NRG Oncology GYN Informed Consent Template

Research Study Informed Consent Document

Study Title for Participants: Testing the combination of olaparib and cediranib in comparison to cediranib alone, and olaparib alone in recurrent endometrial cancer.

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Protocol NRG-GY012: A Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer.

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 research study because you have endometrial cancer which has grown or has returned after earlier treatment. This is a study to look at a different approach to treating endometrial cancer.

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 endometrial cancer growing or spreading by giving a combination of two experimental drugs or one experimental drug rather than the usual approach?

The purpose of this study is to compare any good and bad effects of using experimental study drugs cediranib alone, olaparib alone, or a combination of cediranib and olaparib.

These drugs could shrink your cancer but they could also cause side effects. This study will allow the researchers to know whether one of these approaches is better, the same, or worse than the usual approach.

The usual approach is defined as care most people get for endometrial cancer.

What is the usual approach to my endometrial cancer?

The usual approach for patients who are not in a study is treatment with either surgery, radiation, or with chemotherapy drugs. The only Food and Drug Administration (FDA) approved treatment for endometrial cancer is the progesterone hormone, megestrol acetate (Megace). Common chemotherapy drugs used to treat endometrial cancer are, doxorubicin, liposomal doxorubicin, paclitaxel, carboplatin, cisplatin and topotecan. Sometimes, combinations of these are used and your doctor can explain which may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for several months or more.

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, a computer will by chance assign you to treatment groups in the study. This is called randomization. You will either get the study drugs cediranib and olaparib or you will get cediranib alone or olaparib alone. You will receive the study drug(s) for as long as you continue to benefit and your doctor thinks it is safe to keep you on therapy.

After you finish your treatment, your doctor and study team will watch you for side effects. They will check you in the clinic every 3 months for 2 years after treatment. After that, they will check you every 6 months for 3 years. This means you will keep seeing your doctor for 5 years after treatment for approximately 14 total visits.

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 drugs may not be as good as the usual approach shrinking or stabilizing your cancer.

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

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

- Anemia,
- Diarrhea, nausea, vomiting
- Tiredness
- Loss of appetite
- High blood pressure

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

Benefits

There is evidence that chemotherapy may be effective in extending the time until your cancer grows again by a few months. It is not possible to know now if the drugs included in this study: Olaparib, cediranib, or the combination of olaparib and cediranib will extend the time until your cancer starts to grow again 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.
- You become pregnant while on the study.
- The study is stopped by Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor the National Cancer Institute (NCI). 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?

This study will help the study doctors to compare any good and bad effects of using experimental study drugs cediranib alone, olaparib alone, or a combination of cediranib and olaparib.

These drugs could shrink your cancer but it could also cause side effects which are described in the risks section below. This study will allow the researchers to know whether this different approach is better, the same, or worse than the usual approach.

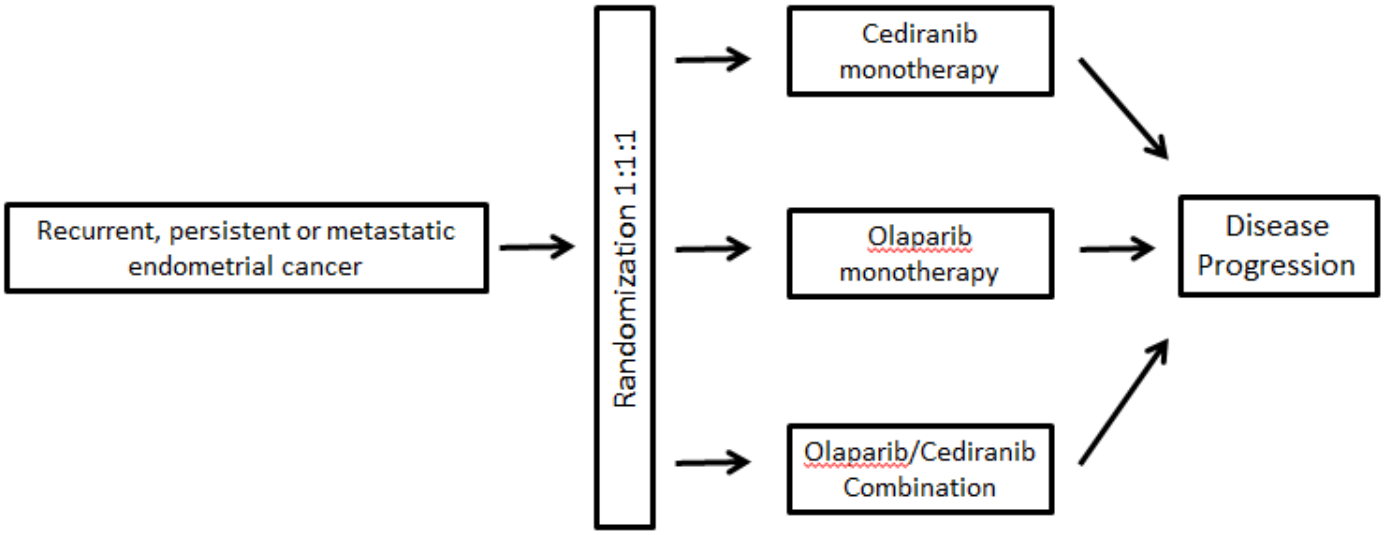
There will be about 120 people taking part in this study.

