

Research Study Informed Consent Document

Study Title for Participants: Gemcitabine, Cisplatin, and Nab-Paclitaxel or Gemcitabine and Cisplatin in Newly Diagnosed Advanced Biliary Tract Cancers

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>:

S1815, A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel Versus Gemcitabine and Cisplatin in Newly Diagnosed Advanced Biliary Tract Cancers

(NCT#03768414)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. 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 advanced biliary tract cancer (cholangiocarcinoma or gallbladder cancer) that is newly diagnosed.

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:

How does treating newly diagnosed, advanced biliary tract cancer (cholangiocarcinoma or gallbladder cancer) with the drugs gemcitabine and cisplatin differ when adding the study drug nab-paclitaxel?

We are doing this study because we want to find out which approach is better for newly diagnosed advanced biliary tract cancer.

What is the usual approach to my newly diagnosed advanced biliary tract cancer?

There are several treatment options for newly diagnosed advanced biliary tract cancer. Patients who are not in a study are usually treated with chemotherapy that is already FDA approved. The standard treatment for patients with newly diagnosed advanced biliary tract cancer is currently a combination of two chemotherapies, gemcitabine and cisplatin. Please talk with your doctor about alternatives before finalizing your decision to take part in this study.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above without joining this study.
- You may choose to take part in a different research study, if one is available.
- You may choose to get only comfort care to help relieve your symptoms and not get treated for your cancer. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will either get treatment with gemcitabine, cisplatin, and nab-paclitaxel or gemcitabine and cisplatin alone.

After you finish your study treatment, your doctor will continue to follow your condition for up to three years after you register to the study. Your doctor will watch you for side effects and to see how your cancer affects you. You will have clinic visits every six months from the time you stop taking treatment until two years after you register to the study, and then once again, at the end of the 3rd year.

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 receiving the additional study drug nab-paclitaxel may not be as good as receiving the standard treatment.

There is also a risk that you could have side effects from any of the drugs on this study.

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

- Kidney Damage
- Abnormal blood tests
- Dehydration

If you are randomly assigned to receive nab-paclitaxel with gemcitabine and cisplatin, it is possible that side effects could worsen or become dangerous.

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

Benefits

This study may or may not help you because it is not possible to know at this time if the study approach is better than the usual approach. This study may help researchers learn things that may 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. 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 cancer or your symptoms get worse
- You have unacceptable side effects to the study drug.
- Your health changes and the study is no longer in your best interest.
- Your treatment is delayed for more than 3 weeks.
- 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 (SWOG). 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 effects of adding the drug nab-paclitaxel to the standard of care drugs cisplatin and gemcitabine versus cisplatin and gemcitabine alone. Nab-paclitaxel is an FDA-approved drug, but it is not approved for use in this disease setting. The addition of the study drug nab-paclitaxel could shrink your cancer but it could also cause side effects. This study will allow researchers to know whether this different approach is better, the same, or worse than the common approach. In this study, you will get either cisplatin and gemcitabine, or nab-paclitaxel with cisplatin and gemcitabine.

There will be about 268 people taking part in this study of which 1/3 will be in the standard of care group and 2/3 will be in the study group.

Talk to your doctor about your choices before you decide if you will take part in this study.

What are the study groups?

This study has 2 study groups. You will be told which group you are in, but you and your doctor will not get to choose which group you go into if you join this study.

- **Group 1**

If you are in this group, you will receive gemcitabine, cisplatin, and nab-paclitaxel by IV in your arm. You will receive nab-paclitaxel first over about 30 minutes followed by **gemcitabine over about 30 minutes, and then cisplatin for about 60 minutes**. You will receive these infusions on Day 1 and Day 8 every 21 days until you no longer receive benefit from the drug. You will not need to be admitted to the hospital for the treatment.

There will be about 179 people in this group.

