**Study Title for Study Participants: Testing the addition of the antibody, atezolizumab, to chemotherapy with liposomal doxorubicin and bevacizumab in recurrent ovarian cancer**

**Official Study Title for Internet Search on http://www.ClinicalTrials.gov:**
**NRG-GY009:** A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin, CTEP-Supplied Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin and CTEP-Supplied Bevacizumab in Platinum Resistant Ovarian Cancer

This study is being carried out under the sponsorship of NRG Oncology, an organization dedicated to clinical research in the field of gynecologic cancer. NRG Oncology is funded by the Federal Government through the National Cancer Institute (NCI).

## What is the usual approach to my ovarian cancer?

You are being asked to take part in this study because you have ovarian cancer, fallopian tube cancer or primary peritoneal cancer which has grown or has recurred. Usual approaches for your type of cancer include pegylated liposomal doxorubicin (liposomal doxorubicin) which is a form of doxorubicin hydrochloride contained inside liposomes (very tiny particles of fat) and the combination of liposomal doxorubicin and bevacizumab (an antiangiogenic agent which works by stopping the formation of blood vessels that bring oxygen and nutrients to tumors), chemotherapy drugs and /or biologic agents. Liposomal doxorubicin is a chemotherapy drug. Sometimes, combinations of these are used and your doctor can explain which may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for several months or more. Bevacizumab and liposomal doxorubicin are FDA approved to treat recurrent platinum-resistant ovarian cancer.

## 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 another treatment, such as 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 study is to compare any good and bad effects of adding Atezolizumab to the usual chemotherapy (liposomal doxorubicin) and to the usual chemotherapy with liposomal

doxorubicin and bevacizumab. Atezolizumab is a PD-L1 inhibitor that may allow the immune system to recognize and destroy tumor cells. It is an experimental medication (not approved by the FDA). The addition of Atezolizumab to the usual chemotherapy with liposomal doxorubicin and bevacizumab could shrink your cancer but it could also cause side effects. This study will allow the researchers to know whether the different approach is better, the same, or worse than the usual approach. To be better, the study drugs should increase life by six months or more compared to the usual approach. There will be about 444 people taking part in this study in total.

The purpose of this study is to test three things:

(1) Compare any good and bad effects of adding atezolizumab to the usual chemotherapy (liposomal doxorubicin and atezolizumab) to using the usual chemotherapy with bevacizumab (liposomal doxorubicin and bevacizumab). Note: this question has been answered and Group 1 (liposomal doxorubicin and atezolizumab) will not enroll any additional patients as of February 9, 2021.

(2) Compare any good and bad effects of adding atezolizumab to the usual chemotherapy with bevacizumab (liposomal doxorubicin and bevacizumab plus atezolizumab) to using the usual chemotherapy with bevacizumab (liposomal doxorubicin and bevacizumab).

In February 2021, the study was changed to stop accrual to one of the study groups (Group 1 patients received the study drugs liposomal doxorubicin (PLD] and atezolizumab) because a planned study review showed that this treatment was not likely to demonstrate better survival than the standard of care (PLD and bevacizumab) by the end of the study. The Group 1 treatment was not shown to be worse than the standard of care, and there were no notable additional risks.

Another purpose of this study is for researchers to learn if a biomarker test is helpful to decide whether or not a patient's tumor has certain characteristics and will respond to study drug. Tissue from your surgery will be used for the biomarker test. Researchers do not know if using the biomarker test is better, the same, or worse than if you enrolled in this study without using the biomarker test.

## What are the study groups?

A computer will by chance assign patients to one of the treatment groups in the study. This is called randomization. This is done by chance because no one knows if one treatment is better or worse than the other. You will have equal chance of being in study Group 2 or Group 3.

