Research Study Informed Consent Document

Study Title for Participants: Testing the addition of an anti-cancer immunotherapy drug, avelumab, to gemcitabine and carboplatin chemotherapy prior to surgery in muscle invasive urinary tract cancer vs. surgery alone in patients who are not able to receive cisplatin therapy.

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: S2011, "Randomized Phase II Trial of Gemcitabine, Avelumab and Carboplatin vs. No Neoadjuvant Therapy Preceding Surgery for Cisplatin-Ineligible Muscle-Invasive Urothelial Carcinoma: SWOG GAP TRIAL.**"**
(NCT# 04871529)

OVERVIEW AND KEY INFORMATION
(This section is a summary of the main consent form)

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 muscle-invasive urinary tract (bladder or upper urinary tract) cancer and cannot receive cisplatin chemotherapy before surgery.

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.

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Why is this study being done?

This study is being done to answer the following question:

Can we lower the chance of muscle invasive urinary tract cancer growing or spreading, in people who cannot receive cisplatin therapy, by combining a new immunotherapy drug, avelumab, to the combination of chemotherapy drugs that can be safely given prior to surgery when compared to surgery alone and increase the chance that cancer completely disappears at the time of surgery?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for muscle-invasive bladder or upper urinary tract cancer. The usual approach is defined as the care most people get for muscle-invasive urinary tract cancer when they cannot receive cisplatin therapy due to poor kidney function, poor physical fitness or other medical problems.

What is the usual approach to treating muscle-invasive urothelial cancer?

The usual approach for patients who can not receive cisplatin chemotherapy and are not in a study is surgery alone (bladder removal, upper urinary tract removal, or upper urinary tract and kidney removal based on the location of the cancer). Your doctor can explain which treatment may be best for you. For patients who get the usual approach for this cancer, about 50 out of 100 are free of cancer after 5 years.

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

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for cancer.

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 the study drugs gemcitabine, carboplatin and avelumab for up to 12 weeks before having surgery or you will have surgery alone (bladder removal, upper urinary tract removal, or upper urinary tract and kidney removal based on the location of the cancer).

After your surgery, your doctor will continue to follow your condition for up to 5 years and watch you for side effects. You will visit the doctor's office for blood tests and scans every 3 months for the first 2 years after registration, then twice a year for 1 year, then once a year for 2 more years. This means that you will keep seeing your doctor in office for a total of 5 years after you are registered to this study.

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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 gemcitabine, carboplatin and avelumab before having surgery may not be as good as the usual approach for the type of cancer you have at shrinking or stopping the cancer from growing.

There is also a risk that you could have side effects from the gemcitabine, carboplatin, and avelumab. These side effects may be worse and may be different than you would get with the usual approach for the type of cancer you have.

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

- Lack of energy
- Muscle pain
- Diarrhea
- Nausea
- Breathing difficulty
- Decreased hunger
- Infections

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

Benefits

There is evidence that having surgery alone is effective in stopping the urothelial cancer from growing. It is not possible to know now if taking gemcitabine, carboplatin and avelumab will extend your life compared to the usual approach. This study will help the study doctors learn things that will help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. This may mean slowly stopping the study drugs so that there is not a sudden unsafe change, risk to your health, etc. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

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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:

- 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.
- 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.

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.

MAIN SCREENING CONSENT FORM

What is the purpose of this study?

The purpose of this study is to compare the usual treatment alone to using gemcitabine, carboplatin and avelumab plus the usual treatment. The addition of gemcitabine, carboplatin, and avelumab to the usual treatment could shrink the cancer or prevent it from returning. But, it could also cause side effects, which are described in the risks section below.

This study will help the study doctors find out if this different approach is better, the same, or worse than the usual approach. To decide if it is better, the study doctors will be looking to see if gemcitabine, carboplatin and avelumab increases the number of people who do not have urothelial cancer at the time of surgery from 15% to 35%.

The chemotherapy drug, avelumab, is already approved by the FDA for use in bladder cancer. However, most of the time it is used after bladder removal surgery. There will be about 196 people taking part in this study.

What are the study groups?

This study has 2 study groups.

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- **Group 1**

  If you are in this group, you will get the drugs gemcitabine, carboplatin, and avelumab for 12 weeks, and then you will get the usual care surgery that is described for Group 2. You will get gemcitabine through a vein in your arm over 30 minutes on Days 1, 8, 22, 29, 43, 50, 61, and 71. You will get carboplatin through a vein in your arm over 30 minutes on Days 1, 22, 43, and 64. You will get avelumab through a vein in your arm over 60 minutes on Days 1, 15, 29, 43, 57, and 71.

