Research Study Informed Consent Document

Study Title for Participants: A study looking at targeted therapy according to tumor markers for people with brain metastases

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: A071701
Genomically-guided treatment trial in brain metastases **(NCT #03994796)**

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.

You are being asked to take part in this study because your tumor has a mutation for which a targeted drug has been developed that may or may not shrink your tumor.

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 anticancer therapies help to treat cancer that has spread to the brain?

The purpose of this study is to test good and bad effects of different drugs against metastatic brain tumors with altered genes. This trial is trying to see if tumor genetic testing would be helpful at guiding treatment in patients such as you. Researchers have looked at the DNA material (genes) that can be affected in brain metastases and have found several genes that are altered, or mutated. There are medications that target these genes.

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

What is the usual approach to my brain metastasis?

The usual approach for patients who are not in a study is FDA-approved treatment with radiation, surgery and in some cases medical therapy/chemotherapy. These treatments can reduce symptoms and may stop the tumor from growing for a few months or longer in some patients.

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 one of three targeted therapies depending on the genetic mutations in your tumor, until your disease gets worse or the side effects become too severe.

After you finish treatment, your doctor will continue to follow your condition with appointments and scans every 2-6 months (every 2 months for the first 2 years, then every 3 months for years 3-4, then every 6 months for year 5) until your disease gets worse and watch you for side effects. Should your disease get worse at any point while on this study, your doctor will check you by appointment or by phone every 6 months for up to 5 years after 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 drug may not be as good as radiation or other chemotherapy at shrinking your cancer.

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

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

- Fatigue
- Diarrhea
- Nausea
- Loss of appetite
- Ulcer, inflammation, pain, numbness, tingling or burning feeling in mouth

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

Benefits

These study drugs have stabilized different types of cancers in a limited number of people with cancer. It is unlikely that it will work in everyone with your cancer or help you live longer. This study may help the 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. 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 test the good and bad effects of the drugs called abemaciclib, paxalisib and entrectinib. These study drugs could shrink your cancer, but could also cause side effects, which are described in the risks section below. The study doctors hope to learn if the study drug will shrink the cancer the cancer by at least 30% compared to its present size.

Abemaciclib and entrectinib have already been approved by the FDA to treat other cancers. Paxalisib has not yet been FDA-approved to treat other cancers.

There will be about 150 people taking part in this study.

Another purpose of this study is for the study doctors to learn if a genetic test is helpful to decide which study group you will be in. Tumor tissue from a past surgery or biopsy was used for the test. The study doctors do not know if using the test is better, the same or worse than not using the test. There will be about 150 people taking part in this study.

What are the study groups?

This study has 3 study groups.

Group 1 - Abemaciclib

For patients who are found to have a genetic change in the CDK pathway, all will get the same study treatment, which is the medicine abemaciclib. If you are in the CDK pathway group, you will receive the abemaciclib until your tumor grows. Abemaciclib is an oral medication that you take twice per day for each 28-day cycle. Pills must be swallowed and cannot be crushed or broken before swallowing.

You also will keep a pill 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 pill diary, any remaining pills, and the pill bottle.

There will be about 69 people in this group.

Group 2 – Paxalisib

For patients who are found to have a genetic change in PI3K pathway, all will get the same study treatment, which is the medicine paxalisib. If you are in the PI3K group, you will receive the

paxalisib until your tumor grows. Paxalisib is an oral medication that you take once/day for each 28-day cycle. Pills must be swallowed and cannot be crushed or broken before swallowing.

You also will keep a pill 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 pill diary, any remaining pills, and the pill bottle.

