Safety Run-in Research Study Informed Consent Document: for patients enrolled before August 8, 2023

Study Title for Participants: Testing the addition of the immune therapy drugs, tocilizumab and atezolizumab, to radiation therapy for recurrent glioblastoma.

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: NRG-BN010, A Safety Run-In and Phase II Study Evaluating the Efficacy, Safety, and Impact on the Tumor Microenvironment of the Combination of Tocilizumab, Atezolizumab, and Fractionated Stereotactic Radiotherapy in Recurrent Glioblastoma (NCT04729959)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. 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 a type of brain cancer called glioblastoma that has come back after receiving treatment.

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?

This study is being done to answer the following question:

Can we shrink or stabilize your brain cancer by adding immune therapy drugs to the usual radiation therapy?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your recurrent glioblastoma. The usual approach is defined as care most people get for recurrent glioblastoma.

What is the usual approach to my recurrent glioblastoma?

The usual approach for patients who are not in a study is treatment with surgery, radiation, or chemotherapy drugs. The only drug that is FDA-approved for recurrent glioblastoma is bevacizumab (Avastin®). Sometimes, combinations of these treatments are used. Your doctor can explain which treatment may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for a few months or longer. For patients who get the usual approach for this cancer, about 5 out of 100 are free of cancer after 5 years.

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?

You are being asked to participate in the initial dose-finding portion of this study (called the safety run-in phase). The purpose of this portion of the study is to determine the safe dose of the study drug, tocilizumab, with or without the study drug, atezolizumab, along with the usual radiation therapy treatment in patients with recurrent glioblastoma who are not candidates for surgery. The study drugs, tocilizumab and atezolizumab, are not approved by the Food and Drug Administration (FDA) for use in patients with brain cancer. There will be about 12 people taking part in this portion of the study. The safety of adding the study drugs to usual treatment will be evaluated by looking at the side effects experienced by patients in this part of the study.

If the addition of the study drugs to usual treatment is safe, a second portion of the study (phase II) will open to additional patients to find out if adding the study drugs to the usual treatment is effective at shrinking or stabilizing recurrent glioblastoma. Researchers will use some of the information obtained from the patients in the dose-finding portion to find this out.

If you decide to take part in this study, you will either get the study drug, tocilizumab, every 4 weeks for up to 2 years or the study drugs, tocilizumab and atezolizumab, every 4 weeks for up to 2 years. After the first dose of the study drug(s), you will receive the usual radiation therapy over 3 to 5 days.

After you finish your study treatment, your doctor and study team will watch you for side effects for the next 2 years. They will check at 1 month after you finish treatment and then every 3 to 6 months for 2 years. After that your participation in the study will be done.

What are the risks and benefits of taking part in this study? (04-OCT-2024)

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 the study drugs may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

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

Some of the most common side effects that the study doctors know about are:

- Tiredness
- Infection
- Nausea
- Decreased appetite
- Headache

The side effects of brain radiation may be increased because you have already had brain radiation.

There may be some risks that the study doctors do not yet know about.

Benefits

There is some evidence in animals that tocilizumab can shrink or stabilize cancer. There is some evidence in people with other types of cancer that adding atezolizumab to the usual approach can shrink or stabilize cancer for longer than the usual approach alone. However, we do not know if this will happen in people with your type of cancer and we do not know what tocilizumab dose is safe and if it can be given with atezolizumab along with the usual approach in people with your type of cancer. This study may help study doctors learn things that may help other people 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. It's important that you stop safely. 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 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.
- Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsors, National Cancer Institute and NRG Oncology, stop the study. 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 first part the study is to test the safety of tocilizumab at different doses and if it can be given with atezolizumab along with the usual radiation therapy. "Dose" is defined as the amount of drug you get, such as 4mg/kg, 8mg/kg, or 8mg/kg plus atezolizumab 1680mg."

We want to find out what effects the drug has on people with recurrent glioblastoma, if any. Tocilizumab has already been approved by the FDA to treat rheumatoid arthritis and atezolizumab has already been approved by the FDA to treat other cancers, but neither drug is approved by the FDA to treat recurrent glioblastoma.

There will be about 12 people taking part in this study.

What are the study groups?

