Study Title for Participants: A study to compare the administration of pembrolizumab after surgery versus administration both before and after surgery for high-risk melanoma

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: S1801 A Phase II Randomized Study of Adjuvant vs. Neoadjuvant MK-3475 (Pembrolizumab) for Clinically Detectable Stage III-IV High-Risk Melanoma

(NCT# 03698019)

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.

We are asking you to take part in this research study because you have melanoma which is ready for removal by surgery.

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:

How does treating melanoma with the study drug pembrolizumab, before versus after surgery affect the disease?

We are doing this study because we want to find out which approach is better for treating high-risk melanoma.

What is the usual approach to my high-risk melanoma?

There are several treatment options for high-risk melanoma. Patients whose melanoma is surgically removable will normally have surgery before getting treatment. Though surgery followed by pembrolizumab has been selected as the "standard" treatment option for this study, other approaches are often used. FDA-approved treatments after surgery include interferon, ipilimumab, and nivolumab. Please talk with your doctor about alternatives before finalizing your decision to take part in this study. We hope to find a more effective and long-lasting treatment for your type of 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 without joining this study.
- You may choose to take part in a different research study, if one is available.
- You may choose to be treated for your cancer only with surgery.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer. This is not recommended for your stage of cancer, which is considered to be potentially curable.

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 treatment with pembrolizumab after your surgery, or you will be treated with pembrolizumab for a few weeks before surgery, then undergo surgery, and get more pembrolizumab after your surgery.

After you finish your study treatment, your doctor will continue to follow your condition for up to 10 years after you register to the study. Your doctor will watch you for side effects and to see how your cancer affects you. You will have clinic visits periodically from the time you stop taking treatment until 10 years after you register to the study.

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 before agreeing to enroll in the study. 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 receiving treatment before and after surgery may not be as good as receiving treatment only after surgery.

There is also a risk that you could have side effects from the study drug. These side effects may be worse or may be different than you would get with the same drug given after surgery.

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

- Tiredness
- Nausea
- Infection
- Loss of appetite
- Joint stiffness
- Swelling and redness of the skin

If you are randomly assigned to receive study drug before surgery, it is possible that side effects could delay your surgery or make your surgery more difficult or dangerous. It is also possible that your tumor would grow or spread during the period of time (generally 8 to 12 weeks) before your surgery is scheduled to take place. If you are randomly assigned to receive drug after surgery, it is possible that the surgery will be more difficult or dangerous than it would have been if you had received study drug before surgery, and your tumor had improved because of it.

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

Benefits

This study may or may not help you because it is not possible to know at this time if the study approach is better than the usual approach. This study may help researchers learn things that may 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 cancer gets worse and you cannot get your planned surgery.
- Your cancer returns or gets worse after surgery.
- If your surgeon is unable to remove all visible signs of cancer.
- You have unacceptable side effects from the study drug.
- 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 (SWOG). The study sponsor is the organization who oversees the study.
- You complete the study 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 outcomes of receiving the study drug either before and after or only after surgery for your type of cancer. Pembrolizumab could shrink your cancer before the surgery but it could also cause side effects. Researchers hope to learn if the treatment before surgery approach will lengthen the time it takes for your disease comes back after surgery or otherwise improve outcomes, and how often it results in tumor shrinkage or side effects. This study will allow the researchers to know whether treatment with pembrolizumab before and after surgery is better, the same, or worse than the usual treatment after surgery.

There will be about 500 people taking part in this study.

What are the study groups?

This study has 2 study groups. You will be told which group you are in, but you and your doctor will not get to choose which group you go into if you join this study.

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 Group 1 or Group 2.

