Research Study Informed Consent Document

Study Title for Participants: A study of chemotherapy without surgery to remove the bladder in patients with muscle-invasive bladder cancer and mutations in DNA damage response genes

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: A031701, A phase II study of gemcitabine plus cisplatin chemotherapy in patients with muscle-invasive bladder cancer with bladder preservation for those patients whose tumors harbor deleterious DNA damage response (DDR) gene alterations (NCT03609216)

Overview and Key Information

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

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 muscle invasive bladder cancer. The standard therapy for your type of cancer is to receive chemotherapy and then have surgery called a radical cystectomy with pelvic lymph node dissection. In this study, we are testing whether or not a certain group of patients can avoid this surgery based on whether their tumor has a certain genetic marker and the stage of their cancer after finishing chemotherapy.

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: Can a certain group of patients with muscle invasive bladder cancer be treated with gemcitabine and cisplatin chemotherapy alone and avoid surgery?

What is the usual approach to my muscle invasive bladder cancer?

The usual approach for patients who are not in a study is treatment with FDA-approved chemotherapy followed by surgery, or chemo-radiation therapy. In this trial, you will still receive the FDA-approved chemotherapy, but you may or may not have surgery or chemo-radiation therapy afterwards.

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

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

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

If you decide to take part in this study, you will get the chemotherapy drugs gemcitabine and cisplatin, along with a drug to help side effects called pegfilgrastim or filgrastim for up to 12 weeks. Your treatment after this first 12 weeks will be dependent on results of tests done on your tissue and blood. You will either have surgery, treatment with more chemotherapy and radiation, or no further treatment.

After you finish your treatment, your doctor and study team will follow you to see if the cancer returns. All patients will get scans every 3 months the first 2 years, then yearly for years 3-5. For patients who do not have surgery, you will be followed with a cystoscopy every 3 months for 2 years, every 6 months during years 3 and 4, and then once during year 5. This means you will keep seeing your doctor for up to 5 years after treatment.

For patients who have surgery you will see your doctor every time you get a scan (every 3 months for 2 years, then yearly for years 3-5).

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 not having surgery may not be as good as having surgery at preventing your cancer from coming back.

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

Benefits

Certain patients may be able to avoid having surgery and keep their bladders. This study may help the study doctors learn things that may help other people in the future.

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

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

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor [National Cancer Institute (NCI)]. The study sponsor is the organization that 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 see if some patients with muscle-invasive bladder cancer can avoid surgery to remove their bladder. New research has shown that bladder tumors with changes in the DNA damage response (DDR) genes are very sensitive to a chemotherapy treatment known as dose-dense gemcitabine and cisplatin (ddGC). In this study, we are testing whether patients whose tumors have a DDR gene mutation and whose bladder tumor shrinks after chemotherapy can keep their bladder and avoid a surgery called a radical cystectomy. The study doctors hope to learn whether this approach is better or worse than the usual treatment. There will be about 271 people taking part in this study.