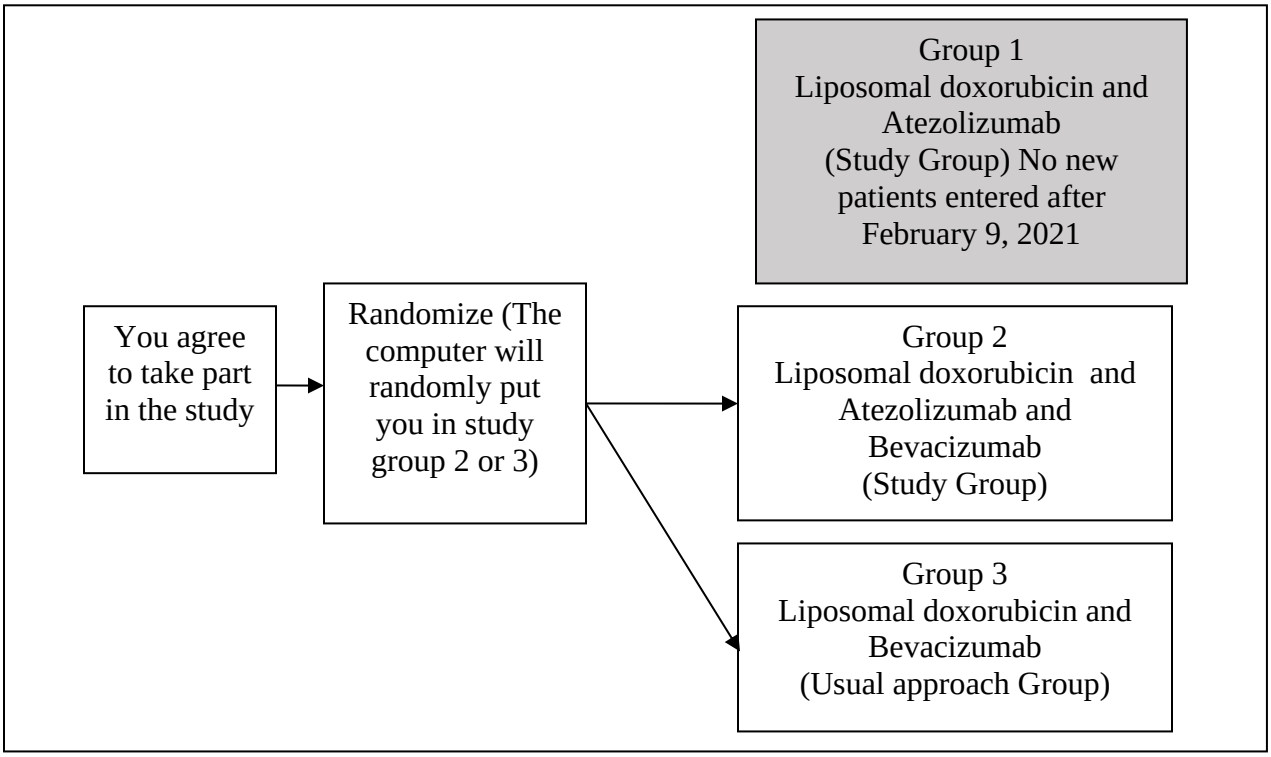
This study has three study groups.

- Group 1 is getting an experimental chemotherapy treatment (liposomal doxorubicin and atezolizumab) Note that this Group is no longer accruing new patients as of February 9, 2021, but the patients entered prior to that date are still part of the study.
- Group 2 will get an experimental chemotherapy treatment (liposomal doxorubicin and bevacizumab plus atezolizumab)

- Group 3 will get a usual chemotherapy treatment for this type of cancer (liposomal doxorubicin and bevacizumab)

The liposomal doxorubicin will be given into your vein over approximately 60 minutes. The bevacizumab will be given into your vein over approximately 90 minutes initially, then faster at later visits if administration goes smoothly at the slower rates. The atezolizumab will be given into your vein over approximately 60 minutes initially, then faster at later visits if administration goes smoothly at the slower rates. **(10/16/2017)**

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.




Treatment will be given on days 1 and 15 of each 28-day period. This period of time is called a cycle, which is a regular schedule of treatment with periods of rest in between.

If you join this study, you will not be able to receive a live, attenuated vaccine (a weakened form of a live virus) for 4 weeks leading up to treatment, during the study, and up to 5 months after the last dose of atezolizumab. Examples include vaccines for measles, mumps and rubella (MMR) and chickenpox (varicella).

