Study Title for Participants: Testing the Addition of a New Anti-Cancer Drug, Niraparib, to the Usual Treatment (Hormone and Radiation Therapy) for Prostate Cancer With a High Chance Of Recurring

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
Protocol NRG-GU007, Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (With Initial Phase I) (NADIR*) (NCT 04037254)
Randomized Phase II Trial of **Niraparib With Standard Combination **A**ndrogen **D**epr**I**vation Therapy (ADT) and **R**adiotherapy In High Risk Prostate Cancer (With Initial Phase I)*

Overview and Key Information

What am I being asked to do?
We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have prostate cancer that has a high chance of coming back.

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 prostate cancer growing or returning by adding a new drug to the usual treatment?

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 that has a high chance of coming back.

What is the usual approach to my prostate cancer?

The usual approach for patients who are not in a study is treatment with Food and Drug Administration (FDA)–approved hormonal drugs and radiation therapy. For patients who get the usual approach for this cancer, about 30 out of 100 are cancer free after 2 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 your cancer.

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

If you decide to take part in this study, you will get either:

- the usual hormonal drugs for up to 24 months plus the usual radiation therapy for 6 to 9 weeks, or
- the usual hormonal drugs for up to 24 months; plus the usual radiation therapy for 6 to 9 weeks; plus the experimental study drug, niraparib, for up to 12 months. Niraparib is not FDA approved for prostate cancer.

After you finish your treatment, your doctor and study team will watch you for side effects. They will check you every 6 months for 3 years after treatment. After that, they will check you every year for 3 years. This means you will keep seeing your doctor for 6 years after treatment.

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 may not be as good as the usual approach for your cancer at preventing your cancer from coming back.

There is also a risk that you could have side effects from the study approach. These side effects may be worse and may be different than you would get with the usual approach for your cancer. Some of the most common side effects that the study doctors know about are:

- Fatigue
- Low blood counts that may cause infection or bleeding
- High blood pressure

- Hot flashes
- Erectile dysfunction
- Bleeding in urine or stool

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

Benefits
There is evidence that this approach may be effective in shrinking or stabilizing your type of cancer. It is not possible to know now if the study approach will extend your time without disease 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 Institutional Review Board (IRB); Food and Drug Administration (FDA); or study sponsors, National Cancer Institute and NRG Oncology. The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to compare the usual treatment alone to using the study drug niraparib plus the usual treatment. The addition of niraparib to the usual treatment could prevent your cancer from growing or 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 be better, the study approach should increase the chance of remaining cancer free to 50 out of 100 participants after 2 years, or a 20% improvement compared to the usual approach.

What are the study groups?

This study has 2 study groups.

- **Arm 1**
  If you are in this group, you will get the usual approach used to treat this type of cancer (hormone therapy and radiation therapy). You will get FDA-approved hormone therapy for 24 months, and you and your doctor will decide which hormone regimen is best for you. Beginning 8 to 28 weeks after you start hormone therapy, you will receive radiation therapy 5 days per week for a period of about 6 or 9 weeks, depending on the type of radiation therapy you receive. See the study chart below for more information.

  There will be about 90 people in this group.

