

Research Study Informed Consent Document

Study Title for Participants: A Study to Determine Whether Chemotherapy, Bevacizumab, and Atezolizumab is Better than Chemotherapy plus Atezolizumab in Patients with Advanced Liver Cancer (cHCC-CC)

Official Study Title for Internet Search on
<http://www.ClinicalTrials.gov>: Protocol EA2205, A Randomized Phase II Trial Evaluating Chemotherapy plus Atezolizumab vs Chemotherapy plus Bevacizumab and Atezolizumab in Advanced Combined Hepatocellular Carcinoma-Cholangiocarcinoma (NCT05211323)

Version Date: October 18, 2023

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 been diagnosed with a type of liver cancer known as hepatocellular carcinoma-cholangiocarcinoma.

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:

Will adding bevacizumab to chemotherapy plus immunotherapy treat your liver cancer better than chemotherapy plus immunotherapy?

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

Rev. Add1

What is the usual approach to my liver cancer?

There is currently no Standard of Care (SOC) for combined hepatocellular carcinoma-cholangiocarcinoma (cHCC-CC). The usual approach for patients who are not in a study is treatment with chemotherapy (cisplatin and gemcitabine) plus immunotherapy. There are no treatments that are proven to help patients with your health condition live 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 either chemotherapy plus immunotherapy (atezolizumab) every 3 weeks, or chemotherapy plus two other drugs (atezolizumab and bevacizumab) every 3 weeks. If you experience unacceptable side effects, or your disease worsens, the study doctors may discontinue these medications.

After you finish your treatment, your doctor will continue to follow your condition for 3 years and watch you for side effects. Follow-up by telephone will occur every 4 months.

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 chemotherapy plus bevacizumab and atezolizumab may not be as good as chemotherapy alone at treating your

cancer.

There is also a risk that you could have side effects from bevacizumab and atezolizumab. 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:

- High blood pressure
- Tiredness
- Infection
- Anemia
- Nausea, fever
- Loss of appetite
- Cough, shortness of breath, runny nose
- Skin changes including rash, dry skin, or changes in color.

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

Rev. Add1 **Benefits**

There is evidence that this chemotherapy plus bevacizumab and atezolizumab is effective in stabilizing your type of cancer. It is not possible to know now if the bevacizumab and atezolizumab will be better at treating cHCC-CC cancer 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. 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.
- 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 (ECOG-ACRIN). 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 of chemotherapy plus atezolizumab to using bevacizumab and atezolizumab plus chemotherapy treatment. The addition of bevacizumab to the usual treatment could shrink your cancer. But it could also cause side effects, which are described in the risks section below.

This study will help 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 bevacizumab and atezolizumab plus chemotherapy increases how long a person lives without the disease worsening compared to the usual approach.

The chemotherapy drugs, gemcitabine and cisplatin, are already approved by the FDA for the treatment of cholangiocarcinoma, a type of liver cancer believed to be similar to your diagnosis (combined hepatocellular carcinoma-cholangiocarcinoma). Atezolizumab and bevacizumab are approved by the FDA for the treatment of hepatocellular carcinoma, another type of liver cancer. There will be about 80 people taking part in this study.

What are the study groups?

This study has 2 study groups.

- **Group 1**

If you are in this group, you will get the usual drugs used to treat this type of cancer, gemcitabine and cisplatin through a vein in the arm on the first and eighth day of each cycle. You will also get immunotherapy (atezolizumab) on the first day of each cycle. Each cycle lasts 21 days. Cycles will be repeated until your doctor sees toxicity or if your doctor does not see that you are benefiting from the treatment.

There will be about 40 people in this group.

- **Group 2**

If you are in this group, you will get the usual drugs used to treat this type of cancer, gemcitabine and cisplatin. You will get these drugs through a vein in the arm on the first and eighth day of each cycle. In addition, you will get two study drugs, bevacizumab and atezolizumab. You will get these drugs through a vein in the arm on day 1 of each cycle. Each cycle lasts 21 days. Cycles will be repeated until your doctor sees toxicity or your doctor does not see that you are benefiting from the treatment.

There will be about 40 people in this group.