Different people taking part in this study will get different doses of the study drug tocilizumab with or without atezolizumab along with radiation therapy.

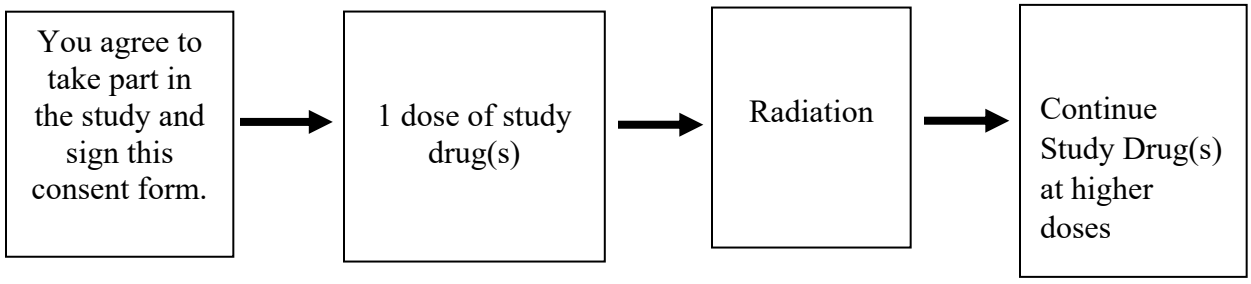
Dosing Schedule:

The study will test up to 3 treatment schedules called dose levels. For each dose level, the study drug or drugs are given through a vein in your arm every 4 weeks for up to two years. Radiation therapy is given 3 to 7 days after the first dose of study drug or drugs.

The first 3 people taking part in this study will get the starting dose of tocilizumab, which is the starting dose approved by the FDA for use in rheumatoid arthritis. If the drug along with radiation therapy does not cause serious side effects, the next group of 3 people in the study will get a higher dose of tocilizumab, which is also FDA-approved for treating rheumatoid arthritis. If the higher dose of tocilizumab is safe, the next group of 3 people will receive this dose of tocilizumab plus atezolizumab at the FDA approved dose used to treat other cancers. The study doctor will watch each group carefully as they increase the dose. If the combination is safe with radiation therapy then 3 more people will receive the treatment. If it is not safe, 3 more people will receive the dose of tocilizumab alone with radiation with manageable side effects and then the study is stopped.

You will not be able to get additional doses of the drugs. The drugs are not approved by the FDA for treatment of your disease.

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?

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.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- Blood counts done every 2 weeks for the first month, then monthly
- Thyroid testing done before the first dose of atezolizumab and then every two months (for participants receiving atezolizumab)

- A blood test for cholesterol and fat about 4 to 8 weeks after you start tocilizumab
- Physical exams done monthly

What risks can I expect from taking part in this study? (04-OCT-2024)

General Risks

If you choose to take part in this study, there is a risk that the study approach 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 tocilizumab and atezolizumab 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 90 days after your last dose of tocilizumab (for female participants) or 60 days after your last dose of tocilizumab (for male participants) or 150 days after the last dose of atezolizumab,if received (for both male and female participants).

Risks of Blood Draws

The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. Rarely, an infection can occur.

Side Effect Risks

The drugs 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 drugs.

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 adjust the study drugs to try to reduce side effects.

This study is looking at a combination of up to two study drugs plus radiation therapy used to treat this type of cancer. This different combination of drugs may increase your side effects or may cause new 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.

Risk Profile for Tocilizumab (Table Version Date: July 24, 2024)

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving tocilizumab (RO4877533), from 4 to 20 may have:
• Pain • Sores in the stomach • Sores in the mouth which may cause difficulty swallowing • Swelling of arms, legs • Swelling and redness at the site of the medication injection • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Infection, especially when white blood cell count is low • Bruising, bleeding • Weight gain • Dizziness, headache • Cough, shortness of breath • Itching, rash, hives • High blood pressure which may cause headaches, dizziness, blurred vision

RARE, AND SERIOUS In 100 people receiving tocilizumab (RO4877533), 3 or fewer may have:

- Swelling and redness of the eye
- A tear or hole in internal organs that may require surgery
- Liver damage which may cause yellowing of the eyes and skin
- Kidney stones
- Severe skin rash with blisters and peeling which can involve mouth and other parts of the body

