For Protocol Amendment 7 to: **NRG-LU004**, "Phase I Trial of Accelerated or Conventionally Fractionated Radiotherapy Combined With MEDI4736 (durvalumab) in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1)"

NCI/Local Protocol #: NRG-LU004

NCI Protocol Version Date: May 28, 2024

Section	Change
Global	The document version date was updated to reflect this amendment. No changes were made to the consent content.

NRG-LU004 Research Study Informed Consent Document for Patients Enrolled in Cohorts 1-4 (16-OCT-2023)

Study Title for Participants: Testing the safety of adding an immunotherapy drug, MEDI4736 (durvalumab), to radiation therapy given in either shorter or usual time frames for locally advanced non-small cell lung cancer (NSCLC)

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
NRG-LU004, Phase I Trial of Accelerated or Conventionally Fractionated Radiotherapy Combined With MEDI4736 (durvalumab) in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1) (NCT03801902) (23-JAN-2019)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have non-small cell lung cancer that has not spread outside your lungs and cannot be removed by surgery, and your cancer cells have a fairly large amount of a protein called PD-L1 that researchers have connected to a good response to immunotherapy treatment for cancer.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

We are doing this study to learn if it is safe to add the immunotherapy drug durvalumab to the usual radiation therapy for your type of lung cancer that has a high level of PD-L1. We also want to learn if it is safer to use the immunotherapy drug with higher doses of radiation therapy

over 3 weeks, or lower doses over 6 weeks.

In studies on patients with more advanced NSCLC, similar agents as durvalumab (but not durvalumab itself) have been shown to be as active or better than chemotherapy in people with PD-L1 high NSCLC.

Because the usual approach, chemotherapy given with radiation, can cause severe side effects, we are testing durvalumab given with radiation and without chemotherapy to learn if it is as good or better than the usual approach. The usual approach is defined as care most people get for non-small cell lung cancer.

What is the usual approach to my cancer?

The usual approach for patients who are not in a study is treatment with chemotherapy and radiation followed by immunotherapy. The immunotherapy commonly given after radiation and chemotherapy is durvalumab. There are several chemotherapy drugs approved by the Food and Drug Administration (FDA) that are commonly used with the radiation. Durvalumab is FDA approved for treating stage III non-small cell lung cancer after completing chemotherapy and radiation. It is not FDA approved for use at the same time as radiation, which is what we are studying in this trial. These treatments can reduce cancer symptoms and may stop the tumor from growing for a few months or longer.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will receive durvalumab and radiation. You will receive radiation for either three weeks or for six weeks (both timeframes deliver the same total dose of radiation). You will receive durvalumab starting two weeks before radiation for up to one year.

After you finish your study treatment, your doctor will continue to follow your condition for another year (for a total of two years of participation in this study) and watch you for side effects. After this time, your treating physician will discuss usual care options and follow up for your cancer.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks
We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that durvalumab combined with radiation alone (no chemotherapy drugs) may not be as good as the usual approach for your cancer.

There is also a risk that you could have side effects from the durvalumab or the radiation. These side effects may be worse and may be different than side affects you would get with the usual approach for your cancer.

Some of the most common side effects of radiation that the study doctors know about are:
- Lung inflammation and scarring
- Esophageal irritation
- Fatigue

Some of the most common side effects of durvalumab that the study doctors know about are:
- Itching, rash
- There may be some risks that the study doctors do not yet know about.

Benefits
It may be possible that adding durvalumab to radiation can delay the time until your disease progresses for the same or longer than the usual approach of chemotherapy and radiation. It is also possible that this treatment approach (immunotherapy plus radiation instead of chemotherapy plus radiation) can have less side effects compared to the usual approach alone; however, we do not know if this will happen. The study may help the study doctors learn things that may help other people with lung cancer in the future.

If I decide to take part in this study, can I stop later?
Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible because it is important that you stop safely and only your doctor can help you make this decision. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your 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.

Are there other reasons why I might stop being in the study?
Yes. The study doctor may take you off the study or discontinue study treatment if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsors, National Cancer Institute and NRG Oncology. The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to test the safety of adding durvalumab to two different radiation therapy schedules. We want to find out what effects durvalumab plus radiation has on the time, if any, until cancer gets worse. There will be about 24 people taking part in this study.