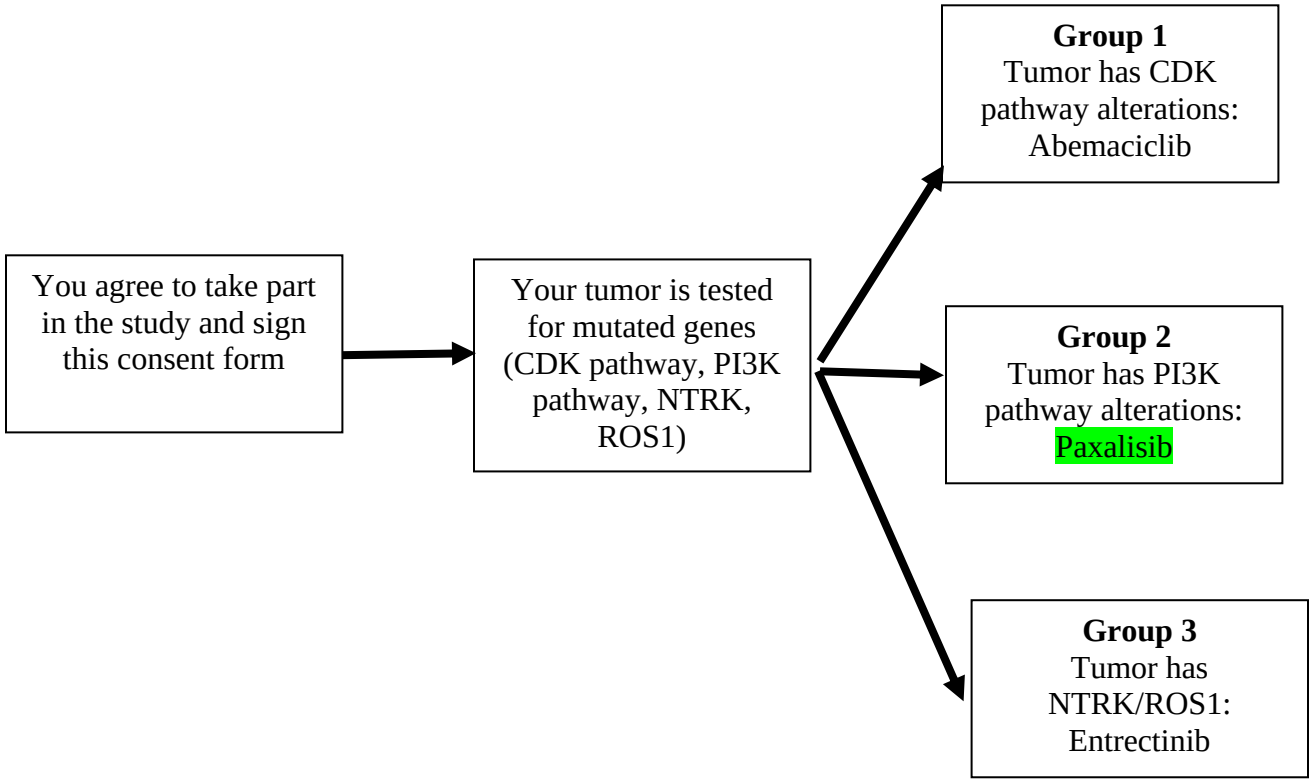
There will be about 69 people in this group.

Group 3 – Entrectinib

For patients who are found to have a genetic change in the genes called NTRK or ROS1, all will get the same study treatment, which is the medicine entrectinib. If you are in the NTRK/ROS1 group, you will receive the entrectinib until your tumor grows. Entrectinib is an oral medication that you take once/per day for each 28-day cycle. Pills must be swallowed and cannot be crushed or broken before swallowing.

You also will keep a pill 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 pill diary, any remaining pills, and the pill bottle.

There will be about 12 people in this group.



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:

Group 1 (Abemaciclib):

Daily during treatment:
A daily medication log where you will record the day, number of tablets taken, and the time of each dose of study treatment. You will be asked to bring the log (diary) with you to your clinic visits.

Group 2 (Paxalisib):

Prior to registration:

- Blood tests to measure your lipids
- EKG

Daily during treatment:
A daily medication log where you will record the day, number of tablets taken, and the time of each dose of study treatment. You will be asked to bring the log (diary) with you to your clinic visits.

Every 8 weeks while on treatment

- EKG

Every 16 weeks while on treatment:

- Blood tests to measure your lipids

Group 3 (Entrectinib):

Prior to registration:

- EKG

Daily during treatment:
A daily medication log where you will record the day, number of tablets taken, and the time of each dose of study treatment. You will be asked to bring the log (diary) with you to your clinic visits.

Day 1 and day 15 of the first treatment cycle:

- EKG

Every 4 weeks while on treatment:

- EKG

If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

You will be getting regular scans of your tumor that is part of your routine care. However, as part of your participation in this study, your scans will be submitted to a central image library. These scans will be saved so that researchers can look back at these scans after the study is over and use the images for additional research to better understand how treatment affects tumors in the brain.

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 may not be as good as radiation or 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 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 (starting at the time of the blood tests you undergo prior to registration) and for about 6 months after you have completed the study.

Side Effect Risks

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 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.

Drug Risks

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

Possible Side Effects of Abemaciclib

COMMON, SOME MAY BE SERIOUS In 100 people receiving abemaciclib, more than 10 and up to 100 may have:
• Tiredness • Loose stools (diarrhea) • Feeling sick to the stomach with a sense of wanting to throw up (nausea) • Loss of appetite • Dry mouth • Infections • Decreased number of white blood cells in the blood; this may make infections more likely to occur (neutropenia and leukopenia) • Being sick to the stomach (vomiting) • Low red blood cell count in the blood, which can cause fatigue and shortness of breath (anemia). May require a blood transfusion • Decreased number of platelets in the blood; this may cause bruising, difficulty with clotting of blood, or bleeding easily (thrombocytopenia)

- Inflammation or ulcers inside the mouth
- Hair loss

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving abemaciclib, 10 or fewer may have:

- Dizziness
- Rash/itchiness
- Muscle weakness
- Increase of blood creatinine (a measure of how well your kidney is working). When the kidneys do not work properly, wastes can build up in your blood, leading to swelling in the arms and legs, tiredness and weakness. This could become severe, requiring hospitalization and dialysis to clean the wastes out of your blood. If the wastes are not removed from your blood, this could cause seizures and be life threatening