## How long will I be in this study?

You will receive the study drugs for as long as you continue to benefit and as long as your doctors think it is safe to keep you on therapy. You will be asked to complete the quality of life

questionnaires for up to two years after you finish treatment. After you finish treatment, your doctor will continue to watch you for side effects and follow your condition, during clinic visits or by phone if you are unable to visit the clinic, every three months for the first two years and then every six months for the next three years.

## What extra tests and procedures will I have if I take part in this study? **(10/16/2017)**

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some exams, tests and procedures that may not be needed with the usual approach, but are needed more frequently if you take part in this study. The purpose of these procedures is to ensure your safety. We will use them to carefully monitor the effects of the study treatment, including preventing and managing side effects.

Below is a list of exams, tests, and procedures that are needed to monitor patient safety for the study agents in this study:

- Thyroid testing will be done every cycle to monitor levels of your thyroid hormone that may have changes from the treatment.
- Echocardiograms of the heart may be done every other cycle to check for any changes in your heart that may be a side effect from treatment.

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

Prior to beginning treatment and during the course of this study you will be asked to answer questions to assess your well-being. These questionnaires are called “quality of life” or “patient-reported outcomes” (PRO) questionnaires. Researchers will use this information to understand how the study treatment affects your quality of life and how it differs between different types of treatment.

You will be asked to fill out this form at up to 12 different times:

Every 8 weeks for the first year:

- Before you begin treatment
- At approximately 8-9 weeks after starting treatment
- At approximately 16-18 weeks after starting treatment
- At approximately 24-26 weeks after starting treatment
- At approximately 32 weeks after starting treatment
- At approximately 40 weeks after starting treatment
- At approximately 48 weeks after starting treatment

Every 12 weeks for the second year:

- At approximately 13 months after starting treatment
- At approximately 16 months after starting treatment
- At approximately 19 months after starting treatment
- At approximately 22 months after starting treatment
- At approximately 2 years after starting treatment

Each form will take about 10 minutes to complete. You may feel uncomfortable answering some of the questions, and you can skip any you do not want to answer.

A sample of the tissue that was collected at the time of your surgery or biopsy will be used for this study. This sample is required in order for you to take part in this study because the research on the sample is an important part of the study.

Any of this sample that is left-over after completion of this research will be stored for biobanking. This will be discussed in the section on optional studies.

Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information.

Your test results will not be given to you or your doctor or be put in your health record.

Neither you nor your health care plan/insurance carrier will be billed for the collection of the tissue that will be used for this study.

## What possible risks can I expect from taking part in this study? **(17-MAY-2021)**

If you choose to take part in this study, there is a risk that the study drugs may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

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 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 heart function 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 study drug(s)/study approach.

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, and some may never go away.
- Some side effects may make it hard for you to have children.
- 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.
- The study doctor will work with you to treat your 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 that researchers 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.

**ALL STUDY GROUPS -** Possible Side Effects of Pegylated Liposomal Doxorubicin (liposomal doxorubicin)

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving liposomal doxorubicin, more than 20 and up to 100 may have: |
|---|
| • Rash<br>• Redness, pain or peeling of palms and soles<br>• Vomiting, nausea, constipation or diarrhea<br>• Sores in mouth which may cause difficulty swallowing<br>• Weakness, tiredness<br>• Infection, especially when white blood cell count is low<br>• Anemia which may require blood transfusions<br>• Bruising, bleeding<br>• Fever |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving liposomal doxorubicin, from 4 to 20 may have: |
|---|
| • Hair loss<br>• Heart attack or failure which may cause chest pain, shortness of breath, swelling of ankles, cough<br>• Swelling and redness at the site of the medication injection<br>• Loss of appetite<br>• Blockage of the stomach<br>• Headache<br>• Dry eye |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving liposomal doxorubicin, from 4 to 20 may have: |
|---|
| • Reaction during or following infusion of the drug |

| **RARE, AND SERIOUS**<br>In 100 people receiving liposomal doxorubicin, 3 or fewer may have: |
|---|
| • Hepatitis which may cause yellow eyes and skin<br>• Severe blood infection<br>• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat<br>• Cancer of bone marrow caused by chemotherapy |