  These drugs are all approved by the FDA for use in patients with the type of cancer you have, but they are not approved for use in patients prior to surgery in the way they are being used in this study.

  There will be about 98 people in this group.

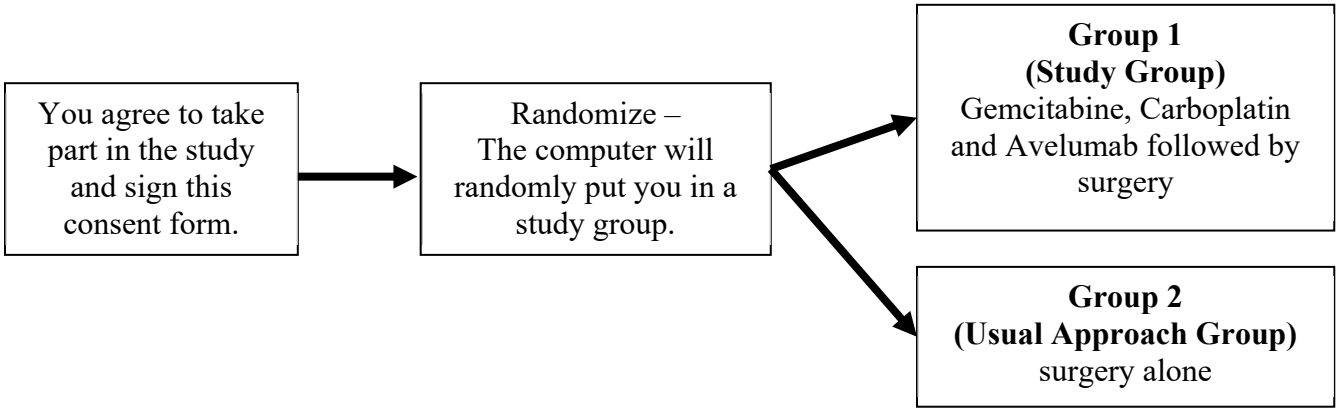
- **Group 2**

  If you are in this group, you will get the usual care surgery. The surgery could include removal of the bladder, removal of the upper urinary tract, or removal of the upper urinary tract and kidney, depending on where the cancer is located

  There will be about 98 people in this group.

We will use a computer to assign you to one of the study groups. This process is called "randomization." It means that your doctor will not choose and you cannot choose which study group you are in. You will be put into a group by chance. You will have an equal chance of being in Group 1 or Group 2.

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



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

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

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

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

- Blood tests done each week you receive study drug.
- Thyroid testing done before you begin treatment, about 7 weeks after you start treatment, and about 3 months after your surgery.

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 the type of cancer you have at preventing the cancer from coming back.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The study 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 1 month after you have completed the study.

This study will use a sample of your tissue. Generally, your hospital will keep some of your tissue from your surgery. This tissue may be used to help treat you for cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up. This is only for participants who consent to banking for future research. This is discussed more later in this consent form in the section about optional procedures.

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Side Effect Risks

The drugs and surgery 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 and surgery. 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 drugs given before surgery vs. surgery alone, which is used to treat this type of cancer. This different combination of drugs may increase your side effects or may cause new side effects.

Drug Risks

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

Study Group 1 – Possible side effects of gemcitabine, carboplatin and avelumab are listed in the tables below.

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Possible Side Effects of Gemcitabine
(Table Version Date: October 17, 2019)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Gemcitabine, more than 20 and up to 100 may have:
• **Infection, especially when white blood cell count is low** • **Bruising, bleeding** • **Anemia which may require a blood transfusion** • **Blood in urine** • **Nausea, vomiting** • **Flu-like symptoms of muscle pain, fever, headache, chills and fatigue** • **Muscle weakness** • **Feeling of "pins and needles" in arms and legs** • **Numbness and tingling of the arms and legs** • **Swelling of arms, legs** • **Tiredness** • **Difficulty sleeping** • **Rash** • **Hair loss**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Gemcitabine, from 4 to 20 may have:
• **Fluid in the organs which may cause low blood pressure, shortness of breath, swelling of ankles** • **Scarring of the lungs** • **Shortness of breath** • **Liver damage which may cause yellowing of eyes and skin, swelling** • **Diarrhea, constipation** • **Sores in mouth which may cause difficulty swallowing** • **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat** • **Swelling and redness of the area of radiation** • **Blisters on the skin**