- **Group 2**

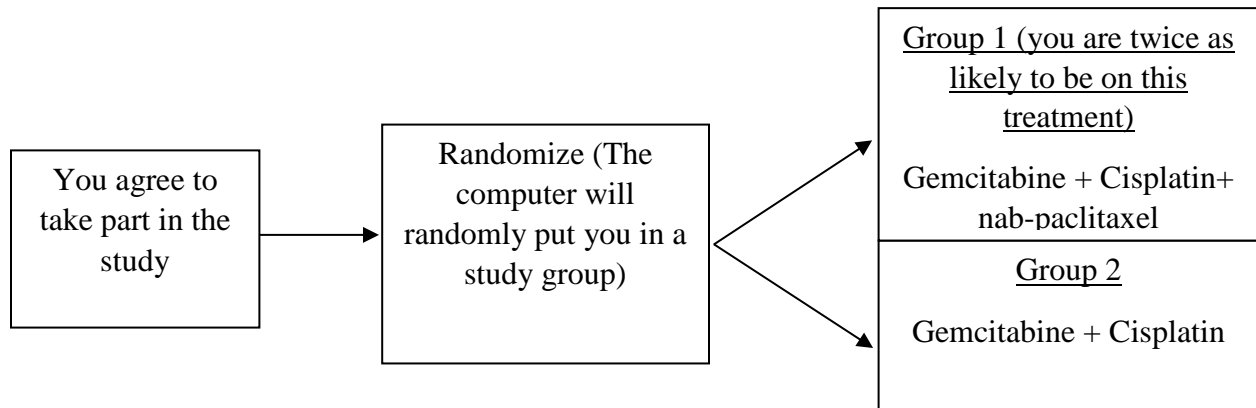
If you are in this group, you will receive gemcitabine and cisplatin by IV in your arm. You will receive **gemcitabine first over about 30 minutes and then cisplatin for about 60 minutes**. You will receive these infusions on Day 1 and Day 8 every 21 days until you no

longer receive benefit from the drug . You will not need to be admitted to the hospital for the treatment.

There will be about 89 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 a higher chance of being in Group 1 than being in Group 2.

Another way to find out what will happen to you during this study is to read the chart below. Start reading from the left and read to the right, following the lines and arrows.



What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

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

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

- Tumor markers
- CT or MRI every 9 weeks until your cancer worsens

- blood counts done weekly during the first 2 weeks of every treatment cycle
- Physical exams done weekly during the first 2 weeks of every treatment 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 the study approach may not be as good as the usual approach for 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 and for 6 weeks 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.

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 Risk Profile for Nab-Paclitaxel

You may have side effects while you are in the study, but you will be carefully checked by the study doctor for any problems. There may be risks or side effects of the study drug that are unknown at this time. You should tell the study doctor/staff about anything that is bothering you or any side effects you have, even if you do not think they are related to the study drug.

The following is a list of the most medically significant or most common side effects reported in completed studies considered to be related to nab-paclitaxel albumin. In some cases, side effects can be serious, long-lasting, or can cause death. Some side effects go away soon after you stop the study drug/therapy, and some may never go away. The study doctor may alter the dosage regimen of nab-paclitaxel (per study criteria) or give you medicines to help lessen the side effects. This is not a complete list of all side effects that may occur. For more information about risks and side effects, please ask the study doctor.

Possible side effects of Nab-paclitaxel

(Table Version Date: October 30, 2019)

COMMON, SOME MAY BE SERIOUS
In 100 people receiving nab-paclitaxel more than 20 and up to 100 may have:
<ul style="list-style-type: none">• Swelling of the body• Infection, especially when white blood cell count is low which can be serious• Bruising, bleeding• Anemia, which may cause tiredness, or may require blood transfusions• Diarrhea, nausea, vomiting, or loss of appetite• Numbness and tingling of the arms and legs, muscle weakness• Fever• Tiredness• Dehydration• Hair loss, rash• Abnormal EKG• Cold symptoms such as stuffy nose, sneezing, sore throat• Pain in muscles and/or joints

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving nab-paclitaxel 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 which may cause shortness of breath
- Pain
- Constipation
- Paralysis, weakness, headache
- Abnormal heartbeat
- Low blood pressure, which may cause feeling faint
- High blood pressure, which may cause headaches, dizziness, blurred vision
- Visual disturbances, blurred, or decreased vision
- Sores in the mouth which may cause difficulty swallowing
- Cough, shortness of breath, infection
- Nosebleed
- Depression
- Infection which may cause painful and frequent urination
- Changes in taste

RARE, AND SERIOUS

In 100 people receiving nab-paclitaxel, 3 or fewer may have:

- Bleeding
- Heart stops beating
- Heart attack, which may cause chest pain, shortness of breath
- Heart Disease
- Blood clot which may cause swelling, pain, shortness of breath
- Mini stroke
- Abnormal heartbeat

Study Group 1 and Group 2

GEMCITABINE

Possible Side Effects of Gemcitabine (*Table Version Date: January 19, 2016*)

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">• Flu-like symptoms of muscle pain, fever, headache, chills and fatigue• Nausea, vomiting• Rash• Hair loss• Infection, especially when white blood cell count is low• Bruising, bleeding• Anemia which may require a blood transfusion• Muscle weakness• Blood in urine• Feeling of "pins and needles" in arms and legs• Numbness and tingling of the arms and legs• Tiredness• Difficulty sleeping• Swelling of arms, legs