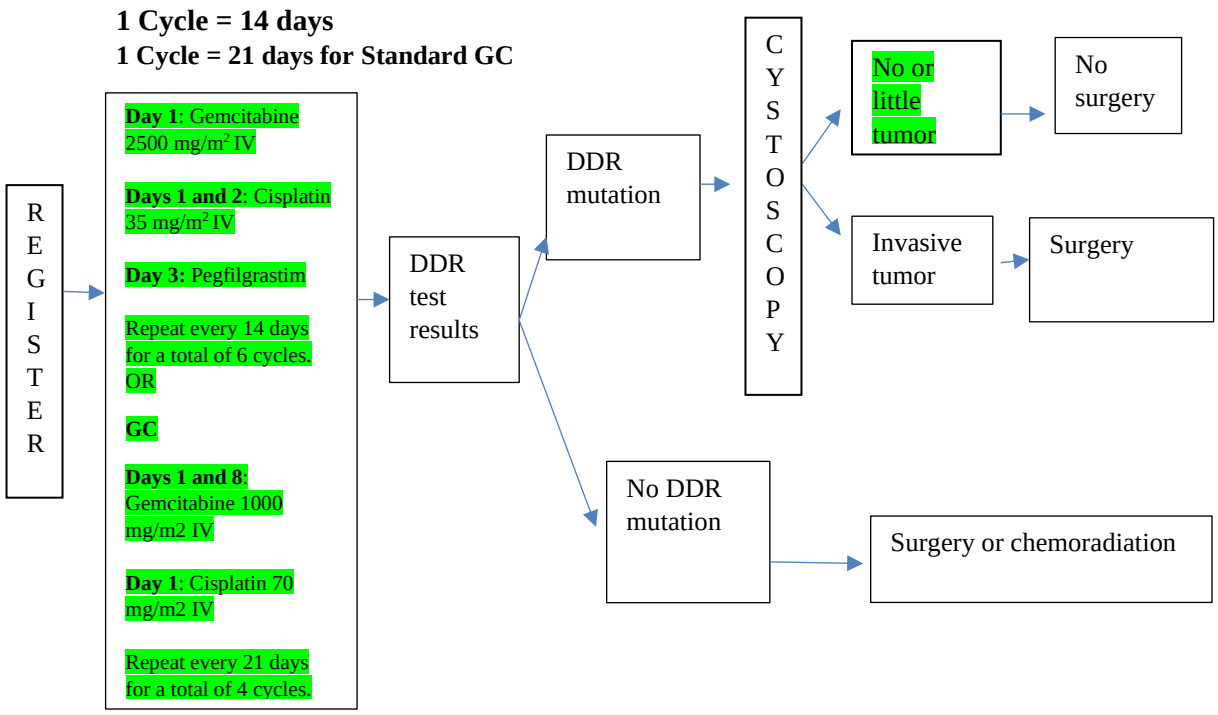
What are the study groups?

In this study, you will get chemotherapy with dose-dense gemcitabine and cisplatin or standard gemcitabine and cisplatin. While receiving chemotherapy, you and your study doctor will receive a report with a list of mutations that were found in your bladder tumor using the MSK-IMPACT test. After finishing chemotherapy, if you have a certain mutation, your surgeon will take another look inside your bladder (a cystoscopy) and measure how much tumor shrinkage has occurred with chemotherapy.

In the dose-dense group, you will get the chemotherapy drug gemcitabine once every 14 days (day 1) and cisplatin for 2 days in a row (days 1 and 2) every 14 days (1 cycle = 14 days). In the standard treatment group, you will get the chemotherapy drug gemcitabine twice every 21 days (day 1 and day 8) and cisplatin on day 1 every 21 days (1 cycle = 21 days). You will also get pegfilgrastim or filgrastim, which will help with the side-effects of the chemotherapy. This treatment with the chemotherapy and pegfilgrastim or filgrastim will last for up to 12 weeks. Before you start the treatment, and after you have been registered to this study, your doctor will send a sample of the biopsy you had that diagnosed your muscle-invasive bladder cancer to a special laboratory at Memorial Sloan Kettering Cancer Center. That laboratory will study the tissue and will look for changes, known as mutations, within genes that are part of DNA damage response (DDR). If your tumor shows that it has mutations within DDR genes, ***and*** you have responded to the gemcitabine and cisplatin, then you may be able to avoid surgery. If your tumor does not have DDR gene mutations, or if the tumor did not respond to the chemotherapy, you will have surgery or chemoradiation. The decision about surgery or chemoradiation will be made by you and the doctors caring for you.

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

Schema



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.

This study includes genetic testing that may identify changes in the genes in your tumor DNA. These results will be returned to you and your study doctor at some point during the 12 weeks that you are receiving chemotherapy. These results will be discussed with you by your study doctor and will help to decide if it is safe for you to avoid surgery to remove your bladder after finishing chemotherapy.