RARE, AND SERIOUS In 100 people receiving Gemcitabine, 3 or fewer may have:
• **Brain damage, Posterior Reversible Encephalopathy syndrome, which may cause headache, seizure, blindness** • **Blockage of the airway which may cause cough** • **Blood clot**

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RARE, AND SERIOUS In 100 people receiving Gemcitabine, 3 or fewer may have:
• **Severe blood Infection** • **Anemia, kidney problems which may require dialysis**

Possible Side Effects of Carboplatin
(Table Version Date: October 15, 2020)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Carboplatin, 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** • **Vomiting, nausea** • **Pain** • **Hair loss**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Carboplatin, from 4 to 20 may have:
• **Diarrhea, Constipation, belly pain** • **Changes in taste** • **Numbness and tingling in fingers and toes** • **Weakness**

RARE, AND SERIOUS In 100 people receiving Carboplatin, 3 or fewer may have:
• **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat** • **Visual loss** • **Difficulty hearing**

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Possible Side Effects of Avelumab
(Table Version Date: April 23, 2019)

Special precautions
Side effects of avelumab may happen anytime during treatment or even after your treatment has ended. Some of these problems may happen more often when avelumab is used in combination with gemcitabine and carboplatin. **Call or see your healthcare provider right away if you develop any problems listed below or the symptoms get worse.**
COMMON, SOME MAY BE SERIOUS In 100 people receiving avelumab, more than 20 and up to 100 may have:
• **Tiredness**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving avelumab, from 4 to 20 may have:
• **Anemia which may require blood transfusion** • **Diarrhea, nausea, vomiting** • **Chills, fever** • **Flu-like symptoms including body aches** • **Infection** • **Reaction during or following a drug infusion which may cause fever, chills, rash, low blood pressure** • **Bruising, bleeding** • **Loss of appetite** • **Cough** • **Dry skin** • **Itching, acne, rash**
Avelumab 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 [the term above is a clinical manifestation of lab values not previously listed on the risk list]** • **Damage to the pancreas which may cause belly pain and hospitalization** • **Pain or swelling of the joints** • **Problem of the muscle (myositis), which can cause muscle pain and severe muscle weakness sometimes with dark urine**

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RARE, AND SERIOUS

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

Avelumab 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 inflammation and heart failure. Symptoms and signs of heart problem may include: Shortness of breath, swelling of the ankle and body**
- **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**
- **A condition with high blood sugar (diabetes) which leads to tiredness, frequent urination or excessive thirst which may require treatment with insulin**
- **Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs and facial muscle movement**
- **Inflammation of the brain (meningitis/encephalitis), which may cause: headache, confusion, sleepiness, seizures, and stiff neck**
- **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**

Additional Drug Risks

The study drug, avelumab, could interact with other drugs. Your study doctor will give you a participant clinical trial wallet card that lists these study drugs. Share this information with your family members, caregivers, other health care providers, and pharmacists.

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

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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. **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 the type of cancer you have. 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 gemcitabine, carboplatin, and avelumab ready and giving them to you.
- your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

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

- The extra blood tests during each cycle of treatment.
- The thyroid tests done before study, at about 7 weeks after starting study treatment, and at about 3 months after surgery.

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

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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 the type of cancer you have. You may:

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

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

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- The study sponsor and any company supporting the study drug avelumab 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 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 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*).

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ADDITIONAL STUDIES SECTION:
(This section is about optional studies you can choose to take part in)

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, urine, and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Unknown future studies

If you choose to take part in this optional study, a sample of tissue from your previous biopsy will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is being run by SWOG and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what research may be done in the future using your blood, urine and tissue samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in

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your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes. If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in the cancer tissue, or in your normal tissue as well.

What is involved in this optional sample collection?

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

1. About 6 teaspoons of blood will be collected from a vein in your arm at up to 3 times. A sample from the tissue that was collected at the time of the biopsy you had when the cancer was first diagnosed will be sent to the biobank. A sample of tissue will be collected from the surgery you have while you are on the study and will be sent to the biobank. A sample of urine will be collected and sent to the biobank at up to 2 times.
2. Your samples will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts.
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 you for cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance.

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

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1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, _____ (*insert name of study doctor for main trial*), at_____ (*insert telephone number of study doctor for main trial*), who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, _____(*insert name of study doctor for main trial*), at _____(*insert telephone number of study doctor for main trial*).

Please circle your answer below to show if you would or would not like to take part in each optional study:

Samples for unknown future studies:

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

YES NO

SWOG Authorized Document

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 circles "yes".

Participant's signature (or legally authorized representative)

_____

Date of signature

_____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature

_____