Study Title for Participants: Testing what happens when an immunotherapy drug (avelumab) is added to a usual drug treatment (cetuximab) compared to avelumab by itself in the treatment of advanced squamous cell carcinoma of the skin (cSCC)

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Alliance A091802, Phase II randomized trial of avelumab plus cetuximab versus avelumab alone in advanced cutaneous squamous cell carcinoma of the skin (cSCC)

Overview and Key Information

This study is being conducted by the Alliance for Clinical Trials in Oncology (Alliance), a national clinical research group supported by the National Cancer Institute (NCI). The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

What am I being asked to do?

We are asking you to take part in a research study because you have advanced squamous cell carcinoma of the skin. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like 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 increase the length of time you live with your cancer without your cancer getting worse (progression-free survival) by adding a new drug, avelumab, to another drug cetuximab, in advanced squamous cell carcinoma of the skin?

What is the usual approach to my advanced squamous cell carcinoma of the skin?

The usual approach for patients who are not in a study is treatment with a drug called cemiplimab. This drug was approved in September 2018 by the U.S. Food and Drug Administration (FDA) and is commonly used for your type of cancer. Although not approved by the FDA for your cancer, cetuximab is another drug than can be given as part of your usual care.

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

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

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

If you decide to take part in this study, you will be assigned to a study treatment arm. You will either receive avelumab plus cetuximab or avelumab alone for up to two years. If you are treated with avelumab by itself, and your cancer grows, you will be given the option to start receiving avelumab plus cetuximab. The total amount of treatment that you may receive is 2 years of treatment on trial.

After you finish your study treatment, your doctor will continue to follow your condition with a clinic visit that includes a physical exam, lab tests, and imaging 12 weeks after treatment is over, and then every 12 weeks (3 months) until disease progression. The purpose of this follow up is to watch for any side effects and to check your cancer.

If your cancer grows (progression) while you are on study treatment, if you are taken off of study treatment, or if study treatment is stopped for side effects or any other reason before 2 years of study treatment, you will have a clinic visit 30 days after that. This clinic visit will include a physical exam and lab tests to watch for any side effects of the study treatment. You will also have a clinic visit 60 days after that (i.e. 90 days after you stop the study). If you are not able to come in for the 90 day visit this follow-up visit can be done over the phone. You will also receive a phone call every 6 months for up to two years, after starting trial treatment to track how you are doing.

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 treatment may not be as good at shrinking or stabilizing your cancer as the usual treatment.

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

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

- Tiredness (Fatigue)
- Nausea
- Rash
- Low magnesium
- An allergic reaction where the drugs are given (infusion)
- Making your thyroid gland either work too much or not enough.

There may be some risks that the study doctors do not yet know about. Because this is a new combination, there may be more side effects, or they may be higher than each drug by itself.

Benefits
The reason for combining the two drugs in this study is because both may work together to make the immune system more effective against your cancer. The combination of cetuximab and avelumab is being tested because the combination shrunk the cancer more than each agent by itself in animals.

It is unlikely that it will work in everyone with your cancer or help you live longer. This study may help the study doctors learn things that may help other 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), EMD Serono (maker of avelumab), or the Alliance for Clinical Trials in Oncology (study sponsor). The study sponsor is the organization who oversees the study.

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

What is the purpose of this study?

The purpose of this study is to test the good and bad effects of the combined treatment, using the drugs cetuximab and avelumab as well as avelumab by itself. The combination of cetuximab and avelumab or avelumab alone could shrink your cancer, but it could also cause side effects, like the ones listed in section below called "What risks can I expect from taking part in this study?". The study doctors hope to learn if the combination of avelumab and cetuximab will increase the length of time people live without their cancer getting worse more than avelumab by itself.

Avelumab is a drug that works by triggering the immune system so it can try to attack the cancer again. Avelumab works in a similar way to cemiplimab, which is the usual drug for treatment of your cancer. Cetuximab can also boost the immune system while working against the cancer in other ways. We know that cetuximab has shrunk or stabilized cSCC in other patients. The study is specifically looking to determine whether the combination of the study drugs avelumab and cetuximab is better than avelumab alone.

Both avelumab and cetuximab have already been approved by the FDA to treat other cancers.

We don't know if the combination of cetuximab and avelumab works to treat cancer in people, but it has shrunk several types of tumors in animals.
There will be about 59 people taking part in this study.

What are the study groups?

This study has 2 study groups.

- **Group 1**

If you are in this group, you will get the study drug avelumab through a vein in your arm every two weeks for up to two years.