**GROUPS 2 and 3 -** Possible Side Effects of Bevacizumab: **(09/13/2018)**

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving bevacizumab (rhuMAb VEGF), more than 20 and up to 100 may have: |
|---|
| • High blood pressure which may cause headaches, dizziness, blurred vision |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving bevacizumab (rhuMAb VEGF), from 4 to 20 may have: |
|---|
| • Anemia which may require blood transfusion<br>• Low white cell count that may increase the risk of infection<br>• Infection, including collection of pus in the belly or rectum<br>• Abnormal heartbeat which may cause palpitations or fainting<br>• Pain in the belly, rectum, chest, joints, muscles, or tumor<br>• Low appetite, constipation, diarrhea, heartburn, nausea, vomiting, or dehydration<br>• Bleeding from multiple sites including the vagina or nose<br>• Internal bleeding which may cause black tarry stool, blood in vomit, coughing up blood, or blood in urine<br>• Blockage of internal organs which may cause vomiting or inability to pass stool<br>• Sores in the mouth<br>• Allergic reaction during or after infusion of bevacizumab which may cause fever, chills, rash, itching, hives, low blood pressure, wheezing, shortness of breath, swelling of the face or throat<br>• Delay in healing of wounds or spontaneous opening of wounds<br>• Weight loss, tiredness, or dizziness<br>• Muscle weakness<br>• Damage to the jawbone which may cause loss of teeth<br>• Headache<br>• Numbness, tingling, or pain in the fingers or toes<br>• Hoarseness, stuffy nose, or cough<br>• Dry skin<br>• Swelling and redness of the skin<br>• Blood clot in limbs or lungs which may cause swelling, pain, shortness of breath<br>• Leakage of protein in the urine, which can rarely lead to damage to the kidney |

| **RARE, AND SERIOUS**<br>In 100 people receiving bevacizumab (rhuMAb VEGF), 3 or fewer may have: |
|---|
| • Clots in the arteries, causing stroke (which may cause paralysis or weakness) or heart attack (which may cause chest pain or shortness of breath). This risk is significantly increased in patients who are elderly or with history of diabetes<br>• Heart failure which may cause shortness of breath, swelling of ankles, and tiredness<br>• Bowel perforation (a tear in the bowel) that can cause pain or bleeding and require surgery to repair<br>• A tear or hole (fistula) in internal organs such as the nose, throat, lungs, esophagus, rectum, or vagina. These conditions may cause serious infections or bleeding and require surgery to repair<br>• Sores in the throat<br>• Flesh-eating bacteria syndrome, an infection in the deep layers of skin<br>• Damage to organs (bone, lungs, others) which may cause loss of motion<br>• Bleeding in the tumor, brain, belly, or lungs which may cause confusion, blood in stool or coughing up blood<br>• Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome)<br>• Kidney damage which may require dialysis<br>• Redness, pain or peeling of palms and soles |

**Additional Notes on Possible Side Effects for Bevacizumab:**

- Risk in children or adolescents: abnormal bone changes which may interfere with growth.
- Risk in pre-menopausal women: more likely to develop menopause when taking bevacizumab.

**GROUPS 1 and 2 -** Possible Side Effects of Atezolizumab (MPDL3280A): **(06/29/2017) (09/13/2018) (17-MAY-2021)**

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving atezolizumab (MPDL3280A), more than 20 and up to 100 may have: |
|---|
| • Tiredness<br>• Infection |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving atezolizumab (MPDL3280A), from 4 to 20 may have: |
|---|
| • Anemia which may require blood transfusion<br>• Diarrhea, nausea, vomiting<br>• Difficulty swallowing<br>• Fever<br>• Flu-like symptoms including body aches<br>• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat<br>• Reaction during or following a drug infusion which may cause fever, chills, rash |

- Loss of appetite
- Pain in back
- Cough, shortness of breath, stuffy nose
- Itching, acne, rash

Atezolizumab (MPDL3280A) 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, 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.
- Pain in belly
- Pain or swelling of the joints
- Rash that develops on skin, nails, scalp and inside of mouth or vagina that may be painful

**RARE, AND SERIOUS**

In 100 people receiving atezolizumab (MPDL3280A), 3 or fewer may have:

- Bruising, bleeding

Atezolizumab (MPDL3280A) 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.
- A condition with high blood sugar which leads to tiredness, frequent urination or excessive thirst.
- Swelling and redness of the eye
- 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.
- 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.
- Swelling of the brain (meningitis/encephalitis), which may cause: headache, confusion, sleepiness, seizures, and stiff neck.
- Problem of the muscle, including swelling, which can cause muscle pain and severe muscle weakness sometimes with dark urine.
- Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs.

