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Research Study Informed Consent Document

Study Title for Participants: Testing the addition of an anti-cancer drug, vorasidenib, to the usual treatment, temozolomide, after radiation therapy for advanced brain cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Protocol A072301, Phase III trial of radiotherapy followed by adjuvant temozolomide in combination with the IDH inhibitor vorasidenib vs. placebo in IDH-mutated newly-diagnosed grade 3 astrocytomas (NCT07215910)

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child; "we" means the doctors and other staff.

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 newly diagnosed advanced brain 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.

This study is conducted by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute. The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

Why is this study being done?

This study is being done to answer the following question:

Can we decrease the chance of your brain cancer growing or returning by adding a second drug to the usual drug after 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 advanced brain cancer. The usual approach is defined as care most people get for advanced brain cancer.

What is the usual approach to my advanced brain cancer?

The usual approach for patients who are not in a study is treatment with surgery, radiation therapy, or drugs. There are several drugs approved by the Food and Drug Administration (FDA) that are commonly used. 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.

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 get the usual radiation therapy, and then you will either get the study drug, vorasidenib, and the usual drug, temozolomide, in combination for one year followed by the study drug, vorasidenib, alone until your disease gets worse or the side effects become too severe, or you will get a placebo and the usual drug, temozolomide, in combination for one year followed by placebo alone until your disease gets worse or the side effects become too severe.

After you finish your study treatment, your doctor will continue to follow your condition and watch you for side effects for 10 years from the day you decided to take part in this study. If you stop study treatment before your cancer gets worse, these follow-up visits will occur in clinic every 3 months for the first 2 years, then every 4 months for the next 2 years, and then every 6 months until your cancer gets worse; if you stop study treatment because your cancer gets worse, then your doctor will follow up with you either in clinic or by phone at least every 6 months for up to 10 years. This means that you will keep seeing your doctor or have contact by phone for 10 years after you start treatment.

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 the study approach 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 approach. 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:

- Headache
- Nausea
- Dizziness
- Tiredness

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

Benefits

There is evidence that the addition of the study drug, vorasidenib, to the usual drug, temozolomide, after radiation therapy is effective in shrinking or stabilizing your type of cancer. It is not possible to know now if the study approach will extend your time without your cancer growing compared to the usual approach. This study will help the study doctors learn things that will help 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. This may mean slowly stopping the study drugs so that there is not a sudden unsafe change, risk to your health, etc. 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.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (Alliance). 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 compare the usual treatment (radiation plus temozolomide alone) to using the study treatment (usual treatment plus the study drug, vorasidenib). The addition of the study drug, vorasidenib, to the usual treatment could shrink or stabilize your cancer. But, it could also cause side effects, which are described in the risks section below.

This study will help the study doctors find out if this different approach is better, the same, or worse than the usual approach. To decide if it is better, the study doctors will be looking to see if the study approach increases patients' time without their cancer growing compared to the usual approach.

The usual chemotherapy drug, temozolomide, is already approved by the FDA for use in other types of brain cancer. The study drug, vorasidenib, is already approved by the FDA for use in other types of brain cancer. There will be about 408 people taking part in this study.

What are the study groups?

This study has a screening step. The purpose of this step is to test your tumor tissue to find out if it has specific mutations. If it does and you meet all the study requirements, then we can assign you to treatment based on these changes. If we find that your tumor does not have the specific mutations that are needed for this study, then your doctor will discuss other options for your care. This screening test is not approved by the FDA for your type of cancer.

This study has 2 study groups. You will not be told which group you are in.

- **Group 1**

  If you are in this group, you will get the usual radiation therapy, followed by the usual drug used to treat this type of cancer, temozolomide, plus a placebo for 1 year, followed by a placebo alone until your disease gets worse or your doctor decides it is in your best interest to stop. A placebo is a pill that looks like the study drug, but contains no medication. You will get the usual drug and placebo as pills you take by mouth once a day. You will get the usual drug on the first through fifth day of each cycle (i.e. Day 1-Day 5). You will get the placebo on the first through twenty-eighth day of each cycle (i.e. Day 1-Day 28). Each cycle lasts 28 days.

  You also will keep a medication diary. This helps you keep track of when you take your pills. The study doctor will show you how to use this diary. Each time you visit the clinic, you must bring the medication diary, any remaining pills, and the pill bottle.

  There will be about 204 people in this group.

- **Group 2**

  If you are in this group, you will get the usual radiation therapy, followed by the usual drug used to treat this type of cancer, temozolomide, plus a study drug called vorasidenib, for 1 year, followed by the study drug, vorasidenib, alone until your disease gets worse or your doctor decides it is in your best interest to stop. You will get these drugs as pills you take by mouth once a day. You will get the usual drug on the first through fifth day of each cycle (i.e. Day 1-Day 5). You will get the study drug on the first through twenty-eighth day of each cycle (i.e. Day 1-Day 28). Each cycle lasts 28 days.

