Study Title for Participants: Comparing the outcome of standard systemic therapy only versus standard systemic therapy with either surgery or radiation therapy, for patients with advanced prostate cancer.

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
S1802, "Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer."

(NCT#03678025)

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.

You are being asked to take part in this study because you have prostate cancer that has spread and you are either beginning hormone therapy for the first time or have been on hormone therapy for less than 28 weeks.

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 we lower the chance of your prostate cancer growing or spreading by adding either prostate removal surgery or radiation therapy to the usual combination of drugs?

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

The purpose of this study is to compare the effects, good and/or bad, of adding either prostate removal surgery or radiation therapy to standard systemic therapy (SST), which is used to treat prostate cancer. Standard systemic therapy includes Androgen Deprivation Therapy (ADT) with or without the use of chemotherapy. ADT is an antihormone therapy whose main use is in treating prostate cancer. The combination of SST and surgery or radiation therapy is considered experimental.

What is the usual approach to my advanced prostate cancer?

The usual approach for patients who are not in a study is to start treatment with Food and Drug Administration (FDA) approved ADT drugs with or without chemotherapy. These medications can cause prostate cancer to slow its growth, may reduce any symptoms from prostate cancer and will help patients live on average 56 months or longer. Radiation and/or surgery for your prostate cancer are not proven to help patients with your health condition live longer or have better quality of life.

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 receive either only standard systemic therapy (SST) or you will get SST and either surgery to remove your prostate or radiation therapy. The choice of radiation or surgery is up to you and your doctor. For all patients, you will get treatment until your disease gets worse.

After you finish your study treatment, your doctor will continue to follow your condition for up to 8 years. Your doctor will watch you for side effects and to see how your cancer affects you. You will have clinic visits every three months for the first two years, then every six months until your prostate cancer becomes worse. After it worsens, you will have clinic visits every six months until four years from when you started the study, and then once a year until eight years after you started the study.

All of the drugs that are used as part of treatment on this study are commercially available, FDA approved and considered standard treatment for your kind of prostate cancer.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that the study approach (treating patients with SST and either prostate removal therapy or radiation therapy) may not be as good as the usual approach (treating patients with SST only).

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

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

- Bladder difficulties: including stress incontinence, involuntary urination, bladder urgency or frequency. Possible blood in the urine.
- Bowel difficulties: loose stools, rectal irritation, blood per rectum.
- Urinary scarring: narrowing of your urethra or bladder, possibly requiring additional procedures to relieve any blockage.
- Surgical risks associated with the operation or receiving anesthesia: infections, injury to tissues, fluid collections, lung infection, blood clots, other.

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

Benefits

There is evidence that the study approach is effective in reducing the amount of cancer in your body. It is not possible to know now if the study drugs, surgery or radiation will affect how long you live 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. 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.
- 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 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 compare the effects, good and/or bad, of adding either prostate removal surgery or radiation therapy to standard systemic therapy (SST), that is used to treat prostate cancer. The addition of the surgery or radiation therapy to the usual treatment could help patients live longer. 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 the study approach increases the life of patients by 10 months or more, on average, compared to the usual approach.

There will be about 1273 people taking part in this study.

What are the study groups?

This study has 2 study groups. You will be told which group you are in.

- **Group 1**
  If you are in this group, you will continue to receive standard systemic therapy until your disease gets worse or your side effects are too great.

  There will be about 636 people in this group.