What are the study groups? (25-NOV-2019)

Everyone taking part in this study will get the same dose of durvalumab and the same total dose of radiation. But one group will get the total dose of radiation over a shorter timeframe, three weeks, and the other group will get the total dose of radiation over the usual timeframe, six weeks.

Group 1: The first six people taking part in this study will get durvalumab intravenously (through a vein in the arm) every four weeks beginning two weeks before radiation. Radiation will be given for three weeks and durvalumab will be given for one year or until you have intolerable or serious side effects or your cancer gets worse, whichever comes first.

Group 2: The next six people who take part in the study will get durvalumab intravenously (through a vein in the arm) every four weeks beginning two weeks before radiation. Radiation will be given over six weeks and durvalumab will be given for one year or until you have intolerable or serious side effects or your cancer gets worse, whichever comes first.

The study doctor will watch each group carefully for serious side effects and determine if one or both of the groups is safe. The next participants who join the study will receive the treatment considered safe. If only Group 1 treatment is considered safe, then the rest of the study participants will receive durvalumab) plus a shorter timeframe (three weeks) of radiation (called Group 3). If only Group 2 treatment is considered safe, then the rest of the study participants will receive durvalumab plus six weeks of radiation (called Group 4).

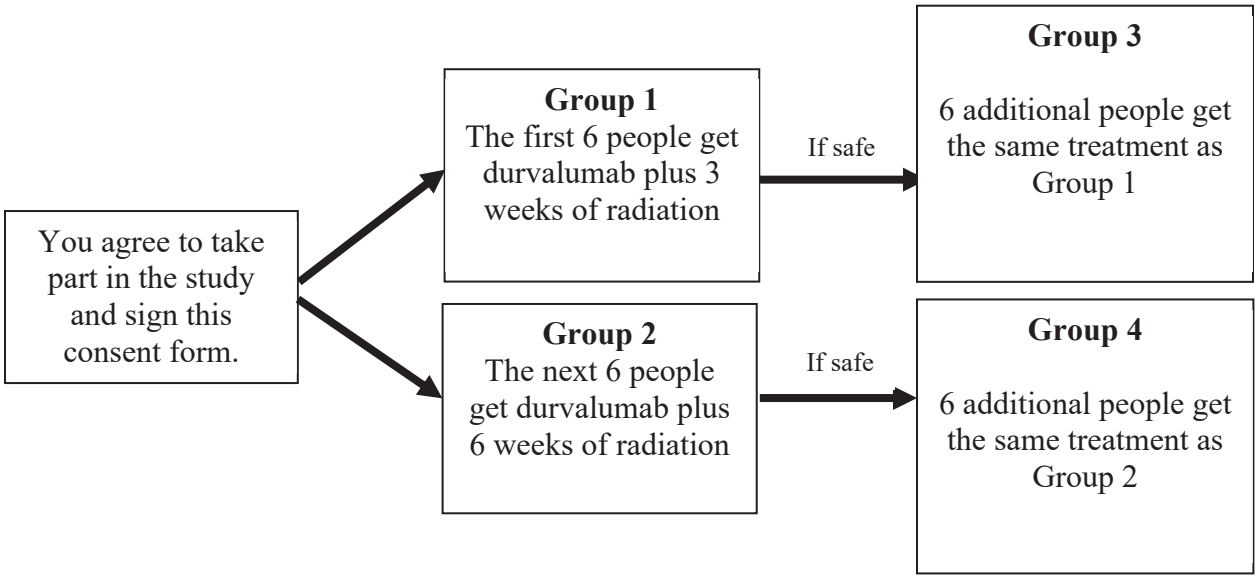
Group 3: same treatment as Group 1 above.

Group 4: same treatment as Group 2 above.

If Group 1 and Group 2 are considered safe, then a computer will assign participants to either treatment. This process is called "randomization." It means that your doctor will not choose and you cannot choose which study group you are in. You will be put into either Group 3 or Group 4 by chance.

If both Groups 1 and 2 are safe (there are no serious side effects of the drug or the radiation), participants will be randomized to either Group 3 or 4 for a total of 9 participants in each group.