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Risk Profile for Atezolizumab (MPDL3280A) (CAEPR Version 2.4, September 14, 2023)

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

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving atezolizumab (MPDL3280A), from 4 to 20 may have:

- Anemia which may require blood transfusion
- Diarrhea, nausea, vomiting
- Difficulty swallowing
- Fever
- Flu-like symptoms including body aches
- 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
- 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.
- Damage to organs in the body when the body produces too many white cells
- Swelling of the brain (meningitis/encephalitis), which may cause: headache, confusion, sleepiness, seizures, and stiff neck.
- Abnormal movement of the facial muscles
- Swelling of the spinal cord
- 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.

Additional Drug Risks

The study drug tocilizumab could interact with other drugs. Specifically, tocilizumab could result in you needing to have your dose of certain medications adjusted. Two of the most important are warfarin and theophylline. Certain other drugs are safe to take with tocilizumab but need to be administered with caution and monitored carefully because tocilizumab could increase or decrease their effectiveness (common examples include oral contraceptives, lovastatin, and atorvastatin). Your study doctor will give you a wallet card that describes the drugs in the

clinical trial. Share this information with your family members, caregivers, other health care providers, and pharmacists.

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 Brain Radiation

COMMON, SOME MAY BE SERIOUS In 100 people receiving brain radiation, more than 20 and up to 100 may have:
• Scalp redness or soreness • Hair loss, which may be temporary or permanent • Temporary hearing decrease or loss • Tiredness • Temporary increase of brain tumor symptoms such as headaches, seizures, or weakness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving brain radiation, from 4 to 20 may have:
• Changes in thinking patterns, decrease ability to concentrate, behavior changes, difficulty walking, difficulty talking • Permanent hearing decrease or loss • Cataracts • Nausea, Vomiting • Dry mouth, changes in taste • Loss of appetite • Abnormal hormone levels related to changes to the pituitary gland may cause symptoms such as low blood sugar, low blood pressure, and fatigue which may require hormone replacement.

RARE, AND SERIOUS In 100 people receiving brain radiation, 3 or fewer may have:
• Damage to the brain • Swelling of the brain • Blurred vision with chance of blindness • A new cancer resulting from treatment of earlier cancer

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.
- You must not receive a live vaccine within 4 weeks of starting study treatment, at any time during the study, and for up to 5 months after the last dose of study drug.

For women: Do not get pregnant or breastfeed while taking part in this study. Tell your study doctor right away if you think that you have become pregnant during the study or within 90 days after your last dose of tocilizumab. **For men:** Do not father a baby while taking part in this study. Tell your study doctor right away if you think that your partner has become pregnant during the study or within 60 days after your last dose of tocilizumab. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 150 days of your last dose of atezolizumab.

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 costs of getting the tocilizumab and atezolizumab (if you receive it) ready and giving it to you.
- the radiation therapy
- 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.

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 or your insurance provider will not have to pay for the tocilizumab and atezolizumab (if you receive it) while you take part in this study.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

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 or receive copies of some of the information in 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, sponsor, NRG Oncology, and any company supporting the study now or in the future. This would include any organization helping the company with the study.
- The NCI Central 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, including the Cancer Trials Support Unit (CTSU).
- The NCI's National Clinical Trials Network and the groups it works with to conduct research including the Imaging and Radiation Oncology Core (IROC).

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now 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 of the 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

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. These optional studies will not benefit your health. 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.

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 storage for possible future studies

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.

Unknown future studies

If you choose to take part in this optional study, blood samples and a sample of tumor tissue from your initial diagnosis 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 blood and 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. About 2-3 tablespoons of blood will be collected from a vein in your arm before you start treatment and once during treatment when you receive the second dose of study drug. A sample from the tumor tissue that was collected at the time of your initial diagnosis will be sent to the biobank.
2. Your samples 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?

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- 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.

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.

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 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 unknown future studies:
I agree that my samples and related health information may be kept in a biobank for use in future health research.

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. I also agree to take part in any additional studies where I circled "yes".

Participant's signature

Date of signature

Signature of person(s) conducting the informed consent discussion

Date of signature