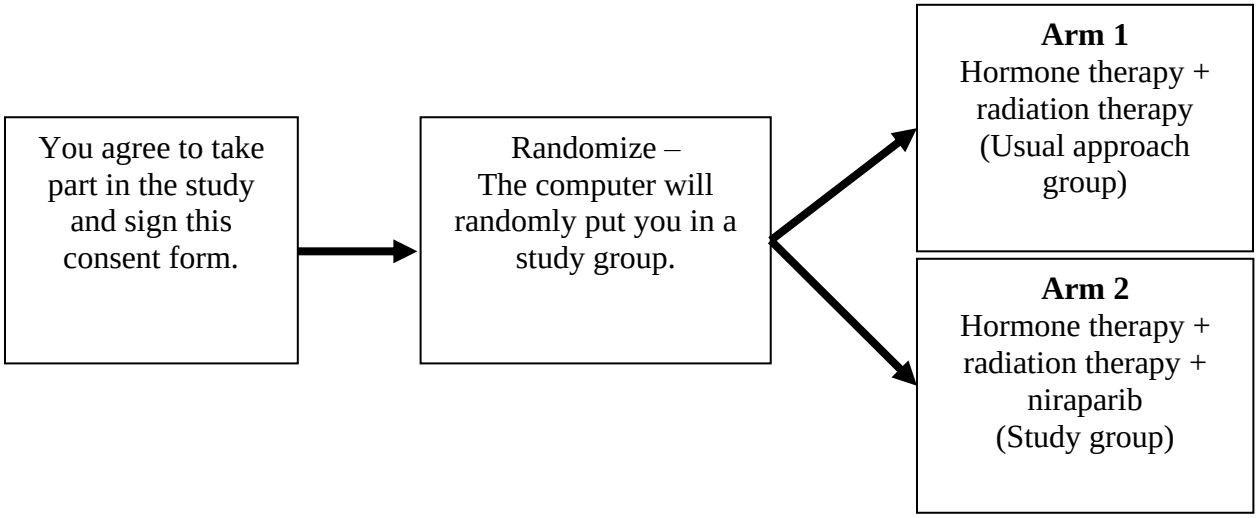
- **Arm 2**
  If you are in this group, you will get a study drug called niraparib plus the usual approach used to treat this type of cancer (hormone therapy and radiation therapy). You will get the hormone and radiation therapy as described above for Arm 1. In addition, you will receive the study drug niraparib as a pill you take by mouth, once a day for 1 year. See the study chart below for more information.

  You will not be able to get additional doses of the drug. This drug is not approved by the FDA for treatment of prostate cancer.

  There will be about 90 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 Arm 1 or Arm 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:

For patients receiving niraparib:

- Blood tests to monitor for side effects including risk of infection, bleeding, and anemia, taken weekly for the first month of niraparib therapy, then every 2 weeks for month 2 and 3, then every month for months 4 through 12.. You or your insurance provider will pay for these tests.
- Blood pressure and heart rate measurements will be taken and recorded weekly for 8 weeks after starting the drug, then monthly until end of treatment. This can be done either in the doctor's office or at home. If needed to be done at home, blood pressure cuffs and instructions will be provided by your study team (there is more information about blood pressure and heart rate monitoring in the Risks section and What are my responsibilities).

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.

Specimen Collection
Your study doctor will need to use some of the tissue left over from your biopsy when you were diagnosed with cancer. This sample is a required part of the study. You will also need to have a blood sample taken for the study. The sample will be taken before you begin study treatment. Patients with breast, ovarian and prostate cancer mutations in certain genes have been shown to have increased sensitivity to drugs like niraparib. Therefore, we would like to perform testing for these gene mutations from the cells from your tumor tissue and blood samples. We will also look at the levels of gene activity in your tumor tissue to help understand response to the niraparib. You and your study doctor will not get the results of this testing.

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 at preventing your 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 treatments used in this study could be very harmful to an unborn 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 3 months (90 days) after you have completed the study treatment.

This study will use a sample of your tissue. Generally, your hospital will keep some of your tissue. This tissue may be used to help treat your 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.

Genetic Testing Risks
The genetic tests used in this study will test your tumor for genetic changes for genes most commonly altered in prostate cancer. These changes also may be in 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.

Since this study is only testing tumor tissue, we will not know if a genetic change in your tumor is also in your normal tissue. If you want to find out if the change is in your normal tissue, then you will need to get other tests done outside of this study.

Genetic tests of normal tissue can reveal information about you and also about your relatives. Your study doctor will talk with you about what testing your normal tissue may mean for you

and your family. He or she also may suggest that you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for any genetic tests and visits to a genetic counselor done outside of this study.

Risks of Blood Draws
The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. Rarely, an infection can occur.

Side Effect Risks
The radiation and drug therapy 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 radiation and drugs.