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.



What exams, tests, and procedures are involved in this study? (25-NOV-2019)

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are tests that will be done for research purposes only.

Blood Sample

A blood sample will be collected for research purposes only at the following time points:

- Before you begin durvalumab treatment;
- During treatment after you've started radiation therapy (on Days 15 and 30);
- At 3, 6 and 12 months after you start durvalumab.

About 4 tablespoons of blood will be collected from a vein in your arm. Researchers will study cells in your blood that carry components from your primary tumor, called Circulating Tumor Cells (CTCs). Researchers want to learn how the study treatment affects the CTCs and if examining CTCs helps to know if the cancer is spreading (metastasis).

Researchers also will study cells in your blood for other components (including white blood cells, immune proteins called "antibodies", and circulating tumor DNA or "ctDNA") to learn more about how your cells react to the study treatment.

Your privacy is very important and the researchers will make every effort to protect it.

What risks can I expect from taking part in this study? (25-NOV-2019)

General Risks

If you choose to take part in this study, there is a risk that the MEDI4736 (durvalumab) plus radiation may not be as good as the usual approach for your cancer or condition at shrinking or stabilizing your cancer. There is also a risk that the durvalumab plus radiation treatment may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer and preventing it from coming back.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The treatments used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for three months after the last dose of durvalumab.

To be part of this study, your cancer must make high levels of a protein called PD-L1. A nurse or doctor will take some of the tumor tissue and perform a test that tells us if your cancer has the protein and if so, how much of it. Although this test is FDA approved, there is a risk that the test results may be wrong. If the test results are wrong, you may be included in this study even though it may not offer the best treatment option for you. Or, you may not be included in this study even though it may offer a good treatment option for you.

This study also uses a sample of your blood for research purposes only. The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.

Genetic Testing Risks

These tests described above are genetic studies that may identify changes in the genes in your body's cells, specifically in the cancer cells. Your genes carry information about you and your

family, from the color of your eyes to health conditions for which you may be at risk, such as certain kinds of cancer.

Finding these changes would not affect your treatment in this study. However, they could affect your health in other ways. The genetic studies are for research purposes only and may help scientists discover new ways to help people who have your type of cancer. The results of these studies will not be discussed with you or your study doctor.

Side Effect Risks
The MEDI4736 (durvalumab) and radiation 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 test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study treatment.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may delay giving the MEDI4736 (durvalumab) to try to reduce side effects.

Drug Risks
The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects of MEDI4736 (durvalumab)
Risk Profile for MEDI4736 (durvalumab) (CAEPR Version 2.4, April 17, 2019)

COMMON, SOME MAY BE SERIOUS
In 100 people receiving MEDI4736 (durvalumab), more than 20 and up to 100 may have:
• Cough

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving MEDI4736 (durvalumab), from 4 to 20 may have:

- Pain in the muscles, joints
- Diarrhea, nausea, vomiting
- Swelling of the body
- Tiredness, fever
- Infections. Infections can be severe and involve jaws and fatty tissues
- Loss of appetite
- Painful urination
- Shortness of breath
- Change in voice
- Increased sweating

MEDI4736 (durvalumab) 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:

- Hormone gland problems (especially the thyroid, pituitary and adrenal glands). Signs and symptoms may include: headaches, extreme tiredness or changes in mood or behavior; decreased sex drive; weight loss or weight gain; excessive thirst or urine; dizziness or fainting
- 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
- Lung problems (including pneumonitis), symptoms may include: new or worsening cough, chest pain, shortness of breath
- Skin: itching; rash; patches of light skin color

RARE, AND SERIOUS

In 100 people receiving MEDI4736 (durvalumab), 3 or fewer may have:

- Reaction during or after infusion which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

MEDI4736 (durvalumab) 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:

- Damage to blood cells that may cause bruises and bleeding
- Blood clots in small blood vessels, which may cause kidney failure, fever, and confusion
- Heart problems including heart failure. Symptoms and signs of heart problems may include: shortness of breath, swelling of the ankle and body or abnormal heartbeat
- A condition with high blood sugar (diabetes) which leads to tiredness, frequent urination or excessive thirst which may require treatment with insulin
- Swelling and redness of the eye
- Intestinal problems (colitis) that can rarely lead to tears or holes in your intestine. Signs and symptoms may include: diarrhea or increase in bowel movements, belly pain, bloody or dark, tarry, sticky stools
- Damage to the pancreas which may cause belly pain and hospitalization
- Problem of the muscle (myositis), which can cause muscle pain and severe muscle weakness sometimes with dark urine
- Swelling of the brain, which may cause headache, blurred vision, stiff neck, and/or confusion
- Problem of the nervous system that can cause weakness and paralysis, which may include: numbness, tingling of hands and feet, and may also cause problems with breathing
- Kidney problems, including kidney failure requiring dialysis. Signs of kidney problems may include: decrease in the amount of urine, blood in your urine, ankle swelling
- Severe skin reactions with blisters and peeling which can involve mouth and other parts of the body

Additional Drug Risks
The study drug could interact with other drugs.

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

Possible Side Effects of Lung Radiation

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

COMMON, SOME MAY BE SERIOUS In 100 people receiving lung radiation, more than 20 and up to 100 may have:
• 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

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.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
  - all medications and supplements you are taking
  - any side effects
  - any doctors' visits or hospital stays outside of this study
  - if you have been or are currently in another research study.

For women: Do not get pregnant or breastfeed while taking part in this study. Women must use an adequate method of contraception to avoid pregnancy during the study and for three months after the last dose of study drug. **For men:** Do not father a baby while taking part in this study. Men must use an adequate method of contraception to avoid pregnancy for the duration of the study and three months after the last dose of study drug. **For all:** The radiation therapy and study drug therapy 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. Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within three months after your last dose of study drug.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your cancer. This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- the cost of the radiation therapy.
- the costs of getting the durvalumab ready and giving it to you.
- your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

You and/or your insurance provider will not have to pay for the study drug, exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- Submission of tumor tissue and blood for research.
- Study drug, durvalumab.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

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, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and 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 look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsors, NRG Oncology and the National Cancer Institute (NCI) and any drug companies supporting the study
- The IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.
- Imaging and Radiation Oncology Core (IROC).

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

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.

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, and email address if appropriate).*

For questions about your rights while in this study, call the _____ (*insert name of organization or center*) Institutional Review Board at _____ *(insert telephone number).*

Optional studies that you can choose to take part in (25-NOV-2019)

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. The optional study will not benefit your health. The researchers leading this optional study hope the results will help other people with your cancer in the future. The results can be requested by your study doctor upon request.

Taking part in this optional study is your choice. You can still take part in the main study even if you say "no" to this study. There is no penalty for saying "no." You and your insurance company will not be billed for this optional study. If you sign up for, but cannot complete this study for any reason, you can still take part in the main study.

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

Optional sample collections for known laboratory studies and storage for possible future studies (03-AUG-2020)

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Known future studies

If you choose to take part in this optional study, researchers will collect any tissue you have left from your original biopsy, to confirm the level of PD-L1 in your cancer cells. The results can be provided by your study doctor upon request.

Unknown future studies

If you choose to take part in this optional study, any tissue leftover after the known future study is performed will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is being run by NRG Oncology and is supported by the NCI. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what research may be done in the future using your tissue samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic

changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes. If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

What is involved in this optional sample collection?
If you agree to take part, here is what will happen next:

1. If there is sufficient tissue leftover from your biopsy, a sample from that tissue that was collected at the time of your biopsy will be sent to the biobank.
2. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?
Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.

4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?
You will not benefit from taking part.

Are there any costs or payments to this optional sample collection?
There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?
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 biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?
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 below to show if you would or would not like to take part in each optional study:

Samples for known future studies:
I agree that my samples and related health information may be used for the laboratory study described above.

YES NO

Samples for unknown future studies:
I agree that my samples and related health information may be used for the laboratory study described above.

YES NO

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor 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.

My signature agreeing to take part in the 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 and dated copy of this form. I agree to take part in the main study.

Participant's signature_____

Date of signature_____

Signature of person(s) conducting the informed consent discussion_____

Date of signature_____