- **Group 1**

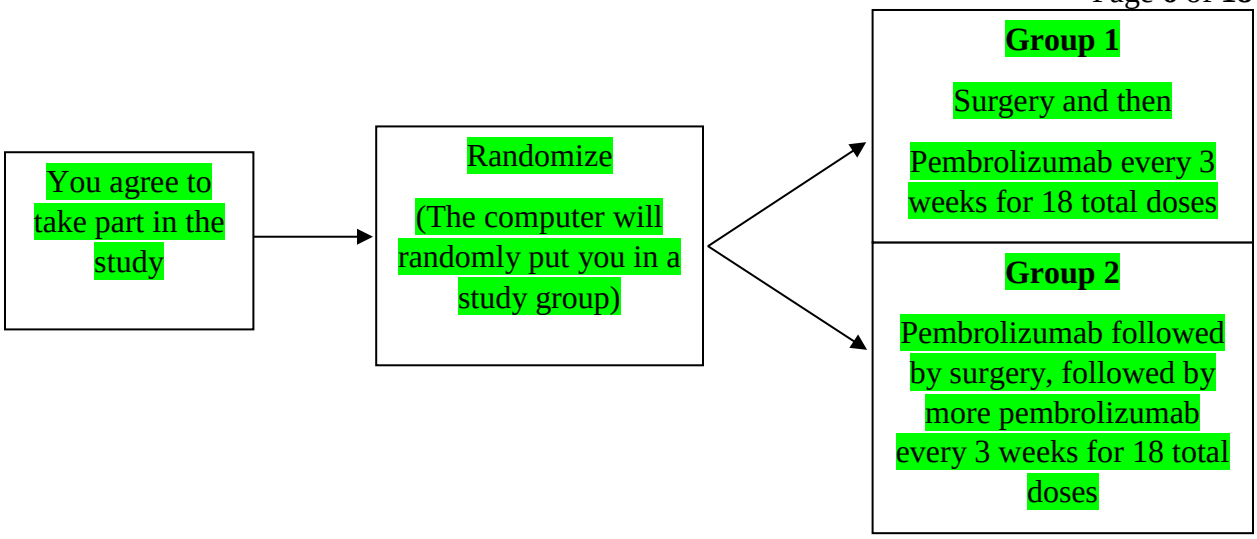
  If you are in this group, you will undergo your surgery and then a few weeks after your surgery, you will receive pembrolizumab by intravenous infusion through a vein in the arm over a 30 minute period in the outpatient setting. You will receive pembrolizumab infusions through a vein in the arm every 3 weeks for 18 doses (approximately one year).

  There will be about 250 people in this group.

- **Group 2**

  If you are in this group, you will receive pembrolizumab by intravenous infusion through a vein in the arm over a 30 minute period in the outpatient setting every 3 weeks for 3 doses and then have surgery a few weeks later. No additional pre-operative pembrolizumab beyond 3 doses may be given. After recovery from surgery, you will receive additional pembrolizumab infusions through a vein in the arm every 3 weeks for a total of 18 doses (before and after surgery, approximately one year).

  There will be about 250 people in this group.



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:

- A heart scan (EKG) before you begin treatment.
- 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).

All patients will have surgery to remove melanoma while on the study as part of the usual care for cancer.

All of the exams, tests, and procedures you will have before you begin the study are part of the usual approach for your cancer.

If you are in Group 2, your doctor will also submit tissue from a previous biopsy at the beginning of the study and after your surgery while on the study to understand how the study drug affects the cancer. The tissue will be sent to a central laboratory where researchers will measure the

tumor to look at whether it shrunk before the surgery. Submission of your tissue is required because the research on the tissue sample is an important part of the study. You and your doctor will not receive the results of this test.

In addition to the tissue submitted to the central laboratories for testing, all patients will be given the option to submit tissue and blood specimens for banking for future studies. You can indicate whether you will allow your specimens to be banked for future studies in the section called "Optional Studies".

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

General Risks

If you choose to take part in this study, there is a risk that the study approach may not be as good as the usual approach for your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.
- The study approach of pembrolizumab before surgery may prevent you from getting the surgery if your cancer continues to grow during treatment.
- The study approach of pembrolizumab before surgery may result in increased side-effects from the surgery.

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 and for four 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 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.

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.

Study Group 1 and Group 2 – Possible side effects of pembrolizumab are listed in the tables below.

Risk Profile for pembrolizumab

(CAEPR Version 2.4, March 16, 2018)

COMMON, SOME MAY BE SERIOUS In 100 people receiving MK-3475 (pembrolizumab), more than 20 and up to 100 may have:
• Tiredness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving MK-3475 (pembrolizumab), from 4 to 20 may have:
• Nausea • Infection • Loss of appetite • Pain in back • Joint stiffness • Cough • Swelling and redness of the skin MK-3475 (pembrolizumab) 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

- 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
- 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
- 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
- Fluid in the joints
- Pain in chest
- Lung problems (pneumonitis and other conditions). Symptoms may include: new or worsening cough, chest pain, shortness of breath.
- Skin: itching; acne; rash (can be severe); blisters and peeling on the skin, mouth; skin changes; hives

RARE, AND SERIOUS

In 100 people receiving MK-3475 (pembrolizumab), 3 or fewer may have:

- Feeling of "pins and needles" in arms and legs
- Redness, pain or peeling of palms and soles

MK-3475 (pembrolizumab) 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 h**eart problems may include: Shortness of breath, swelling of the ankles and body.
- Swelling and redness of the eye
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

- Reaction during or following a drug infusion which may cause fever, chills, rash
- 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.
- Swelling or tenderness of blood vessels

Study Group 1 and Group 2 – Possible Side Effects of Surgery

The surgery in this study is part of the usual care for cancer.

Regardless of whether you receive study drug before or after surgery, your surgeon will do the surgery that he/she feels is appropriate and proper for your cancer. The type of surgery performed will not be changed by your participation in this study, although your surgeon will be asked to adhere to standard guidelines for your type of cancer. You should specifically discuss the nature of the planned surgery and the risks of surgery with your surgeon, and you will be asked to sign a separate consent form specifically for that surgery.

Patients receiving pembrolizumab sometimes require treatment for side effects using drugs such as steroids and other immune-suppressing agents. Whether these drugs are given before or after surgery, they could increase the risk of infections and wound-healing problems after surgery.

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving surgery, from 4 to 20 may have:
• Infection at the surgical incision • Moderate to severe pain • Numbness in or around the incision, which may be permanent • Bruising or Bleeding at the surgical site, not requiring blood transfusion or additional surgery • Swelling of the arm or leg (lymphedema) on the side of surgery
RARE, AND SERIOUS In 100 people receiving surgery, 3 or fewer may have:
• Bruising or Bleeding at the surgical site, requiring blood transfusion or additional surgery • Post-operative bleeding requiring blood transfusion

- Blood clot which may cause swelling, pain, shortness of breath
- Pneumonia

Other side effects of surgery are possible, and depend on the exact location and type of surgery. Your surgeon will discuss the possible side effects of your surgery with you prior to performing the surgery. Please be sure to ask your surgeon if you have any questions about possible side effects of your surgery

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 foods. You should avoid grapefruit juice and any other drugs your doctor discusses with you.

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

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
    - all medications and supplements you are taking
    - any side effects
    - any doctors' visits or hospital stays outside of this study
    - if you have been or are currently in another research study.

For women: Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 4 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 melanoma. 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 pembrolizumab ready and giving it to you.
- the cost of surgery as part of the usual care for cancer during the study
- 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

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

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

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

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 your type of cancer in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

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

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

Optional sample collections for known laboratory studies and/or storage for possible future studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Unknown future studies

If you choose to take part in this optional study, blood and tissue will be collected and store:

Storing samples for future studies is called "biobanking." The biobank is being run by Nationwide Children's Hospital and is supported by the NCI. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use. 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 tumor tissue, or blood samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- Future research studies may include sequencing of all or part of your DNA called genomic sequencing. All your genetic information makes up your genome. Genomic sequencing is a test that records all or part of the pieces of DNA that are in your genes, piece by piece. This is usually done to look for changes in your genome that may cause health problems.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also 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. These are called germline changes. If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps

researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

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. About 4 teaspoons of blood will be taken at the same time blood is being collected for your treatment on the study. You will have this blood taken before you begin treatment, about 15 weeks after you begin the study, about 27 weeks after you begin the study, at the time if you are removed from treatment for any reason, and if your cancer returns.
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. Researchers will not be given your name or contact information.
6. 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?

- **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.

- 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:

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

YES NO

This is the end of the section about optional studies.

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

Contact for Future Research

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

YES NO

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)