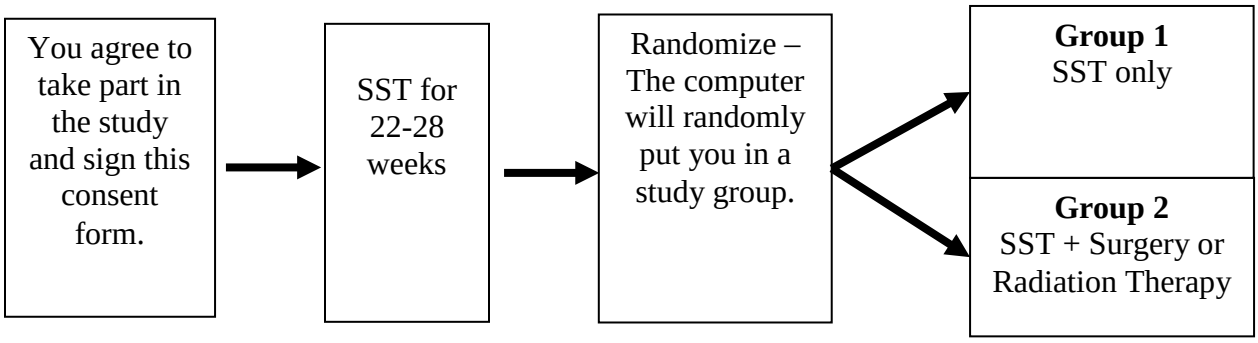
- **Group 2**

  If you are in this group, you will continue to receive standard systemic therapy, but you will also either have surgery to remove your prostate or receive radiation therapy. Your treating study doctor will help to determine in advance whether you are a good candidate for either surgery or radiation.

  There will be about 636 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 study 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 either group.

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, the exams, tests, and procedures performed will be part of your usual standard of care.

Quality of Life

Patients in both study groups who can read and write in English, Spanish or French, must take part in the quality of life study. This is the part of the study that looks to compare whether urinary function and urinary bother worsen using only SST versus SST and surgery or radiation therapy.

You will complete one form with questions about your physical and emotional well-being. Researchers will use this information to learn more about how cancer and cancer treatment affects people. You will be asked to fill out the forms at the following times:

- before you begin treatment
- about 6 months after starting treatment
- about 18 months after starting treatment
- about 30 months after starting treatment
- about 42 months after starting treatment

You will complete forms by paper and pencil. It should take you about 20 minutes or less to fill out the forms at each time point.

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.

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 when receiving any systemic drug therapy after you have completed the study.

Side Effect Risks

The treatment 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 treatment, surgery or radiation.
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 treatment to try to reduce side effects.

This study is looking at a combination of the usual treatment used to treat this type of cancer plus surgery or radiation therapy. This different grouping of treatments may increase your side effects or may cause new side effects. To find out more about the risks of the specific treatment you will get, or any other risks, ask your study doctor.

Drug Risks

The tables below show the most common and most serious side effects doctors know about.

Study Group 1 and Group 2 – Possible side effects of SST drugs are listed in the tables below. These drugs are part of the usual approach for treating this type of cancer.

Possible side effects of Goserelin include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving goserelin, more than 20 and up to 100 may have:
• **Swelling of arms, legs** • **Headache** • **Change in sexual desire** • **Depression, mood swings** • **Abnormal sexual function** • **Shrinkage of the breast** • **Diabetes** • **Vaginal discharge** • **Acne, dandruff** • **Increased sweating** • **Flushing** • **Pain**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving goserelin, from 4 to 20 may have:
• **Heart attack, heart failure which may cause shortness of breath, swelling of ankles, and tiredness** • **Change in the heart rhythm** • **Excessive bleeding leading to weakness or fainting, which requires emergency treatment** • **Bleeding and bruising after injection** • **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat** • **Stroke which may cause paralysis, weakness** • **Kidney damage which may cause swelling, may require dialysis** • **Shortness of breath**

RARE, AND SERIOUS In 100 people receiving goserelin, 3 or fewer may have:
• **A new cancer resulting from treatment of earlier cancer**

Possible side effects of Histrelin include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving histrelin, more than 20 and up to 100 may have:
• **Hot flashes**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving histrelin, from 4 to 20 may have:
• **Fatigue** • **Implant site reaction** • **Erectile dysfunction** • **Breast tenderness, pain, or change in breast size** • **Shrinkage of the testis** • **Kidney damage which may require dialysis** • **Constipation**