RARE, AND SERIOUS
In 100 people receiving abemaciclib, 3 or fewer may have:

- Swelling of the lungs with symptoms that may include shortness of breath, cough, difficulty breathing

Possible Side Effects of Paxalisib

COMMON, SOME MAY BE SERIOUS
In 100 people receiving paxalisib, more than 10 and up to 100 may have:

- Tiredness
- Loose stools (diarrhea)
- Feeling sick to the stomach with a sense of wanting to throw up (nausea)
- Loss of appetite
- Being sick to the stomach (vomiting)
- Ulcers inside the mouth
- Rash
- High sugar levels in the blood
- Abnormal cholesterol blood test

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving paxalisib, 10 or fewer may have:

- Inflammation inside the mouth
- Tremor
- Dry or itchy skin

RARE, AND SERIOUS In 100 people receiving paxalisib, 3 or fewer may have:
• Heart attack • Dizziness or lightheadedness • Slow heart rate

Possible Side Effects of Entrectinib

COMMON, SOME MAY BE SERIOUS In 100 people receiving entrectinib, more than 10 and up to 100 may have:
• Tiredness • Tingling, tickling, prickling or burning sensation of skin • Loose stools (diarrhea) • Feeling sick to the stomach with a sense of wanting to throw up (nausea) • Loss of taste or a bad taste in your mouth • Being sick to the stomach (vomiting) • Low red blood cell count in the blood, which can cause fatigue and shortness of breath (anemia). May require a blood transfusion • Dizziness • Constipation • Confusion • Low blood pressure, which may cause dizziness, lightheadedness, or fainting • Headache • Pain in arms or legs, neck, or back • Pain in muscles or joints • Swelling of the limbs, face or body in general • Neuropathy (nerve injury which could result in feeling of numbness or pain, or cause weakness) • Difficulty with coordination (moving body parts), balance or walking • Shortness of breath • Cough • Abnormal liver test (possible liver damage) which may be associated with fatigue, nausea and abdominal pain • Weight gain • Rash – anywhere including face, arms, and legs • Fever • Lung infection • Infection which may cause painful and frequent urination • Increase of creatinine (a measure of how well your kidney is working)

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving entrectinib, 10 or fewer may have:
• Difficulty with understanding, memory (forgetfulness), and attention • Pain, numbness, dryness, tingling or burning feeling in mouth or throat • Decreased appetite • Indigestion • Low levels of white blood cells or neutrophils (which fight infection) • Dry or itchy skin • Abdominal pain • Difficulty swallowing • Low levels of electrolytes (which may cause vomiting, headache, confusion, fatigue, blood pressure changes) • Abnormal blood pancreas blood test, which may be associated with nausea, vomiting or abdominal pain • General sensitivity to light or eyes sensitive to light • Pain of skin • Broken bone

RARE, AND SERIOUS In 100 people receiving entrectinib, 3 or fewer may have:
• Allergic reaction involving the heart muscle • Weakness of the heart muscle causing decreased pumping of blood, which may cause breathing difficulty, reduced kidney function and fluid accumulation • Irregular rate or rhythm of heartbeat

Risk of sun exposure: Some drugs have a potential to be photo-reactive. This means that your body could experience side effects (such as a sunburn) through sunlight exposure after taking a drug. Entrectinib has a potential to be photo-reactive. You should be careful with sun exposure by using daily sunscreen, lip balm, and wearing protective clothing, sunglasses, and a hat when going outdoors.

Additional Drug Risks

The study drug could interact with other drugs. Your study doctor will give you a drug information handout and wallet card that lists these possible interactions. 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.

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 6 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.

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

- EKGs (for paxalisib and entrectinib groups)
- Blood tests to measure your lipids (for paxalisib group)

You or your insurance provider will not have to pay for the study drugs 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. Contact information for your study doctor is listed on the consent cover page. 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.

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. 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:

- Montana Cancer Consortium
- The study sponsor 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.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research including the Imaging and Radiation Oncology Core (IROC)
- The Alliance for Clinical Trials in Oncology Foundation and the groups it works with, including Alliance Foundation Trials, LLC and its research partners, is collaborating with the sponsor and a select number of NCTN institutions on a special project called ICAREdata™. Please ask your study team if this will pertain to you. The ICAREdata™ project will be collecting data from the electronic medical record. This information will be stored in a secured location. Please ask your study doctor if you have any questions.

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.

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

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.

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 brain metastases 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, in addition to the tissue you provided in the screening step of this study, additional blood samples and tissue from your prior surgeries and biopsies 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. 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 be 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.

What is involved in this optional sample collection?

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

1. About 2 tablespoons of blood will be collected from a vein in your arm every 2 months while you are receiving study treatment, and if your disease gets worse. A sample from the tissue that was collected at the time of your surgery, and a sample from the tissue collected if your disease gets worse, will be sent to the biobank.
2. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- 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 study doctor who will let the biobank know. Contact information for your study doctor is listed on the consent cover page. 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. Contact information for your study doctor is listed on the consent cover page.

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 Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)

(Required for initial consent only)