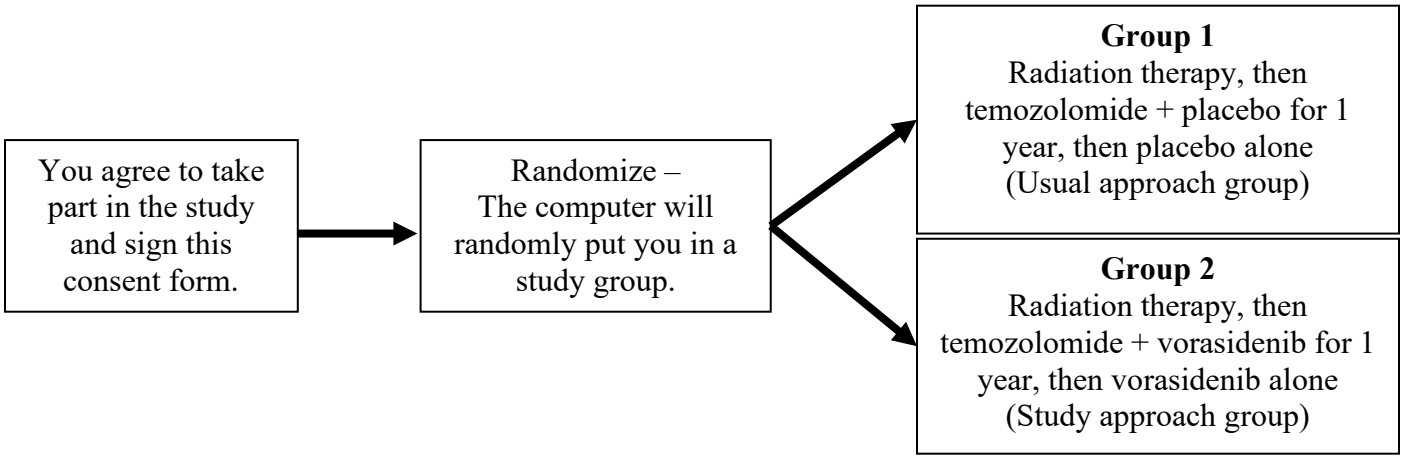
You also will keep a medication diary. This helps you keep track of when you take your pills. The study doctor will show you how to use this diary. Each time you visit the clinic, you must bring the medication diary, any remaining pills, and the pill bottle.

You will not be able to get additional doses of the drug. This drug is not approved by the FDA for treatment of your disease.

There will be about 204 people in this group.

We will use a computer to assign you to one of the study groups. 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 a group by chance. You will have an equal chance of being in Group 1 or Group 2.

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.

During study treatment, in addition to your doctor's usual follow-up of your condition, you will be asked to complete the following assessments:

- A medication diary where you will record the day, number of pills taken, and time of each dose of temozolomide and vorasidenib/placebo. You will be asked to bring the medication diary, any remaining pills, and the pill bottle to your clinic visits.

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

Your study doctor will need to use some of the tissue left over from your previous biopsy or surgery when you were diagnosed with cancer. This sample is a required part of the study. Part of this tumor tissue will be sent to the Alliance Laboratory at the Mayo Clinic, and it will be reviewed by a pathologist to confirm your diagnosis. The other part of this tumor tissue will be sent to the Alliance Laboratory at the Mayo Clinic, and it will be reviewed by a researcher to determine any changes in your tumor tissue. You and your study doctor will get the results of this testing.

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

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 study drug 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 3 months after you have completed the study.

This study will use a sample of your tissue. Generally, your hospital will keep some of your tissue. This tissue may be used to help treat your cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.

Genetic Testing Risks

As part of this study, we are also studying a genetic test. The test is designed to find out if your tumor has the genetic changes that are needed for this study. If it does, we will assign you to a study group based on the genetic changes in your tumor.

Because this genetic test is still being studied, 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.

Side Effect Risks

The radiation therapy and study drug 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 radiation therapy and study drug.

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 the usual drug used to treat this type of cancer plus a study drug. 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.