RARE, AND SERIOUS In 100 people receiving histrelin, 3 or fewer may have:
• **Weight increased** • **Insomnia** • **Change in sexual desire** • **Headache**

Possible side effects of Leuprolide include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving leuprolide, more than 20 and up to 100 may have:
• **Swelling of the body** • **Pain** • **Nausea, vomiting** • **Vaginal discharge** • **Depression, mood swings** • **Difficulty sleeping** • **Flushing** • **Tiredness** • **Redness or swelling at the site of injection**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving leuprolide, from 4 to 20 may have:
• **Heart attack or heart failure, which may cause shortness of breath, swelling of ankles, and tiredness** • **Blood clot which may cause swelling, pain, shortness of breath** • **Change in the heart rhythm** • **Cough** • **Anemia, which may require blood transfusions** • **Damage to the liver which may cause bleeding** • **Painful urination** • **Constipation** • **Breast tenderness, pain, or change in breast size** • **Shrinkage of the testis** • **Broken bone** • **Thoughts of suicide** • **Dizziness, headache** • **Weight gain** • **Acne** • **Rash**

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

Possible side effects of Triptorelin include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving triptorelin, more than 20 and up to 100 may have:
• **Hot flashes**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving triptorelin, from 4 to 20 may have:
• **High blood pressure which may cause blurred vision** • **Seizure** • **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat** • **Swelling of arms, legs** • **Blockage of the airway which may cause cough** • **Severe blood infection** • **Infection which may cause frequent urination** • **Headache** • **Pain** • **Painful urination** • **Difficulty emptying the bladder or urinating** • **Abnormal sexual function** • **Breast tenderness or swelling** • **Shrinkage of the testis** • **Change in sexual desire** • **Difficulty sleeping** • **Swelling or redness at the site of injection**

RARE, AND SERIOUS In 100 people receiving triptorelin, 3 or fewer may have:
• **Nausea, vomiting** • **Dizziness** • **Tiredness**

Possible side effects of Nilutamide include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving nilutamide, more than 20 and up to 100 may have:
• **High blood pressure which may cause headaches** • **Blurred vision, decreased vision at night** • **Constipation, nausea** • **Difficulty in having or maintaining an erection** • **Dizziness** • **Hot flashes**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving nilutamide, from 4 to 20 may have:
• **Infection, especially when white blood cell count is low** • **Bruising, bleeding** • **Anemia which may cause tiredness, or may require transfusion**

RARE, AND SERIOUS In 100 people receiving nilutamide, 3 or fewer may have:
• **Heart failure which may cause shortness of breath, swelling of ankles, and tiredness** • **Scarring of the lungs which may cause cough or shortness of breath** • **Inflammation of the liver which may cause yellow eyes and skin**

Possible side effects of Flutamide include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving flutamide, more than 20 and up to 100 may have:
• **Diarrhea, nausea** • **Hot flashes** • **Rash**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving flutamide, from 4 to 20 may have:
• **Anemia which may cause tiredness, or may require blood transfusions** • **Liver damage which may cause yellowing of eyes and skin, swelling**

RARE, AND SERIOUS In 100 people receiving flutamide, 3 or fewer may have:
• **Bruising, bleeding** • **Infection, especially when white blood cell count is low**

Possible side effects of Bicalutamide include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving bicalutamide, more than 20 and up to 100 may have:
• **Hot flashes** • **Breast swelling or pain** • **Constipation** • **Pain** • **Tiredness**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving bicalutamide, from 4 to 20 may have:
• **Diarrhea, nausea** • **Swelling of arms, legs** • **Liver damage which may cause yellowing of eyes and skin, swelling** • **Inflammation of the liver** • **Infection** • **Blood in urine** • **Increased urination at night** • **Heart attack or heart failure which may cause chest pain, shortness of breath, swelling of ankles, and tiredness**