What are the study groups?

This study has three study groups. You will be placed in 1 of the 3 study groups:

- Group 1 – cediranib alone
- Group 2 – olaparib alone
- Group 3 – cediranib and olaparib

A computer will by chance assign you to a treatment group in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the others. You will have an equal chance of being placed in each group. 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.



Cediranib alone is taken at 30mg once a day on an empty stomach, one hour before or two hours after a meal. If a dose is missed, the next dose should be taken on time. A treatment cycle is 28 days.

Olaparib alone is taken at 300mg twice a day. If a dose it missed, the next dose should be taken on time. A treatment cycle is 28 days.

Olaparib and cediranib together are taken as follows: Olaparib 200mg twice a day, cediranib 30mg once per day on an empty stomach, one hour before taking the morning dose of olaparib. If a dose is missed the next dose should be taken on time. A treatment cycle is 28 days.

Please note: olaparib and cediranib tablets should be swallowed whole and not chewed, crushed, dissolved or divided.

You will be asked to maintain a medication diary and must bring it to each medication visit along with the pill bottle and any remaining medication.

Cediranib and olaparib interact with other drugs you may be taking. You will be given a drug information handout and wallet card that lists these possible interactions. The intent is for you to share this information with family members, caregivers, other health care providers, and pharmacists.

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.

- A pregnancy test if of child-bearing capacity

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.

During the study:

Your study doctor will need to use some of the tissue left over from your surgery or biopsy when you were diagnosed with cancer and will also collect some of your blood. These samples are a required part of the study. The tumor tissue will be used to look at changes in certain genes and the blood will be used to look for certain proteins. You and your study doctor will not get the results of this testing.

For patients receiving cediranib blood pressure measurement twice daily for 8 weeks after starting the drug will be required. If there are no issues with the blood pressure blood pressure measurement can be reduced to once daily. If high blood pressure medication is required or cediranib is discontinued further twice daily measurement may be required. Equipment and instructions will be provided by your study team for measuring blood pressure at home.
You will require computed tomography (CT) scans to determine if the study drugs are working every two cycles, 8 weeks.

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 drugs may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

You also may have the following discomforts:

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

The drugs used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study.

Patients randomized to cediranib must use 2 effective forms of contraception while receiving study treatment and for at least 6 weeks after the last dose of cediranib. Patients randomized to

olaparib must use 2 effective forms of contraception while receiving study treatment and for at least 3 months (12 weeks) after the last dose of olaparib. Patients of childbearing potential will need to have a negative serum or urine pregnancy test within 3 days prior to the start of study treatment. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

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 test used in this study will test your tumor and blood for genetic changes; specifically, homologous recombination deficiency (HRD). Changes found in your blood may be passed down in families. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Genetic tests of normal tissue can reveal information about you and also about your relatives. Your doctor will talk with you about what the tests results may mean for you and your family. He or she also may suggest you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for visits to a genetic counselor.

Side Effect Risks

The drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study drugs.