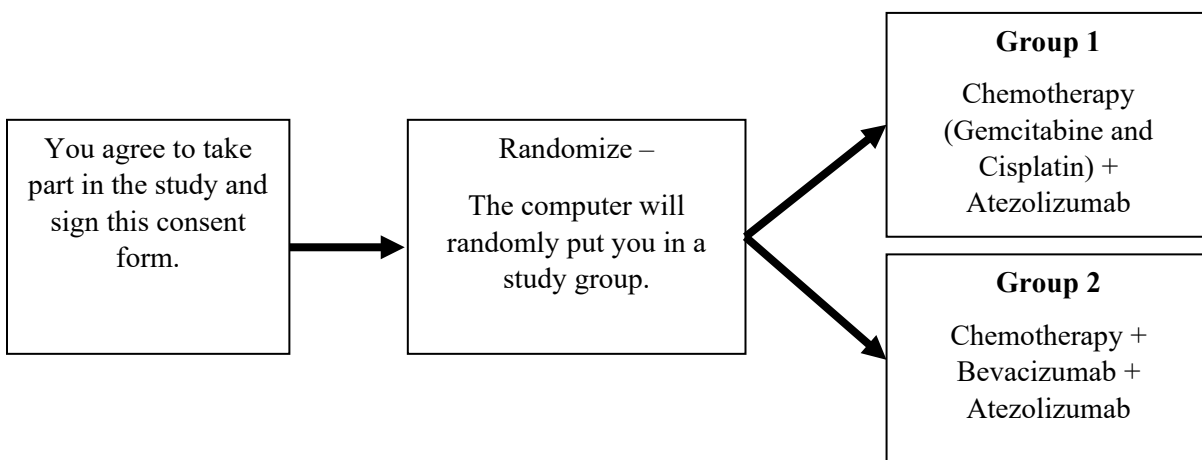
We will use a computer to assign you to one of the study groups. This process is called

“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.

A very simple schema example is provided below. Additional, more complicated schema examples are provided on the NCI CTEP consent website:

https://ctep.cancer.gov/protocoldevelopment/informed_consent.htm



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 prior to each chemotherapy treatment on day 1 of the 21 day cycle.
- Physical exams are to be done on day 1 of the each 21 day cycle.

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 bevacizumab and atezolizumab 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 bevacizumab 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 6 months after you have completed treatment on this 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.

This study is looking at a combination of the usual drugs 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 cisplatin and gemcitabine are listed in the tables below. These drugs are part of the usual approach for treating this type of cancer:

Possible Side Effects of Cisplatin

(Table Version Date: January 25, 2021)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, more than 20 and up to 100 may have:
<ul style="list-style-type: none">• Infection, especially when white blood cell count is low• Bruising, bleeding• Anemia which may cause tiredness, or may require blood transfusions• Kidney damage which may cause swelling, may require dialysis• Hearing loss including ringing in the ears• Nausea, vomiting• Confusion• Numbness, pain and tingling of the fingers, toes, arms and/or legs, loss of balance

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, from 4 to 20 may have:
<ul style="list-style-type: none">• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat• Diarrhea• Change in taste• Swelling and redness at the site of the medication injection• Hair loss

RARE, AND SERIOUS In 100 people receiving Cisplatin, 3 or fewer may have:
<ul style="list-style-type: none">• Brain damage, Posterior Reversible Encephalopathy syndrome, which may cause headache, seizure, blindness• Seizure• A new cancer, including leukemia, resulting from treatment of a prior cancer

Possible Side Effects of Gemcitabine

(Table Version Date: January 25, 2021)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Gemcitabine, more than 20 and up to 100 may have:
<ul style="list-style-type: none">• Swelling of arms, legs, and body• Shortness of breath

COMMON, SOME MAY BE SERIOUS

In 100 people receiving Gemcitabine, more than 20 and up to 100 may have:

- Infection, including in the blood, especially when white blood cell count is low
- Bruising, bleeding
- Anemia which may require a blood transfusion
- Blood in urine
- Sores in mouth which may cause difficulty swallowing
- Nausea, vomiting, diarrhea, constipation
- Flu-like symptoms of muscle pain, fever, headache, chills and fatigue
- Burning, numbness, tingling or "pins and needles" feelings
- Difficulty sleeping
- Rash, itching
- Hair loss

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving Gemcitabine, from 4 to 20 may have:

- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Damage to the lungs and/or fluid around the lungs, which may cause shortness of breath, cough
- Weight loss, loss of appetite

RARE, AND SERIOUS

In 100 people receiving Gemcitabine, 3 or fewer may have:

- Heart failure or heart attack which may cause chest pain, shortness of breath, swelling of ankles, and tiredness
- Stroke which may cause paralysis, weakness, headache
- Liver damage which may cause yellowing of eyes and skin, swelling

NOTE: Study Group 2 – In addition to side effects listed above, people who are in Group 2 may also have some side effects from bevacizumab and atezolizumab. These side effects are listed below.