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

Before starting chemotherapy:

- You will have a piece of tumor from your initial biopsy that diagnosed muscle-invasive bladder cancer sent for genetic testing.
- You will have a blood draw sent in for genetic testing

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

General Risks

If you choose to take part in this study, you 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 chemotherapy and surgery 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.

Blood Draw Risks

The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.

Genetic Testing Risks

There are protections in place that restrict who can see the results of your genetic tests. However, there remains a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may increase in the future as people come up with 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. There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

We are only using your normal (non-tumor) cells from your blood to find the changes that are unique to your tumor cells. The test results of your tumor cells will be returned to your doctor who will discuss the results with you. Looking for inheritable mutations in your normal cells (blood) is not the purpose of this study. If you want to have testing done to find inherited mutations, your doctor may recommend that this testing be done separately from this study. This testing may have additional costs outside of this study.

The MSK-IMPACT test has been authorized by the FDA for the genetic testing of tumors. It has been evaluated for accurate and consistent performance by the FDA. As with all medical screening tests, there is a chance of a false positive or false negative result. A "false positive" refers to the identification of a genetic change that is not present. A "false negative" is the failure to find a genetic change that indeed exists. MSK-IMPACT has been designed to ensure that the possibility of incorrect results is low. Either a false positive or a false negative test would mean that you receive an incorrect type of treatment due to an error in the test.

While MSK-IMPACT does not look for inherited genetic changes, testing of the genes in your tumor may rarely show that you have inherited a genetic change that increases the risk of cancer or another disease.

We will now ask if you want to be contacted if tumor genetic testing done as part of this study suggests that you may have inherited a genetic change (mutation) that increases you and your family's risk for cancer or another disease. We will also ask if there is a family member you would like us to tell about this kind of genetic change if you are unable to receive the results, for instance, because you have died or are otherwise incapacitated.

Please read each sentence below and think about your choice. After reading each sentence, circle "YES" or "NO". No matter what you decide to do, it will not affect your care. You will still be allowed to participate in this study even if you don't want to be re-contacted in the future. If you have any questions, please talk to your doctor.

1. Someone may contact me in the future to discuss research findings which may come from my sample. Y/N

   If you circled "Yes" to Question 1, please answer Question 2.

2. If I am unavailable, I give permission to my health care provide to discuss research findings with a family member. Y/N

   Designated family member:
   Name:
   Address:
   Phone:
   Relationship:

Side Effect Risks

The chemotherapy 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.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

Drug Risks

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

Possible side effects of gemcitabine and cisplatin are listed in the tables below. These drugs are part of the usual approach for treating this type of cancer:

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, Gemcitabine, more than 20 and up to 100 may have:
• Nausea, vomiting • Infection, especially when white blood cell count is low • Anemia which may require blood transfusions • Bruising, bleeding • Kidney damage which may cause swelling, may require dialysis • Hearing loss including ringing in ears • Flu-like symptoms of muscle pain, fever, headache, chills and fatigue • Rash • Hair loss • 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 Cisplatin, 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 • Confusion • Difficulty with balance • Diarrhea, constipation • Sores in mouth which may cause difficulty swallowing • Fluid in the organs which may cause low blood pressure, shortness of breath, swelling of ankles

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, Gemcitabine, from 4 to 20 may have:
• Brain damage, Reversible Posterior Leukoencephalopathy Syndrome, which may cause headache, seizure, blindness

RARE, AND SERIOUS In 100 people receiving Cisplatin, Gemcitabine, 3 or fewer may have:
• Cancer of bone marrow (leukemia) caused by chemotherapy later in life • Seizure • Abnormal heartbeat • Heart failure or heart attack which may cause shortness of breath, swelling of ankles, and tiredness • Blisters on the skin • Sores on the skin • Blood clot • Liver damage which may cause yellowing of eyes and skin, swelling • Damage to organs which may cause shortness of breath • Scarring of the lungs • Fluid around lungs • Blockage of the airway which may cause cough