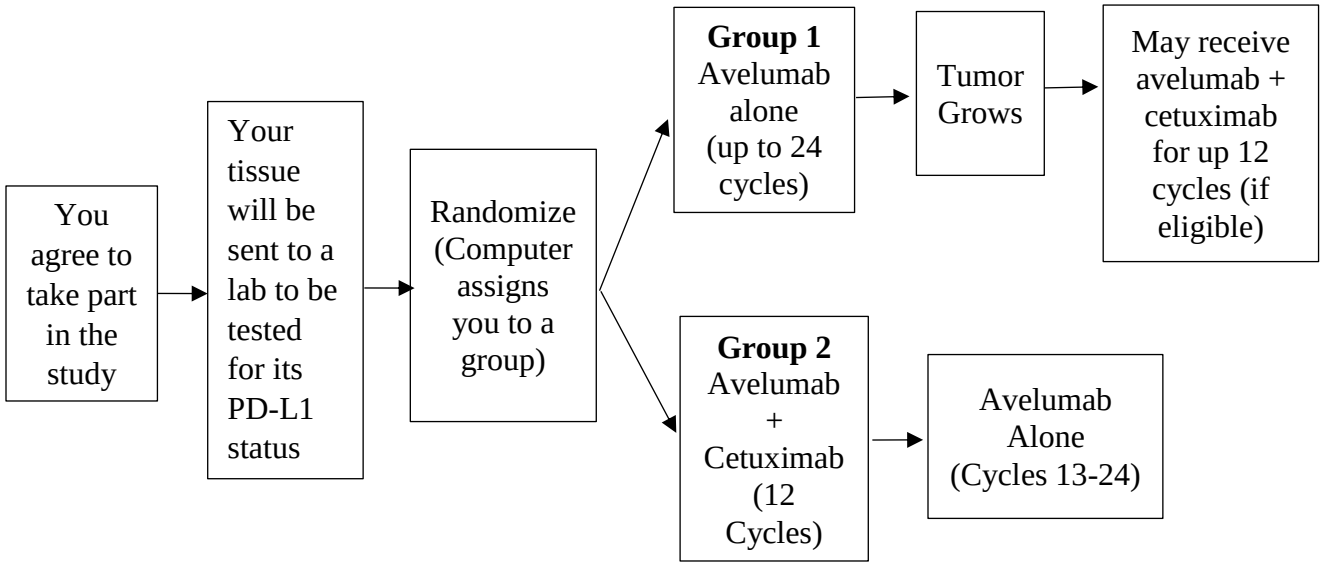
- **Group 2**

If you are in this group, you will get the study drug avelumab plus cetuximab through a vein in your arm every two weeks. Each cycle lasts 28 days. This will last for 1 year (12 cycles). Starting in year 2 (cycle 13) you will receive avelumab alone every two weeks for an additional year.

If you are assigned to Group 1 and your cancer grows while taking avelumab alone, you will be given the opportunity to receive cetuximab in addition to avelumab for up to 1 year (12 cycles). Your treating physician will discuss with you whether you are eligible for this, which is based on how you are doing at that time.

A computer will by chance assign you to treatment groups 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 other.

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 your usual care, even if you are not in a study.

Below are exams, tests, and procedures that check your safety and health while on this study, but may not be included in your 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:

- Thyroid testing done prior to registration and as clinically indicated.
- Electrocardiogram to measure the electricity in your heart

Your study doctor will need to use some of the tumor tissue left over from your biopsy or surgery when you were diagnosed with cancer. This sample is a required part of the study for all patients. The sample from your cancer will be examined to determine whether the tumor has a marker called PD-L1. PD-L1 may affect the ability of your immune system to respond to the study treatment. You can go on the study no matter what the result of the PD-L1 testing is, however this test result is needed before you can go on the study. Your study doctor will get the results of this testing and can discuss the results with you.

If there is not enough tissue left over from your previous biopsy or surgery to test for PD-L1, your study doctor will need to do another biopsy to get this tissue. This would be done during the screening tests. The study biopsy takes small pieces of cancer tissue from your body. This is like the biopsy you had that helped diagnose your cancer.
If you agree to take part in the study and a new biopsy is required, you may need to sign a separate consent form for the study biopsy at your hospital or clinic where the biopsy is done.

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 treatment may not be as good as the usual treatment 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.

The study 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 at least 2 months after the last dose of study medication. Appropriate methods of birth control include abstinence, oral contraceptives, implantable hormonal contraceptives or double barrier method (diaphragm plus condom). Women should also not breastfeed during the study and for at least 2 months after the last dose of study medication.

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.

Biopsy Risks (if a new biopsy is required)
Common side effects of a biopsy include a small amount of bleeding during the procedure, bruising, and pain at the biopsy site. Pain can be treated with regular pain medications. Rarely, an infection can occur. You may sign a separate consent form for the study biopsy that describes the risks in more detail. If there is any leftover cancer tissue after the biopsy, it may be stored if you give consent. This will be discussed in the section under "Optional Studies".

Side Effect Risks
The study 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 lower side effects.