Study Group 1 and Group 2 – Possible side effects of Temozolomide are listed in the tables below. This drug is part of the usual approach for treating this type of cancer:

Possible Side Effects of Temozolomide
(Table Version Date: April 21, 2023)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Temozolomide, more than 20 and up to 100 may have:
• Headache, seizure • Constipation, nausea, vomiting, diarrhea, belly pain, loss of appetite • Trouble with memory • Difficulty sleeping • Muscle weakness, paralysis, difficulty walking • Dizziness • Tiredness • Hair loss

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Temozolomide, from 4 to 20 may have:
• Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may cause tiredness, or may require transfusions • Cough, shortness of breath • Sores in mouth, changes in taste, difficulty swallowing • Changes in vision • Pain in joints, back • In females: breast pain • Swelling of arms, legs

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Temozolomide, from 4 to 20 may have:
• Feeling of "pins and needles" in arms and legs • Loss of bladder control or frequent urination • Depression, worry, confusion • Fever • Weight gain • Rash, itching, dry skin

RARE, AND SERIOUS In 100 people receiving Temozolomide, 3 or fewer may have:
• Damage to the lungs which may cause shortness of breath or cough • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require blood transfusions • Liver damage which may cause yellowing of eyes and skin, swelling • A new cancer including leukemia resulting from treatment • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

Study Group 2 - In addition to side effects listed above, people who are in Group 2 may also have some side effects from vorasidenib. These side effects are listed below.

Possible Side Effects of Vorasidenib
(Table Version Date: December 06, 2024)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Vorasidenib, more than 20 and up to 100 may have:
• Headache • Dizziness • Tiredness • Nausea

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Vorasidenib, from 4 to 20 may have:
• Infection, especially when white blood cell count is low • Constipation • Diarrhea • Seizure • Pain in belly • Shortness of breath • Anemia which may require blood transfusion • Vomiting • Cough • Loss of appetite

RARE, AND SERIOUS In 100 people receiving Vorasidenib, 3 or fewer may have:
• Damage to the lungs which may cause shortness of breath or cough

RARE, AND SERIOUS In 100 people receiving Vorasidenib, 3 or fewer may have:
• Breathing problems in patients related to retinoic acid which may cause shortness of breath • Blockage of internal organs • A tear or hole in the bowels that may require surgery which may cause pain • Swelling of the spinal cord which may cause pain • Blood clot which may cause swelling, pain, shortness of breath

Additional Drug Risks

The study drug could interact with other drugs and food. Your study doctor may give you a clinical trial wallet card that lists the drug(s) you are on, be sure to keep it in your wallet. 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 Radiation Therapy

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, 20 to 100 may have:
• Reddening, tanning, or peeling of the skin • Mild pain • Hair loss • Tiredness • Diarrhea, nausea • Anemia, which may require transfusion • Infection, especially when white blood cell count is low

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, 4 to 20 may have:
• Thickening and numbness of the skin • Sores or ulcers on the skin or near the cancer location • Permanent hair loss • Bleeding from the skin • Sores in mouth which may cause difficulty swallowing

RARE, AND SERIOUS In 100 people receiving radiation therapy, 3 or fewer may have:
• Damage to internal organs • Abnormal opening in internal organs which may cause pain and bleeding

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.
- Write down in your medication diary when you take the study drug at home.

For women: Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 3 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 costs of getting the vorasidenib/placebo 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.

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 vorasidenib/placebo 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 date of birth, 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 and any company supporting the study or the study agent 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.
- The NCI's National Clinical Trials Network (NCTN) 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 research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

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 _____ at _____.

For questions about your rights while in this study, call the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at (888) 657-3711.

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

If you are an English, French, or Spanish speaker and choose to take part in this study, you will be asked to fill out a form with questions about your physical and emotional well-being. Researchers will use this information to learn more about how cancer and cancer treatment affects people.

Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

You will be asked to fill out this form at the following times:

- Before you start treatment
- 6 months after you start the study
- 12 months after you start the study, and then
- Every 12 months (i.e. 1 year) until 3 years after you start the study or until your cancer gets worse

The forms will take about 20 minutes to complete. The forms will ask about things like tiredness, diarrhea, etc. You don't have to answer any question that makes you feel uncomfortable.

Please circle your answer: I choose to take part in the quality of life study and will fill out these forms:

YES NO

Optional sample collections for known laboratory studies and/or 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, a sample of leftover tissue from your previous biopsy or surgery, blood samples, and a sample of tissue from any biopsies/surgeries should your cancer get worse will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is being run by the Alliance for Clinical Trials in Oncology and is supported by the NCI. 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/or 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 1.5 tablespoons of blood will be collected from a vein in your arm before you start treatment, on Day 1 of Cycle 4, and in the event your cancer gets worse. A sample from the tissue that was collected at the time of your previous biopsy or surgery will be sent to the biobank. A sample of tissue will be collected in the event your cancer gets worse.
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?

- 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. 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.

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 Cancer Research Consortium of West Michigan at (616) 391-1230, 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 Cancer Research Consortium of West Michigan at (616) 391-1230.

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 blood and tissue samples may be collected and that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

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

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