Research Study Informed Consent Document

Study Title for Participants: Testing the addition of Pembrolizumab, an immunotherapy cancer drug to Olaparib alone as therapy for patients with pancreatic cancer that has spread with unhealthy tumor suppressor genes.

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: "S2001 Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab vs. Olaparib Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline *BRCA1 or BRCA2* Mutations." (NCT04548752)

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 pancreatic cancer with a germline *BRCA1 or BRCA2* gene mutation that has spread to other parts of your body. *BRCA 1 or BRCA 2* are genes in which mutations can be inherited that have been linked to a higher risk of developing certain cancers.

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?

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

What is the usual approach to treating metastatic pancreatic cancer?

The usual approach for patients who are not in a study is treatment with FDA approved chemotherapy regimens such as 5-fluorouracil, capecitabine, FOLFOX, FOLFIRI, FOLFIRINOX, gemcitabine, gemcitabine and nab-paclitaxel, or gemcitabine and cisplatin. Olaparib alone has been approved as maintenance therapy for patients with germline *BRCA1* or *BRCA2* mutated pancreatic cancer.

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

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

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

If you decide to take part in this study, you will either get Olaparib and Pembrolizumab or Olaparib alone until the cancer worsens, you have worsening side effects of the drugs, or you are unable to tolerate the drugs.

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. This means you will keep seeing your doctor for 5 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 Olaparib and Pembrolizumab may not be as good as the usual approach for the type of cancer you have at shrinking or stabilizing the cancer.

There is also a risk that you could have side effects from Olaparib and Pembrolizumab. These side effects may be worse and may be different than you would get with the usual approach for patients with pancreatic cancer that has spread with unhealthy tumor suppressor genes.

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

- Tiredness
- Joint stiffness
- Anemia, which may require transfusion
- Infection, especially when white blood cell count is low
- Reddening, tanning, swelling, or peeling of the skin
- Mild pain
- Nausea, vomiting, diarrhea, loss of appetite

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

Benefits

Olaparib alone is FDA approved for patients with germline *BRCA1* or *BRCA2* mutated pancreatic cancer. There is evidence that olaparib alone is effective in stabilizing your type of cancer. It is not possible to know now if olaparib and pembrolizumab together will improve the effectiveness compared to olaparib alone. 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.
- For women: You become pregnant while on the study.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor. The study sponsor is the organization who oversees the study.
- Your stop receiving olaparib treatment.

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 pembrolizumab plus the usual treatment. The addition of pembrolizumab to the usual treatment could help to shrink your cancer 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 drug pembrolizumab increases the time it takes for the cancer to grow by 5 months or more compared to the usual approach.

What are the study groups?

This study has 2 study groups.

- **Group 1**

  If you are in this group, you will receive olaparib plus the study drug pembrolizumab. Olaparib will be taken during the pembrolizumab infusion. You will receive pembrolizumab infusions through a vein in the arm over a 30-minute period in the outpatient setting every 3 weeks. If your disease is still responding after 1 year of treatment, the pembrolizumab infusions will be given every 6 weeks from that point going forward.

  Olaparib is to be taken twice daily with water, swallowed whole and not chewed or crushed. Olaparib may be taken with or without food. You should avoid grapefruit, grapefruit juice and Seville oranges while taking Olaparib. You should also not receive

live viruses or live bacterial vaccines while receiving Olaparib and during the 30-day follow-up. If you are assigned to Group 1, you will keep a medication diary. This helps you keep track of when you take your Olaparib tablets. The study doctor will show you how to use this diary. Each time you visit the clinic, you must bring the pill diary, any remaining tablets, and the Olaparib bottles.

There will be about 44 people in this group.