Here are important things to know about side effects:

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

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

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

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 Olaparib

COMMON, SOME MAY BE SERIOUS In 100 people receiving olaparib (AZD2281), more than 20 and up to 100 may have:
• Anemia which may require blood transfusion • Diarrhea, nausea, vomiting • Tiredness • Loss of appetite
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving olaparib (AZD2281), from 4 to 20 may have:
• Bloating, constipation, heartburn • Pain • Swelling of arms, legs • Fever • Infection • Dizziness, headache • Changes in taste • Cough, shortness of breath
RARE, AND SERIOUS In 100 people receiving olaparib (AZD2281), 3 or fewer may have:
• Cancer of bone marrow caused by chemotherapy • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions • Damage to the lungs which may cause shortness of breath

Myelodysplasia (the occurrence of irreversible abnormal blood counts and bone marrow damage, which may lead to leukemia) has been reported in a small number of patients who have received olaparib. Your study doctor will monitor your blood counts closely while you are on study treatment and may ask you to undergo additional tests if they are concerned you are at risk for developing myelodysplasia.

Possible Side Effects of Cediranib

COMMON, SOME MAY BE SERIOUS In 100 people receiving cediranib (AZD2171), more than 20 and up to 100 may have:
• Diarrhea, nausea • Tiredness • Loss of appetite • Changes in voice • High blood pressure which may cause headaches, dizziness, blurred vision

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving cediranib (AZD2171), from 4 to 20 may have:
• Pain • Constipation, vomiting • Dry mouth • Difficulty swallowing • Sores in the mouth • Infection • Bruising, bleeding • Weight loss • Dehydration • Muscle weakness • Dizziness, headache • Cough, shortness of breath, sore throat • Redness, pain or peeling of palms and soles • Blood clot which may cause swelling, pain, shortness of breath, confusion, or paralysis

RARE, AND SERIOUS In 100 people receiving cediranib (AZD2171), 3 or fewer may have:
• Anemia, kidney problems which may cause tiredness, bruising, swelling, or may require dialysis • Heart failure which may cause shortness of breath, swelling of ankles, and tiredness • A tear or hole in internal organs that may require surgery • Liver damage which may cause yellowing of eyes and skin, swelling • Non-healing surgical site • Damage to the brain which may cause changes in thinking • Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome) • Kidney damage which may require dialysis • Blood clot in artery which may cause swelling, pain, shortness of breath or change of color in extremity

Other effects that have been reported by other participants taking the combination of cediranib and olaparib, although it is not clear that they are related to taking both cediranib and olaparib, include:

- Muscle tear in the shoulder(s): this can cause pain and inability to lift your arm(s).

Additional Drug Risks

The study drug could interact with other drugs Over-the-counter drugs (including herbal supplements, such as St. Johns Wort) may contain ingredients that could interact with your study drug. Speak to your doctor about any over the counter drugs or supplements you may be taking.

- Avoid ingesting grapefruit, grapefruit juice and Seville oranges while taking olaparib.
- Avoid taking the herbal supplement St. Johns Wort while taking olaparib

Your study doctor will give you a drug information handout and wallet card that lists these possible interactions. Share this information with your family members, caregivers, other health care providers, and pharmacists.

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

Imaging Risks

The CT scans that you get in this study will expose you to low amounts of radiation. Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. This type of radiation is called “background radiation.” No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The CT scan that you get in this study will expose you to more radiation than you get from everyday background radiation. The amount of radiation from this scan is the same as 2 years' worth of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

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.
- Do not get pregnant or breastfeed while taking part in this study. Tell your study doctor right away if you think that you have become pregnant during the study or within 3 months after your last dose of study drug.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your 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 cost of getting the study drug(s) ready and giving it to you is not paid by the study sponsor so you or your insurance company may have to pay for this. It is possible that the study drug(s) may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options
- your insurance co-pays and deductibles.

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

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

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

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:

- Submission of the tissue left over from your surgery or biopsy when you were diagnosed with cancer for research purposes
- Collection of some of your blood for research purposes

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:

- The study sponsor- NCI-CTEP and Astra Zeneca.
- 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, including NRG Oncology.
- The NRG Oncology Biospecimen Bank-Columbus (Biobank) and laboratories designated by NRG Oncology to perform testing as part of the study.
- Montana Cancer Consortium

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, 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 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 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 each of the following studies.

Optional bio-banking 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, any tumor tissue and blood remaining after completion of the study testing will be 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.

We don't know what research may be done in the future using your tumor tissue and 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. 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.
2. 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.
3. 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?

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

How will information about me be kept private?

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

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

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

You will not benefit from taking part.

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

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

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

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

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

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)