Possible Side Effects of Pegfilgrastim

COMMON, SOME MAY BE SERIOUS In 100 people receiving Pegfilgrastim, more than 20 and up to 100 may have:
• Pain in bone

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Pegfilgrastim, from 4 to 20 may have:
• Anemia which may cause tiredness, or may require transfusion • 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

RARE, AND SERIOUS In 100 people receiving Pegfilgrastim, 3 or fewer may have:
• Rupture of the spleen causing sudden or severe pain in the left side of abdomen spreading up to your shoulder

Possible Side Effects of Filgrastim

COMMON, SOME MAY BE SERIOUS In 100 people receiving Filgrastim, more than 20 and up to 100 may have:
• Nose bleed • Anemia which may require transfusion • Pain • Diarrhea • Fever • Tiredness • Hair loss

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Filgrastim, from 4 to 20 may have:
• Fluid in the organs which may cause low blood pressure, shortness of breath, swelling of ankles • Damage to the lungs which may cause shortness of breath • Internal bleeding which may cause coughing up blood • Cough • Swelling or tenderness of vessels • Headache

RARE, AND SERIOUS In 100 people receiving Filgrastim, 3 or fewer may have:
• Rupture of the spleen causing sudden or severe pain in the left side of abdomen spreading up to your shoulder

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.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your cancer. This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- the costs of getting the cisplatin and gemcitabine ready and giving it to you.
- your insurance co-pays and deductibles.

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

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

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

- The submission of the biopsy for testing for DDR gene mutations at the beginning of the study.
- Blood tests that are sent in with the biopsy to test for the DDR gene mutations

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

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. Contact information for your study doctor is listed on the consent cover page. The study sponsors will not pay for medical

treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

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

No funds have been set aside to compensate you in the event of injury.

Who will see my medical information?

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

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the central research 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 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
- The laboratory at Memorial Sloan Kettering doing the DDR testing on the tissue and blood. Information they need includes your name, date of birth, gender, zip code and country. They also need the pathology report from the bladder cancer surgery/biopsy you had, which is a report that has information about the tumor but also includes information about you, like your name and date of birth. The hospital will send this report in when they send in the tissue for DDR testing. Your contact information will not be shared with Memorial Sloan Kettering. This information is needed to generate a medical record in order to perform and report the DDR testing results to your doctor.

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.

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 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. This optional study will not benefit your health. The researchers leading this optional study hope the results will help other people with cancer in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

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

Circle your choice of "yes" or "no" for the following study

Optional sample collections for 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.

Known future studies

If you choose to take part in this optional study, researchers will collect blood, urine, and tissue for research on DNA and comparing how it looks before and after chemotherapy.

Unknown future studies

If you choose to take part in this optional study, urine, any leftover tissue from your biopsy, or blood specimens will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is being run by the Alliance 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 blood and tissue samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- 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. Some urine will be collected in a container. About 2 tablespoons of blood will be collected from a vein in your arm. A sample from the tissue that was collected at the time of surgery will be sent to the biobank
2. Urine will be collected in a urine specimen cup and sent to the biobank.
3. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
4. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
5. 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 for to protect your privacy. Other than giving your name and other personal information to the laboratory at Memorial Sloan Kettering to do the DDR testing as discussed above in the "who may see my medical information?" section, the study researchers and biobank doing the optional studies:

1. Will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.

2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

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

You will not benefit from taking part.

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

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

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

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

If you decide you no longer want your samples to be used, you can call the study doctor who will let the biobank know. Contact information for your study doctor is listed on the consent cover page. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor. Contact information for your study doctor is listed on the consent cover page.

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

Samples for known future studies:

1) I agree that my samples and related health information may be used for the laboratory studies described above.

   YES NO

Samples for unknown future studies:

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

   YES NO

Contact for Future Research

3) I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

   YES NO

This is the end of the section about optional studies.

My signature agreeing to take part in the study

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

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)

(Required for initial consent only)