Possible Side Effects of Bevacizumab (rhuMAb, VEGF)

(Table Version Date: May 2, 2018)

COMMON, SOME MAY BE SERIOUS
In 100 people receiving bevacizumab (rhuMAb VEGF), more than 20 and up to 100 may have:
<ul style="list-style-type: none">• High blood pressure which may cause headaches, dizziness, blurred vision

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving bevacizumab (rhuMAb VEGF), from 4 to 20 may have:
<ul style="list-style-type: none">• Anemia which may require blood transfusion• Low white cell count that may increase the risk of infection• Infection, including collection of pus in the belly or rectum• Abnormal heartbeat which may cause palpitations or fainting• Pain in the belly, rectum, chest, joints, muscles, or tumor• Low appetite, constipation, diarrhea, heartburn, nausea, vomiting, or dehydration• Bleeding from multiple sites including the vagina or nose• Internal bleeding which may cause black tarry stool, blood in vomit, coughing up blood, or blood in urine• Blockage of internal organs which may cause vomiting or inability to pass stool• Sores in the mouth• Allergic reaction during or after infusion of bevacizumab which may cause fever, chills, rash, itching, hives, low blood pressure, wheezing, shortness of breath, swelling of the face or throat• Delay in healing of wounds or spontaneous opening of wounds• Weight loss, tiredness, or dizziness• Muscle weakness• Damage to the jawbone which may cause loss of teeth• Headache• Numbness, tingling or pain in the fingers or toes• Hoarseness, stuffy nose, or cough• Dry skin• Swelling and redness of the skin• Blood clot in limbs or lungs which may cause swelling, pain, shortness of breath• Leakage of protein in the urine, which can rarely lead to damage to the kidney

<p>RARE, AND SERIOUS</p>
<p>In 100 people receiving bevacizumab (rhuMAb VEGF), 3 or fewer may have:</p>
<ul style="list-style-type: none"> • Clots in the arteries, causing stroke (which may cause paralysis or weakness) or heart attack (which may cause chest pain or shortness of breath). This risk is significantly increased in patients who are elderly or with history of diabetes. • Heart failure which may cause shortness of breath, swelling of ankles, and tiredness • Bowel perforation (a tear in the bowel) that can cause pain or bleeding and require surgery to repair • A tear or hole (fistula) in internal organs such as the nose, throat, lungs, esophagus, rectum, or vagina. These conditions may cause serious infections or bleeding and require surgery to repair. • Sores in the throat • Flesh-eating bacteria syndrome, an infection in the deep layers of skin • Damage to organs (bone, lungs, others) which may cause loss of motion • Bleeding in the tumor, brain, belly or lungs which may cause confusion, blood in stool or coughing up blood • Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome) • Kidney damage which may require dialysis • Redness, pain or peeling of palms and soles

Possible Side Effects of Atezolizumab

(Table Version Date: September 14, 2023)

<p>COMMON, SOME MAY BE SERIOUS</p>
<p>In 100 people receiving atezolizumab (MPDL3280A), more than 20 and up to 100 may have:</p>
<ul style="list-style-type: none"> • Tiredness • Infection

<p>OCCASIONAL, SOME MAY BE SERIOUS</p>
<p>In 100 people receiving atezolizumab (MPDL3280A), from 4 to 20 may have:</p>
<ul style="list-style-type: none"> • 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

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving atezolizumab (MPDL3280A), from 4 to 20 may have:

- 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

RARE, AND SERIOUS

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

- 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 drugs 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

Do not get pregnant or breastfeed while taking part in this study. Do not father a baby while taking part in this study. Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 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 liver 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 bevacizumab and atezolizumab ready and giving it to you.
- your insurance co-pays and deductibles.

You or your insurance provider will not have to pay for the atezolizumab and/or bevacizumab while you take part in this study.

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.

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.

The ECOG-ACRIN Cancer Research Group is conducting this study. ECOG-ACRIN is a cancer research group that conducts studies for the National Cancer Institute. Your doctor is a member of ECOG-ACRIN or another group that is participating in this study. To help protect your privacy, ECOG-ACRIN has obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, ECOG-ACRIN cannot be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state or local civil, criminal, administrative, legislative or other proceeding. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

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 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.

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 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 (*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*).

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study.

Participant's signature _____

Date of signature _____

Signature of person(s) conducting the informed consent discussion _____

Date of signature _____