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving Gemcitabine, from 4 to 20 may have:
<ul style="list-style-type: none">• Swelling and redness of the area of radiation• Blisters on the skin• Diarrhea, constipation• Sores in mouth which may cause difficulty swallowing• Liver damage which may cause yellowing of eyes and skin, swelling• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat• Scarring of the lungs• Shortness of breath• Fluid in the organs which may cause low blood pressure, shortness of breath, swelling of ankles• Brain damage, brain swelling, which may cause headache, seizure, blindness

RARE, AND SERIOUS

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

- Severe blood Infection
- Anemia, kidney problems which may require dialysis
- Blood clot
- Blockage of the airway which may cause cough

Possible Side Effects of Cisplatin (Table Version Date: April 10, 2019)

COMMON, SOME MAY BE SERIOUS

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

- 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
- Nausea, vomiting
- Confusion
- Numbness and tingling of the arms and legs

OCCASIONAL, SOME MAY BE SERIOUS

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

- Brain damage, Posterior Reversible Encephalopathy syndrome, which may cause headache, seizure, blindness
- Change in taste
- Diarrhea
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Difficulty with hearing and balance
- Hair loss

RARE, AND SERIOUS

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

- Seizure

Additional Drug Risks

- A very rare condition known as Posterior Reversible Encephalopathy Syndrome has occurred when gemcitabine is given alone or in combination with other chemotherapy medications. Therefore, you should tell your study doctor if you have one or more of the following symptoms; headache, abnormal shaking of body, sleepiness, increased blood pressure, feeling confused, abnormal vision including loss of vision, loss of muscle control or muscle weakness, numbness or tingling in extremities.
- A very rare condition known as Capillary Leak Syndrome that causes leaking of fluid outside of blood vessels has occurred when gemcitabine is given alone or in combination with other chemotherapy medications. Therefore, you should tell your study doctor if you have one or more of the following symptoms: fatigue; lightheadedness or fainting; pain in arms, legs, or stomach or all over body; swelling in face or body; difficulty breathing; low blood pressure.
- an inflammation of the small blood vessels described as pain, heat, and redness to the affected part of the body.
- dying tissue due to lack of blood supply described as skin discoloration, severe pain, foul smelling leakage from a sore, and may include swelling, and increased temperature to the affected region of the body.

The study drugs could interact with other drugs and foods. You should avoid grapefruit juice and any other drugs your doctor discusses with you.

Rarely, there are problems getting enough supplies of the study drugs. If that happens, your doctor will talk with you about your options.

Risks of Venipuncture/Intravenous Needle Insertion:

Occasional, some may be serious: Mild pain and discomfort at the injection or needle insertion site as well as possible infection, bleeding, bruising, and soreness.

Rare: Severe pain, swelling, infection from the actual injection, and fainting.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

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.

For Women: Do not get pregnant or breastfeed while taking part in this study. Tell your doctor right away if you think that you or your partner have become pregnant during the study or up to 1 month after your last dose of study drug. **For men:** Do not father a baby while taking part in this study and up to 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 biliary tract 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.
- your insurance co-pays and deductibles.
- the cost of gemcitabine, and cisplatin

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 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.

You or your insurance provider will not have to pay for the nab-paclitaxel while you take part in this study.

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 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 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.
- The Institutional Review Board (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 Food and Drug Administration (FDA) and the groups it works with to review research
- The National Cancer Institute (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

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, 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 your type of cancer in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

Taking part in this optional study is your choice. You can still take part in the main study even if you say “no” to this optional 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.

1. Contact for Future Research

Occasionally, researchers working with SWOG may have another research idea that relates to people who were on a SWOG study. In some cases, to carry out the new research, we would need to contact participants in a particular study. You can agree or not agree to future contact.

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

Yes No

2. 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, blood and tissue (from a previous biopsy) will be collected and stored.

Storing samples for future studies is called "biobanking." The biobank is being run by Nationwide Children's Hospital 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.

We don't know what research may be done in the future using your tumor tissue, or blood 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.
- Future research studies may include sequencing of all or part of your DNA called genomic sequencing. All your genetic information makes up your genome. Genomic sequencing is a test that records all or part of the pieces of DNA that are in your genes, piece by piece. This is usually done to look for changes in your genome that may cause health problems.
- You will not get reports or other information about any research that is done using your samples.

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. A sample from the tissue that was collected will be sent to the biobank before you start treatment. A sample from the tissue that was collected at the time of your biopsy (or the entire block of tissue) will be sent to the biobank for use in future studies.
2. About 4 teaspoons of blood will be taken at the same time blood is being collected for your treatment on the study. You will have this extra blood taken before you begin treatment and every time you have a scan for your disease (either a CT or MRI), which is about every 9 weeks if that happens.
3. Your samples will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
4. Researchers can only get samples from the biobank after their research has been approved by experts.
5. Researchers will not be given your name or contact information.
6. 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. Samples that remains in the biobank will not be used. 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 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 Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)

(Required for initial consent only)