Here are important things to know about side effects:

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

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

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

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 Arm1 and Arm 2 – Possible side effects of hormone therapy are listed in the tables below. These drugs are part of the usual approach for treating this type of cancer:

Possible Side Effects of Hormone Therapy
There are a number of different drugs that can be used for hormone suppression therapy. You and your doctor will choose the drug that is best for you. The risks below describe the side

effects of hormone suppression therapy, in general. Your study doctor will discuss any side effects specific to the drug selected for your hormone suppression therapy.

COMMON, SOME MAY BE SERIOUS In 100 people receiving hormone suppression therapy, 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 hormone suppression therapy, 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 hormone suppression therapy, 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

Study Arm 2 - In addition to side effects listed above, people who are in Arm 2 may also have some side effects from niraparib. These side effects are listed below.

Possible Side Effects of Niraparib

Potential Discomforts, Side Effects, and Risks Associated with Niraparib

High Blood Pressure

High blood pressure and changes in heart rate are common side effects of niraparib. Rarely extremely high blood pressure can occur, called hypertensive crisis. To watch for changes in blood pressure, your doctor will check your blood pressure and heart rate every week for 8 weeks and then once a month until you stop niraparib. If it is not possible to visit your doctor, you will be given equipment and instructions to monitor your blood pressure and heart rate at home and instructions to communicate the results to your doctor. The blood pressure cuff should only be used by you.

Potential for a new blood cancer myelodysplastic syndrome and acute myeloid leukemia (MDS / AML), a new primary cancer, pneumonitis (inflammation of the lungs), or embolic and thrombotic events (blood clots):

Niraparib belongs to a group of drugs called PARP inhibitors. This group of drugs are suspected of causing new blood cancers known as myelodysplastic syndrome (MDS and acute myeloid leukemia (AML). Because niraparib is a PARP inhibitor there is a potential risk of developing a new blood cancer leading to leukemia. If you have had MDS or leukemia before entering this study, you are at increased risk for developing leukemia again and must tell your Study Doctor before starting this study. Although rare, approximately 9 out of 1379 patients in niraparib clinical trials have had MDS/AML. In a randomized trial comparing niraparib to placebo (i.e. sugar pill) of recurrent ovarian cancer patients, the incidences of MDS/AML in patients who took niraparib were similar to those in patients who took placebo. PARP inhibitors may also cause a new primary cancer (that is, a cancer other than the one for which you were treated).

Safe Handling of Drug

Caregivers should wear gloves if they need to touch the niraparib capsules. You should notify any caregivers of this information, to ensure the appropriate precautions are taken.

VERY COMMON, SOME MAY BE SERIOUS In 100 people receiving niraparib, more than 10 and up to 100 may have:
• Anemia which may require blood transfusion • Bruising, bleeding which may require platelet transfusion • Constipation • Nausea, vomiting, diarrhea • Decreased appetite, change in taste • Pain including in the belly, muscles, joints, and back • Heart burn

VERY COMMON, SOME MAY BE SERIOUS In 100 people receiving niraparib, more than 10 and up to 100 may have:
• Difficulty sleeping • Headache • Tiredness, weakness • Infection , especially when white blood cell count is low, which may cause painful and frequent urination, upper airway infection, nose and throat infection • Shortness of breath • High blood pressure • Dizziness • Cough • Abnormal heart beat

COMMON, SOME MAY BE SERIOUS In 100 people receiving niraparib, from 1 to 10 may have:
• Infection related to low neutrophils (a type of white blood cell that fights infection) • Dry mouth • Worry, depression • Nose bleeds • Rash • Swelling of arms and legs • Swelling or irritation of lining of throat or bowels • Liver damage which may cause yellowing eyes and skin, swelling • Kidney damage which may require dialysis • Weight loss • Swelling and redness of the eye • Low blood potassium • Increased skin sensitivity to sunlight and increased risk of sunburn.