- 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.
- Lung problems (pneumonitis and pleural effusion). Symptoms may include: new or worsening cough, chest pain, shortness of breath.
- Skin: blisters on the skin, including inside the mouth (can be severe), rash with blisters, skin rash developing 1-8 weeks after a drug is given, which may be accompanied by fever, lymph node swelling and organ failure.

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 or breast feed while in this study or for 5 months after the last dose. The drugs used in this study could be very damaging to an unborn baby. If you could possibly become pregnant, you will need to use birth control during the study and for 6 months after finishing your treatment. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study and how long to use them. You should notify your health care team immediately if you think you have become pregnant while participating in this study.

## 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 Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

## What are the costs of taking part in this study?

The atezolizumab and bevacizumab will be supplied at no charge by NCI while you take part in this study. The cost of getting the atezolizumab and bevacizumab ready and giving them to you is not paid by the study sponsor so you or your insurance company may have to pay for this. It is possible that the atezolizumab or bevacizumab may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

The costs of the other study drug (liposomal doxorubicin) as well as the costs of getting this drugs ready and giving it to you, and any exams, tests, and procedures that may be needed to manage side effects and to monitor your safety will be billed to your health plan or insurance company.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while 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 be responsible for paying any deductibles, coinsurance, and co-payments as required under the terms of your insurance plan(s).

Costs related to the research sample collection will be covered by the study and will not be billed to you and/or your health plan/insurance company.

You will not be paid for taking part in this study. The institution receives payment that covers some but not all of the costs of the 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. Contact information for your study doctor is listed on the consent cover page. 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.

No funds have been set aside to compensate you in the event of injury.

## Who will see my medical information?

Your privacy is very important to us and the researchers 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. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information and/or information about your specimen(s) from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

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. Some of these organizations are:

- Montana Cancer Consortium
- The study sponsor, NCI-CTEP, NRG Oncology and any drug company supporting the study.
- The NRG Oncology Biospecimen Bank-Columbus (Biobank) and laboratories designated by NRG Oncology to perform testing as part of the study.
- 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 (FDA) and the National Cancer Institute (NCI) in the U.S., and similar ones if other countries are involved in the study.

## 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 information for your study doctor is listed on the consent cover page.

# 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 Biobanking for Possible Future Studies

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.

If you choose to take part in this study, the study doctor for the main study would like to collect blood for research on your immune system's response to your tumor and any affect the study drug has on this response.

## WHAT IS INVOLVED?

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

1) About two teaspoons of blood will be collected from a vein in your arm at two different times during the study.
2) Your sample and some related health information will be sent to a researcher for use in the study described above. Storing samples for future studies is called "biobanking." Remaining samples may be stored in the Biobank, along with samples from other people who take part. The samples will be kept until they are used up.
3) Qualified researchers can submit a request to use the materials stored in the Biobank. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also 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 stored 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. *(For non-US participants, please verify existence of such laws before including the following text.)* 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 sample(s) is 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 the 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, who will let the researchers know. Contact information for your study doctor is listed on the consent cover page. 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. Contact information for your study doctor is listed on the consent cover page.

**Please circle your answer** to show whether or not you would like to take part in each option:

**SAMPLES FOR THE LABORATORY STUDIES:**
I agree to have my specimen(s) collected and I agree that my specimen sample(s) and related information may be used for the laboratory study(ies) described above.
**NOTE: This question only applies to the optional specimen collection and research described in this additional studies section.**

YES NO

**SAMPLES FOR FUTURE RESEARCH STUDIES:**
**NOTE: These questions apply to both the optional specimen collection and research described in this additional studies section and any left-over specimens from the mandatory specimen collection included in the main study.**

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.

## My Signature Agreeing to Take Part in the Main Study **(03/19/2018)**

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 Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)
(Required for initial consent only)