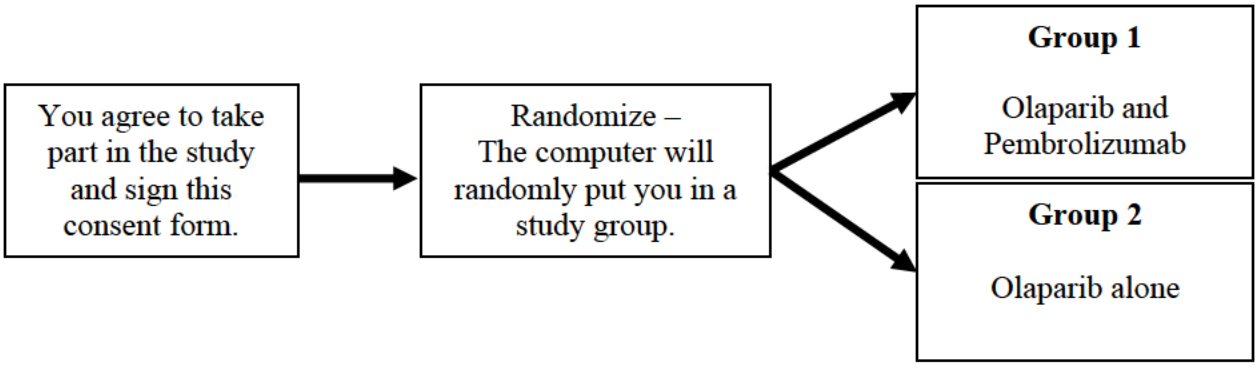
- **Group 2**

  If you are in this group, you will receive Olaparib only. Olaparib is to be taken twice daily with water, swallowed whole and not chewed or crushed. Olaparib may be taken with or without food. You should avoid grapefruit, grapefruit juice and Seville oranges while taking Olaparib. You should also not receive live viruses or live bacterial vaccines while receiving Olaparib and during the 30-day follow-up. If you are assigned to Group 2, you will keep a medication diary. This helps you keep track of when you take your Olaparib tablets. The study doctor will show you how to use this diary. Each time you visit the clinic, you must bring the pill diary, any remaining tablets, and the Olaparib bottles.

There will be about 44 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 equal chance of being in Group 1 or Group 2.

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



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

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

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

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

- Blood to test your kidneys, liver, thyroid, inflammation, and pregnancy test (for females) at the same time you receive the treatment (within 28 days before you are randomized, within 72 hours before you begin the study treatment, and then as recommended by your doctor).
- If you have a history of any heart conditions, please inform your doctor. Heart tests will be done as part of your routine health care to ensure your safety on the trial.

Before you begin the study:

A small piece of cancer tissue that was removed from a previous biopsy will be taken at the beginning of the study if this cancer tissue is available to your treating physician. Since this biopsy has already been performed, there are no physical risks related to this “archival” tissue submission. Neither you nor your health care plan/insurance carrier will be billed for the collection or submission of the tissue that will be used for this study. If there is leftover, tissue it will be banked in a central laboratory. This will be discussed in the section on optional studies. If this “archival” tissue is unavailable for submission, your doctor will decide if you need another biopsy for testing. If your doctor determines you need another biopsy, a small piece of that tissue will be banked for this study. This standard of care biopsy may have risks. Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, which can be treated with regular pain medications, and bruising. Rarely, an infection can occur. You will sign a separate consent form before the biopsies are taken. This will be a standard surgical consent form from the institution where the biopsy procedures take place.

[redacted]

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 olaparib and pembrolizumab (MK-3475) may not be as good as the usual approach for the type of cancer you have or condition at shrinking or stabilizing the 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.

Olaparib and pembrolizumab (MK-3475) or olaparib alone used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for 6 months after you have completed the 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 you for cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.

Side Effect Risks

Olaparib and pembrolizumab (MK-3475) or olaparib alone 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 olaparib and pembrolizumab (MK-3475) or olaparib alone.

Here are important things to know about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it hard for you to have children.
- 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 Group 1 and Group 2 – Possible side effects of olaparib listed in the tables below. This drug is part of the usual approach for treating this type of cancer:

Risk Profile for Olaparib (AZD2281) (CAEPR Version 2.6, June 5, 2023)

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 • Pain • 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 • Sores in the mouth which may cause difficulty swallowing • Swelling of arms, legs • Cold symptoms such as stuffy nose, sneezing, sore throat • Infection which may cause painful and frequent urination • Infection, especially when white blood cell count is low • Dizziness, headache • Changes in taste • Cough, shortness of breath • Rash
RARE, AND SERIOUS In 100 people receiving olaparib (AZD2281), 3 or fewer may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Bruising, bleeding • 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 • Blood clot

Study Group 1 - In addition to side effects listed above, people who are in Group 1 may also have some side effects from Pembrolizumab (MK-3475). These side effects are listed below.

Risk Profile for Pembrolizumab (MK-3475) (CAEPR Version 2.9, January 31, 2025)

(Group 1 only)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Pembrolizumab (MK-3475), more than 20 and up to 100 may have:
• Tiredness Pembrolizumab (MK-3475) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to: • Anemia which may require blood transfusion

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving Pembrolizumab (MK-3475), from 4 to 20 may have:

- Constipation, nausea
- Loss of appetite
- Pain in back
- Joint stiffness
- Cough
- Swelling and redness of the skin

Pembrolizumab (MK-3475) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:

- Pain in lymph nodes
- Blood clot which may cause bleeding, confusion, paralysis, seizures and blindness
- Hormone gland problems (especially the thyroid, pituitary and adrenal glands, and pancreas). Signs and symptoms may include: headaches that will not go away or unusual headaches, extreme tiredness or changes in mood or behavior; decreased sex drive; weight loss or weight gain; excessive thirst or urine; dizziness or fainting
- Intestinal problems (colitis) that can rarely lead to tears or holes in your intestine. Signs and symptoms of colitis may include: diarrhea or increase in bowel movements, blood in your stools or dark, tarry, sticky stools, severe belly pain or tenderness
- Diarrhea
- Sores in the mouth which may cause difficulty swallowing
- Pain in belly
- Sores in the bowels
- Chills, fever
- Reaction during or following a drug infusion which may cause fever, chills, rash, low blood pressure
- Liver problems (hepatitis) which can cause liver failure. Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes, severe nausea or vomiting; drowsiness; pain in the right upper belly
- Lung problems (pneumonitis and other conditions). Symptoms may include: new or worsening cough, chest pain, shortness of breath.
- Pain or swelling of the joints
- Problem of the muscle, including swelling, which can cause muscle pain and severe muscle weakness sometimes with dark urine
- Skin: itching; acne; rash (can be severe); blisters and peeling on the skin; skin changes; hives

RARE, AND SERIOUS
In 100 people receiving Pembrolizumab (MK-3475), 3 or fewer may have:

- A syndrome starting with flu-like symptoms and followed by swelling, tenderness which may cause flu-like symptoms, blurred vision, ringing in the ears, changes in hair or hair loss
- Inability to digest food which may cause bloating
- Swelling of the gall bladder
- Swelling of the spinal cord
- Feeling of "pins and needles" in arms and legs
- Redness, pain or peeling of palms and soles

Pembrolizumab (MK-3475) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:

- Heart problems including swelling and heart failure. Symptoms and signs of heart problems may include: Shortness of breath, swelling of the ankles and body.
- Swelling and redness of the eye which may cause blurred vision with a chance of blindness
- Swelling of the bowels
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Damage to organs in the body when donor cells attack host organs which may cause yellowing of eyes and skin, itchy dry skin
- Damage to organs in the body when the body produces too many white cells
- A condition with high blood sugar which leads to tiredness, frequent urination, excessive thirst, headache, nausea and vomiting, and can result in a coma
- Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs.
- Swelling of the brain (encephalitis/meningitis) which may cause headache, confusion, sleepiness, seizures and stiff neck
- Kidney problems, including nephritis and kidney failure requiring dialysis. Signs of kidney problems may include: decrease in the amount of urine, blood in your urine, ankle swelling.
- Skin rash developing 1-8 weeks after a drug is given which may be accompanied by fever, lymph node swelling and organ failure
- Swelling or tenderness of blood vessels

Pembrolizumab works by helping your immune system to fight your cancer. However, pembrolizumab can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects. These side effects may be serious (i.e. causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time.

Risks of Blood Draw:

Occasional, some may be serious: Mild pain and discomfort at the injection or needle insertion site as well as possible infection, bleeding, bruising, and soreness.

Rare: Severe pain, swelling, infection from the actual injection, and fainting.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Additional Drug Risks

The study drug could interact with other drugs and food. You should avoid grapefruit, grapefruit juice and Seville oranges. You should also not receive live viruses or live bacterial vaccines while receiving olaparib and during the 30-day follow-up.

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

Your study doctor will give you a patient clinical trial wallet card that lists the medications you are taking. Share this information with your family members, caregivers, other health care providers, and pharmacists.

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.

For women: Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 6 months after your last dose of study drug.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for the 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 the drug olaparib
- the costs of getting Pembrolizumab 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 study drug pembrolizumab

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

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

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

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

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

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

Who will see my medical information?

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

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

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

Some of these organizations are:

- The study sponsor and any company supporting the study now or in the future. This would include any organization helping the company with the study.
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it work with to review research.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

[redacted] However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.

- You will not get reports or other information about any research that is done using your information.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor (*insert name of study doctor[s]*) at (*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

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

Unknown future studies

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

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

Right now, we don't know what research may be done in the future using your 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.
- You will not get reports or other information about any research that is done using your samples.

[redacted]

What is involved in this optional sample collection?

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

1. A sample from the tissue that was collected at the time of your surgery or biopsy will be sent to the biobank for use in future studies. A sample of tissue will also be sent at the time of relapse should this occur.
2. [redacted] You will have this blood taken before you begin treatment, about 9 weeks after you begin the study, and at the time you are removed from treatment for any reason.
3. 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.
4. Researchers can only get samples from the biobank after their research has been approved by experts.
5. [redacted] The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- Risks of Blood Draw:
    a. The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat you for cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. 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 and/or images from you and others, might make discoveries that could help people in the future.

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

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

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

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

What if I have questions about this optional sample collection?

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

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

Samples for unknown future studies:

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

YES NO

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's signature (or legally authorized representative)

_____

Date of signature _____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature _____