especially with swallowing • Dry mouth, changes in taste, reduced sense of smell—may be permanent • Thick saliva • Hoarseness • Skin changes that may be permanent, swelling and redness of the skin in the area of radiation • Pain or pressure in the ear • Tiredness • Weight loss • Permanent hair loss in the area of radiation (face, chin, neck) • Cavities, tooth decay; loss of teeth; tooth sensitivity
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving head and neck radiation, from 4 to 20 may have:
• Decrease in function of the thyroid gland that may require you to take thyroid replacement medicine • Damage to the nerves of the shoulder and arm which may cause decreased movement and feeling • Ear infection • Hearing loss • Difficulty swallowing which may require a long term or permanent feeding tube
RARE, AND SERIOUS In 100 people receiving head and neck radiation, 3 or fewer may have:
• Breathing and swallowing problems that may require a surgical procedure to create an opening through the neck into the windpipe • Damage to the nerves in the head and neck that control sensation, expression, or other motor functions • Damage to the jawbone which may cause jaw pain and loosening of teeth • Damage to the voice box or nerves to the voice box which may cause hoarseness, shortness of breath, inability to speak • Damage to the skin, soft tissues, or other parts of the head and neck that may require a major operation to correct and, rarely, can be life threatening • Damage to the spinal cord which may cause permanent weakness

Possible Side Effects of Radiation Therapy to the **LIVER OR ABDOMEN (BELLY)**

COMMON, SOME MAY BE SERIOUS

In 100 people receiving radiation therapy to the LIVER OR ABDOMEN (BELLY), more than 20 and up to 100 may have:

- Fatigue, which generally goes away after the radiation therapy is completed
- Skin irritation, redness, sunburn or ulcer in the skin of upper abdomen and chest wall, itchiness, and discomfort
- Temporary changes in blood work (decrease in blood counts, increase in liver enzymes), without symptoms.

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving radiation therapy to the LIVER OR ABDOMEN (BELLY), from 4 to 20 may have:

- Nausea, vomiting (during therapy): more common if stomach or gastrointestinal tract receives radiation
- Stomach, esophagus, small or large intestine irritation/ulceration, bleeding, obstruction, changes in bowel habits, or a tear or hole that may require medications or surgery.
- Chest wall pain requiring medications, rib fracture
- Temporary bleeding due to low platelet count

RARE, AND SERIOUS

In 100 people receiving radiation therapy to the LIVER OR ABDOMEN (BELLY), 3 or fewer may have:

- Liver damage that can cause swelling of your abdomen (belly) and pain in the liver and spleen (right and left upper abdomen) within 3 months of completing therapy.
- A decline in liver function within 12 weeks from start of therapy. This can cause similar symptoms to those above, plus fatigue, confusion, itchiness and/or change in skin color. This can lead to liver toxicity that can lead to death. There is an increased risk of liver toxicity in patients with large tumors and in patients with pre-existing liver disease.
- Permanent low platelets which may lead to bleeding.
- Kidney injury which may lead to a need for medication.

Possible Side Effects of Radiation Therapy to the **SPINE**

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy to the **SPINE**, more than 20 and up to 100 may have:
• Inflammation of the lining of the mouth, throat and esophagus (passageway from mouth to stomach), which can result in difficulty swallowing, and if you cannot swallow water, dehydration can occur (the state in which your body does not have as much water and fluids as it should). • Inflammation of the part of the airway that includes the vocal cords, which can result in hoarseness or loss of voice.
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy to the **SPINE**, from 4 to 20 may have:
• Inflammation of the lungs due to radiation treatment, which can result in cough, phlegm (thick mucus), difficulty breathing, and/or pneumonia. • Fracture or compression of the treated bones of the spine, which can result in pain and which may need nonsurgical or surgical treatment. • Discomfort or anxiety due to 60-90 minutes lying in a specific position, possibly within a frame device, for the planning session and 60 minutes for treatment; your doctor may give you medicine to decrease the discomfort and/or anxiety.
RARE, AND SERIOUS In 100 people receiving radiation therapy to the **SPINE**, 3 or fewer may have:
• Esophageal fistula (abnormal opening in the passageway from mouth to belly). • Scarring of the small or large bowel, which can result in a blockage in the bowel that would require treatment. • Temporary or permanent damage to the spinal cord, which can result in: ▪ Skin sensations, such as burning, prickling, itching, or tingling ▪ Muscle weakness causing inability to walk (paralysis)

Possible Side Effects of Radiation Therapy to the **BONE**

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy to the **BONE**, more than 20 and up to 100 may have:
• Skin irritation in the treatment area • Hair loss • Reddening, rash or peeling of the skin in the treatment area.
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy to the **BONE**, from 4 to 20 may have:
• Pain
RARE, AND SERIOUS In 100 people receiving radiation therapy to the **BONE**, 3 or fewer may have:
• Weakening of your bone(s), potentially resulting in a fracture.