RARE, AND SERIOUS In 100 people receiving bicalutamide, 3 or fewer may have:
• None

Possible side effects of Degarelix include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving degarelix, more than 20 and up to 100 may have:
• **Hot flashes** • **Abnormal sexual function** • **Change in sexual desire** • **Tiredness** • **Breast tenderness or enlargement** • **Diarrhea** • **Loss of bone tissue**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving degarelix, from 4 to 20 may have:
• **Anemia, which may require blood transfusions** • **Headache** • **Pain** • **Liver damage which may cause yellowing of eyes and skin** • **Swelling of the body** • **Infection** • **Nausea** • **Bruising, bleeding** • **Mood swings, depression** • **Increased urination** • **Weight gain** • **Shrinkage of the testis** • **Broken bone**

RARE, AND SERIOUS In 100 people receiving degarelix, 3 or fewer may have:
• **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat** • **Heart attack, heart failure which may cause shortness of breath, swelling of ankles, and tiredness** • **Diabetes**

Possible side effects of Docetaxel include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving docetaxel, more than 20 and up to 100 may have:
• **Swelling of the body** • **Hair loss** • **Change in nails** • **Rash, itching** • **Vomiting, diarrhea, nausea, constipation** • **Sores in mouth which may cause difficulty swallowing** • **Infection, especially when white blood cell count is low** • **Anemia which may require blood transfusions** • **Bruising, bleeding** • **Tiredness** • **Numbness and tingling of the arms and legs** • **Fever** • **Absence of menstrual period** • **Swelling and redness of the arms, leg or face** • **Pain** • **Watering, itchy eyes**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving docetaxel, from 4 to 20 may have:
• **Severe skin rash with blisters and peeling which can involve inside of mouth and other parts of the body** • **Belly pain** • **Kidney damage which may require dialysis** • **Blood clot which may cause swelling, pain, shortness of breath** • **Abnormal heart rate** • **Shortness of breath, wheezing** • **Chest pain**

RARE, AND SERIOUS In 100 people receiving docetaxel, 3 or fewer may have:
• **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat** • **Cancer of bone marrow (leukemia) caused by chemotherapy**

Docetaxel may cause you to become intoxicated from the alcohol it contains. You should avoid driving, operating machinery, or performing other activities that are dangerous within one to two

hours after the infusion of docetaxel. In addition, some medications, such as pain relievers and sleep aids, may interact with the alcohol in the docetaxel infusion and worsen the intoxicating effects. Less than 3% of people may experience scarring and thickening or inflammation of the tissue around the air sacs of the lungs.

Possible side effects of Prednisone include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving prednisone, more than 20 and up to 100 may have:
• **High blood pressure which may cause headaches, dizziness, blurred vision** • **Pain in belly** • **Loss of bone tissue** • **Mood swings** • **In children and adolescents: decreased height** • **Swelling of the body, tiredness, bruising** • **Increased appetite and weight gain in the belly, face, back and shoulders** • **Difficulty sleeping** • **Skin changes, acne**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving prednisone, from 4 to 20 may have:
• **Blood clot which may cause swelling, pain, shortness of breath** • **Infection** • **Kidney stones** • **Diabetes** • **Glaucoma** • **Cloudiness of the eye, visual disturbances, blurred vision** • **A tear or a hole in the bowels which may cause belly pain or that may require surgery** • **Heartburn** • **Damage to the bone which may cause joint pain and loss of motion** • **Numbness and tingling of the arms, legs and upper body** • **Muscle weakness** • **Non-healing wound**
RARE, AND SERIOUS In 100 people receiving prednisone, 3 or fewer may have:
• **Bleeding from sores in the stomach** • **Broken bones**