This study is looking at a combination of a usual drug used to treat this type of cancer (cetuximab) plus a study drug (avelumab). This different combination of drugs may increase your side effects or may cause new 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 Avelumab (CAEPR Version 2.0, April 23, 2019)

COMMON, SOME MAY BE SERIOUS In 100 people receiving avelumab, more than 20 and up to 100 may have:
• Tiredness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving avelumab, from 4 to 20 may have:
• Anemia which may require blood transfusion • Diarrhea, nausea, vomiting • Chills, fever • Flu-like symptoms including body aches • Infection • Reaction during or following a drug infusion which may cause fever, chills, rash, low blood pressure • Bruising, bleeding • Loss of appetite • Cough • Dry skin • Itching, acne, rash Avelumab 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: • 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 [the term above is a clinical manifestation of lab values not previously listed on the risk list] • Damage to the pancreas which may cause belly pain and hospitalization • Pain or swelling of the joints • Problem of the muscle (myositis), which can cause muscle pain and severe muscle weakness sometimes with dark urine

RARE, AND SERIOUS In 100 people receiving avelumab, 3 or fewer may have:
Avelumab 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 inflammation and heart failure. Symptoms and signs of heart problem may include: Shortness of breath, swelling of the ankle and body • Swelling and redness of the eye

- 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
- 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
- A condition with high blood sugar (diabetes) which leads to tiredness, frequent urination or excessive thirst which may require treatment with insulin
- Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs and facial muscle movement
- Inflammation of the brain (meningitis/encephalitis), 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
- Lung problems (pneumonitis and pleural effusion). Symptoms may include: new or worsening cough, chest pain, shortness of breath

Possible Side Effects of Cetuximab

(Table Version Date: January 19, 2016)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cetuximab, more than 20 and up to 100 may have:
• Change in nails • Swelling and redness of the area of radiation • Rash, itching, dry skin, acne • Diarrhea, constipation, nausea, vomiting, loss of appetite, weight loss • Sores in mouth which may cause difficulty swallowing • Infection, especially when white blood cell count is low • Difficulty sleeping • Headache, tiredness • Numbness and tingling of the arms and legs • Blurred vision • Shortness of breath, cough • Fever • Pain

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cetuximab, from 4 to 20 may have:
• Hair loss • Severe skin rash with blisters and can involve inside of mouth and other parts of the body • Blood clot which may cause swelling, pain, shortness of breath • Allergic reaction or infusion reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

RARE, AND SERIOUS In 100 people receiving Cetuximab, 3 or fewer may have:
• Heart stops beating • Kidney damage which may require dialysis • Scarring of the lungs • Severe blood Infection • Sudden death

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

You should limit sun exposure (use sunscreen, wear hats) while receiving and for 2 months after the last dose of cetuximab.

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 two 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 squamous cell carcinoma.

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.
- your insurance co-pays and deductibles.

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 test to check the functioning of your thyroid gland, which is one of the hormone producing glands in your body, before starting treatment.
- The biopsy for PD-L1 testing (sample of your tumor) at the beginning of the study if required.

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 the avelumab while you take part in this study.

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

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

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

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. Contact information for your study doctor is listed on the consent cover page. The study sponsors will not pay for medical

treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

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

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

Who will see my medical information?

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

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

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

Some of these organizations are:

- Montana Cancer Consortium
- The study sponsor and any company supporting the study, now or in the future.
- MD Anderson CLIA lab (This is the laboratory that will be testing your tumor for PD-L1). Your initials, gender, and date of birth will be sent to MD Anderson along with your tumor for the PD-L1 testing.
- The IRB, a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research.

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new

study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

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

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact information for your study doctor is listed on the consent cover page.

For questions about your rights while in this study, call the Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health.

The researchers leading this optional study hope the results will help other people with cSCC in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

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

Optional sample collections for 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, tumor tissue that was previously collected from your cancer as well as blood will be stored. The tumor tissue that would be stored is the left over tissue that would have been already collected as part of the study if you need to go through a new biopsy to submit tumor tissue for PD-L1 testing; or from your previous surgery or biopsy. Storing samples for future studies is called "biobanking." The biobank is being run by the Alliance for Clinical Trials in Oncology and is supported by the NCI. Any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will also be stored for future use.

We don't know what research may be done in the future using your blood and/or tissue 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 can be 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. It takes many samples from different people to develop an accurate test.

What is involved in this optional sample collection?

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

1. About 3-4 tablespoons of blood will be collected from a vein in your arm at five different time points: during screening, first day of cycle 4 and 7, when you complete the study treatment, and when your cancer gets worse.

2. Some tumor tissue from your biopsy or surgery that was collected during screening for the study will be sent to the biobank.
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. Researchers will not be given your name or contact information.
5. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- 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 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 due to ongoing privacy protections. 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 take:

1. They 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 that is kept separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

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

You will not benefit from taking part.

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

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

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

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

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

What if I have questions about this optional sample collection?

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

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

Samples for unknown future studies:

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

YES NO

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)

(Required for initial consent only)