SURGERY:
Possible sites for surgery include: lung, liver, abdomen, lymph nodes and bone. Common side effects of surgery include (but are not limited to) pain, bleeding, infection, wound healing difficulties, and injury to surrounding areas. The table below lists some of the common side effects of surgery depending on the type and location of your surgery. Prior to your surgery, you will need to sign a surgical consent form provided by your doctor, which is separate from this trial and specific to the type of surgery you will undergo. The surgical consent will include risks specific to the type and location of your surgery. When you sign the surgical consent and during discussions with your surgeon, you should ask your surgeon about those risks.

COMMON, SOME MAY BE SERIOUS In 100 people undergoing surgery, more than 20 and up to 100 may have:
• Nausea, anorexia (loss of appetite) • Pain

OCCASIONAL, SOME MAY BE SERIOUS In 100 people undergoing surgery, from 4 to 20 may have:
• Surgery to the liver may result in liver damage that can causes yellowing of the skin and eyes, bleeding/bruising, fluid in the abdominal, tiredness, confusion, and itching • Bleeding • Infection • Wound healing difficulties • Swelling of the body • Injury to the nerves causing numbness

RARE, AND SERIOUS In 100 people undergoing surgery, 3 or fewer may have:
• Prolonged need to be on a breathing machine with a breathing tube in place, and/or prolonged need to have a tube in the chest because of damage to the lung • Injury to the areas near the site of abdominal surgery: ▪ Injury to the bowels resulting in the need for a "bag" so that the bowels drain outside of the body ▪ Kidney damage ▪ Pancreas injury

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study. The radiation and chemotherapy used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study. If you are able to have children, you must use effective contraception during treatment on this study and for up to 180 days after completion of all treatment to prevent pregnancy or fathering a child. Your study doctor will discuss with you what types of birth control or pregnancy prevention to use while on this study and for how long you will need to use them, to prevent pregnancy. The treatment in the study may make you unable to have children in the future. You should consult with your doctor for information about pre-treatment or post-treatment reproductive or fertility options prior to agreeing to participate in the study. If you are a woman and become pregnant or suspect you are pregnant while participating in this study, please inform your treating physician immediately.

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if the study approach is better than the usual approach so this study may or may not help you. This study will help researchers learn things that will help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Central Institutional Review Board at 888-657-3711.

What are the costs of taking part in this study?

You and/or your health plan/insurance company will need to pay for all of the costs of treating your cancer while you participate in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database. If information

from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. They must keep your information private, unless required by law to give it to another group. Some of these organizations are:

- The study sponsor [NRG Oncology (NRG)]
- Other organizations in the National Clinical Trials Network (NCTN): Alliance for Clinical Trials in Oncology (ALLIANCE), ECOG-ACRIN Cancer Research Group (ECOG-ACRIN), SWOG and Imaging and Radiation Oncology Core (IROC).
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.
- The Cancer Trials Support Unit (CTSU), an organization sponsored by the NCI to provide greater access to cancer trials

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

ADDITIONAL STUDIES SECTION:

THIS SECTION IS ABOUT OPTIONAL STUDIES YOU CAN CHOOSE TO TAKE PART IN

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say ‘no’ to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies (18-MAY-2018)

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

Optional Sample Collection for Laboratory Study
If you choose to take part in this study, the study doctor for the main study would like to collect samples of your blood at 3 time points: before you begin treatment, at 3 months after you start study treatment, and at the time your disease worsens. These samples will be used for research on tumor DNA to help understand response to treatment and long-term outcomes. If you agree to the biobanking described next, any leftover samples will be saved for future studies.

Optional Sample Collection for Biobanking for Possible Future Studies
If you choose to take part, a sample of your tissue from your surgery will be collected, and samples of blood will be collected. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by NRG Oncology and supported by the National Cancer Institute.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) If you agree to both the Laboratory Study and the Biobanking, about 3-4 tablespoons of blood from a vein in your arm will be collected 3 times (before you start treatment, at 3 months after the start of treatment, and if your disease gets worse). If you agree to only the biobanking, then blood will still be collected 3 times (before you start treatment, at 3 months after start of treatment, and if your disease gets worse). These samples (along with the leftover tissue from your prior surgery) will be sent to the Biobank.
2) Your sample and some related health information may be stored in the Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There also will be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
2) There is a risk that someone could get access to the personal information in your medical records or other information researchers have kept about you.
3) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
4) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and NRG Oncology staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom NRG Oncology sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial),* at _____ *(insert telephone number of study doctor for main trial).*

Please circle your answer to show whether or not you would like to take part in each option (*include only applicable questions)*:

SAMPLES FOR THE LABORATORY STUDY:

I agree to have my specimen collected and I agree that my specimen samples and related information may be used for the laboratory study described above.

YES NO

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to learn about results from this study.

YES NO

SAMPLES FOR FUTURE RESEARCH STUDIES:

My samples and related information may be kept in a Biobank for use in future health research.

YES NO

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

Release

By signing this form you authorize NCORP-KC to access and obtain information that is required for the study. this may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

You will get a copy of this form. If you want more information about this study, ask your study doctor.

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study *and any additional studies where I circled "yes."*

Participant _____

Participant's signature_____

Date of signature_____

Person obtaining consent_____

Signature of person obtaining consent_____

Date of signature_____