Possible side effects of Abiraterone Acetate include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving abiraterone acetate, more than 20 and up to 100 may have:
• **Swelling of the body** • **Flushing** • **Diarrhea** • **Anemia which may require blood transfusion** • **Tiredness**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving abiraterone acetate, from 4 to 20 may have:
• **High blood pressure which may cause headaches, dizziness, blurred vision** • **Abnormal heartbeat** • **Heart attack, which may cause chest pain, or fatal heart attack** • **Bruising** • **Vomiting** • **Urine infection, which may cause painful and frequent urination** • **Cough** • **Shortness of breath**

RARE, AND SERIOUS In 100 people receiving abiraterone acetate, 3 or fewer may have:
• **Heart failure which may cause swelling of ankles** • **Pain in chest**

Study Group 2 - In addition to side effects listed above, people who are in Group 2 may also have the following side effects:

Possible Side Effects of Surgery

Side effects from surgery could include, bleeding, infection, temporary abdominal pain during recovery, possible urinary stress incontinence, possible erectile dysfunction. Additional potential side effects should be discussed with your treating urologist.

Possible Side Effects of Radiation Therapy

Side effects of radiation may include: skin irritation/rash, temporary loose or watery stools, possible rectal bleeding, possible urinary irritation. Additional risks should be discussed with your treating Radiation Oncologist.

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, 20 to 100 may have:
• Reddening, tanning, or peeling of the skin • Mild pain • Hair loss • Tiredness • Diarrhea, nausea • Anemia, which may require transfusion • Infection, especially when white blood cell count is low

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, 4 to 20 may have:
• Thickening and numbness of the skin • Sores or ulcers on the skin or near the cancer location • Permanent hair loss • Bleeding from the skin • Sores in mouth which may cause difficulty swallowing

RARE, AND SERIOUS In 100 people receiving radiation therapy, 3 or fewer may have:
• Damage to internal organs • Abnormal opening in internal organs which may cause pain and bleeding

You should talk to your study doctor about any side effects that you have while taking part in the study.

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 patients: Do not father a baby while taking part in this study. Tell your study doctor right away if you think that your partner has become pregnant during the study or at any point if you are on continuous drug therapy.

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

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

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

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

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

Who will see my medical information?

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

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

There are organizations that may look at 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 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

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, you may contact 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.

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, the following samples will be collected and stored.

You have had a biopsy (or surgery) to see if you have cancer. Your doctor removed some body tissue to do some tests. The results of these tests will be given to you by your doctor and will be used to plan your care. If you agree, we would like to take a sample of your blood and some of the tumor tissue to keep for future research. The specimens will be kept and may be used in research to learn more about cancer and other diseases. This research may include studying the biology of your cancer and whether bone markers (or other biomarkers) predict how prostate cancer responds to treatment. One blood sample (about 6 teaspoons) will be collected at the following four time points: study enrollment, randomization to Group 1 or Group 2, at month 3 visit, and at disease advancement. The tumor tissue sample will be taken from your prostate cancer specimen (obtained from your prostate biopsy). (You will not need to have another surgery for this purpose.) These collections are optional.

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. Tumor tissue: A small amount of tissue will be taken from the biopsy. Blood: About six teaspoons of blood will be collected from a vein in your arm.
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. 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?

- 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/
- The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. However, the blood sample will be drawn when you are having blood drawn for laboratory tests needed to check your general health.

How will information about me be kept private?

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

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

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

You will not benefit from taking part.

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

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

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

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

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

What if I have questions about this optional sample collection?

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

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

Samples for unknown future studies:

My samples and related information may be kept in a Biobank for use in future health research.

YES **NO**

Contact for Future Research

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**

This is the end of the section about optional studies.

Signature:

This study has been explained to me, and I have been told what my enrollment in the study involves. I have read all pages of this consent and have had my questions answered to my satisfaction at this time. I consent to participate in this study and any additional studies where I circled 'yes'. I understand that by signing this form I have not given up any of my legal rights. I will be given a copy of this consent form. I may also request a copy of the protocol (full study plan).

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)

(Required for initial consent only)