UNCOMMON, AND SERIOUS In 100 people receiving niraparib, 1 or fewer may have:
• Fever along with a decrease in neutrophils (a type of white blood cell that fights infection). • Low counts of all three types of blood cells: red blood cells, white blood cells, and platelets

VERY RARE, AND SERIOUS In less than 1 out of 1,000 people but more than 1 out of 10,000 people:
• Posterior reversible encephalopathy syndrome (PRES) - changes in the brain that can cause symptoms including headache, confusion, seizures and visual loss associated with magnetic resonance imaging (MRI) finding. The symptoms tend to resolve after a period of time, although visual changes sometimes remain. • A potentially life threatening condition affecting multiple organ systems, caused by the body's response to an infection related to low counts of a type of white blood cell called neutrophils. • Extremely high blood pressure—a top number (systolic pressure) of 180 millimeters of mercury (mmHg) or higher or a bottom number (diastolic pressure) of 120 mmHG or higher—that can damage blood vessels, cause a stroke, or other problems.

Additional Drug Risks
All drugs have a possible risk of an allergic reaction, which if not treated right away, could become life-threatening.

The study drug could interact with other drugs.

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

Radiation Therapy Risks

Study Arm 1 and Arm 2 – Possible side effects of prostate bed radiation are listed in the tables below. Prostate bed radiation is part of the usual approach for treating this type of cancer:
Possible Side Effects of Radiation Therapy to the Prostate Bed (excluding pelvis)

COMMON, SOME MAY BE SERIOUS In 100 people receiving prostate radiation, more than 20 and up to 100 may have:
• Need to urinate more often • Urgency with urination • Slower urinary flow • Pain, including with urination and/or bowel movements • Hair loss in the treatment area, may be permanent • Tiredness • Abnormal sexual function, may be permanent

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving prostate radiation, from 4 to 20 may have:
• Chronic bowel/bladder symptoms as described above • Blood in urine

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving prostate radiation, from 4 to 20 may have:
• Inability to control urine, inability to control bowel movements • Diarrhea • Bleeding of the rectum • Swelling, redness, rash, skin changes, or itching in the area of radiation

RARE, AND SERIOUS In 100 people receiving prostate radiation, 3 or fewer may have:
• Blockage of internal organs that may require surgery • Damage to or bleeding of the rectum requiring surgery • A new cancer resulting from treatment of earlier cancer

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.
- Write down in your medication diary when you take the study drug at home.
- If you are taking Niraparib, measure your heart rate and blood pressure at home and write down the results in a diary as instructed.

Do not father a baby while taking part in this study. If you agree to participate in this study, you are expected to inform your female sexual partner(s) that you are participating in a clinical research study of an investigational drug and that the effects of the drug on sperm, an unborn baby and on a pregnant woman are unknown.

Tell your study doctor right away if you think your partner has become pregnant during the study or within 3 months after your last dose of study treatment.

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 hormone therapy ready and giving it to you.
- the costs of getting the radiation therapy 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 collection, shipment, and processing of your pre-treatment tissue and research-related blood samples

Niraparib will be supplied by Janssen at no charge while you take part in this study. You or your insurance provider will not have to pay for the niraparib while you take part in this study.

Blood pressure cuffs will be provided to patients receiving niraparib at no charge for use in this study.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

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

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

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. 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
- NRG Oncology and any company supporting the study now or in the future.
- 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, including the Imaging and Radiation Oncology Core (IROC)

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.

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. These optional studies 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 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, a sample of tissue from your previous biopsy, along with blood and urine will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is being run by NRG Oncology 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. 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 tissue, blood, and urine 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.

What is involved in this optional sample collection?

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

1. About 2 tablespoons of blood will be collected from a vein in your arm at the following times: before you begin radiation (Arm 1 patients) or niraparib (Arm 2 patients); within 7 days after finishing either niraparib or 12 months of hormone treatment; and if your cancer comes back. The blood can be collected at the same time as blood draws taken for the main part of the study.
   About 2 tablespoons of urine will be collected before you begin radiation (Arm 1 patients) or niraparib (Arm 2 patients). The urine can be collected at the same time as your study visit for the main part of the study.
   Remaining tissue from the sample of tissue that was collected as part of your participation on the main study will be sent to the biobank.

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. Researchers will not be given your name or contact information.
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.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

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

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

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

You will not benefit from taking part.

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

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

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

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

If you decide you no longer want your samples to be used, you can call the study doctor, who will let the biobank know. Contact information for your study doctor is listed on the consent cover page. 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:

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

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)