Research Study Informed Consent Document

Study Title for Participants: Testing immunotherapy versus observation in patients with HPV throat cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
EA3161, A Phase II/III Randomized Study of Maintenance Nivolumab versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPCA

Overview and Key Information

We are seeking your consent to participate in a research study. It is important to understand that participation is voluntary, and any decision you make will not affect future care.

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 HPV positive oropharynx 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:

Does maintenance nivolumab following definitive therapy with radiation and chemotherapy (cisplatin) result in significant improvement in overall survival (OS) (time being alive) and progression-free survival (PFS) (time being alive without cancer) for patients with your type of cancer (intermediate risk HPV positive oropharynx cancer).

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

What is the usual approach to my HPV positive oropharynx cancer?

The usual approach for patients who are not in a study is treatment with surgery, chemotherapy, and radiation therapy. Usually, combinations of these treatments are used. Your doctor can explain which treatment may be best for you. The most commonly used chemotherapy drug approved by the Food and Drug Administration (FDA) to use with radiation therapy in your type of cancer is cisplatin. For patients who get the usual approach for this cancer, about 55 out of 100 are free of cancer after 5 years. The usual approach is proven to help patients with your health condition live longer.

The usual approach for patients who are not in a study includes monitoring the effect of treatment by taking pictures of their tumor(s) with a PET/CT scan at 12 weeks after radiation, and CT scans every 3 months for 3 years after radiation therapy. This means that you will get more than one CT or PET scan with a machine that uses radiation. It is not expected that participation in this study will expose you to any significant increased radiation exposure in comparison to exposure resulting from the accepted standard of 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 get chemotherapy weekly for up to 7 weeks and radiation daily excluding weekends, for up to 7 weeks. Then you will either get nivolumab for up to 12 months and be monitored and observed, or you will be monitored and observed without getting nivolumab. If your cancer grows during observation, you will then be offered nivolumab for up to 12 months.

After you finish your treatment, your doctor and study team will watch you for side effects. They will check you every 3-6 months for 3 years after treatment. After that, they may check you every year. This means you may keep seeing your doctor for 10 years after treatment.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that the nivolumab after chemotherapy and radiation may not be as good as observation after chemotherapy and radiation at preventing your cancer from growing.

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

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

Benefits

There is evidence that nivolumab is effective in extending life of patients with advanced incurable HPV related head and neck cancer without disease and increasing survival. It is not possible to know now if the nivolumab will extend your time without disease or your life span compared to the usual approach. This study will help the study doctors learn things that will help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- 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 (ECOG-ACRIN). The study sponsor is the organization who oversees the study.

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

What is the purpose of this study?

The purpose of this study is to compare the usual treatment alone (radiation and chemotherapy) to adding maintenance nivolumab to the usual treatment. The addition of nivolumab to the usual treatment could shrink your cancer or prevent it from returning. But, it could also cause side effects, which are described in the risks section below.

This study will help the study doctors find out if this different approach is better than the usual approach. To decide if it is better, the study doctors will be looking to see if the nivolumab increases the lifetime of the patient without progression for 10 years.

This immunotherapy drug, nivolumab, is already approved by the FDA for use in advanced and incurable head and neck cancer. But, most of the time it is not used until the cancer is very advanced and chemotherapy stops working. In this study we believe the use of nivolumab has a chance of preventing the cancer from coming back for patients with your type of cancer. There will be about 286 people taking part in the first part (phase II) of the study and 458 more people taking part in second part (phase III), if the results of the phase II portion are promising and if there is evidence that nivolumab may prolong your life.

What are the study groups?

This study has 2 study groups.

- **Group 1**

  If you are in this group, you will get the usual therapy used to treat this type of cancer, chemotherapy plus radiation therapy, then a study drug called nivolumab. You will get nivolumab by vein (intravenously) every 4 weeks.

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

  There will be about 143 people in this group for the phase II portion of the study. If the study continues to the phase III portion, an additional 229 patients will be accrued to the phase III portion (data from a total of 372 patients in this group will be used for the final analysis). The phase III portion will be done if the results of the phase II portion are promising and if there is evidence that nivolumab may prolong your life if given after radiation and chemotherapy.

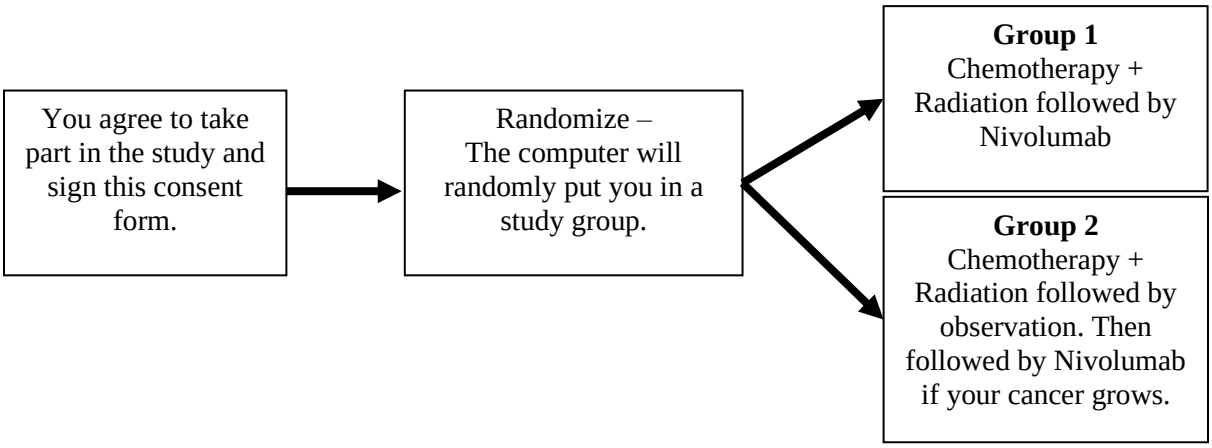
- **Group 2**

  If you are in this group, you will get the usual therapy used to treat this type of cancer, chemotherapy plus radiation therapy. If you your cancer grows during observation, you will get nivolumab by vein (intravenously) every 4 weeks.

  There will be about 143 people in this group for the phase II portion of the study, and if the study continues to the phase III portion, an additional 229 patients will be accrued to the phase III portion (data from a total 372 patients in this group will be used for the final analysis), if applicable.

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 50% chance of being in Group 1 (study group) or Group 2 (usual approach) and will be told which group you are in. Your doctor will also be able to tell you if you are in the phase II or phase III part of the study.

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 counts done weekly during the first 4 weeks of treatment.
- Thyroid testing done every 8 weeks while on nivolumab.
- Physical exams done weekly during the radiation and chemotherapy and every 4 weeks during the nivolumab portions of the study.

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

Use of Existing Tissue Specimen

If available, your doctor will submit some of the tissue left over from your biopsy when you were diagnosed with cancer. This sample is a required part of the study. The study team will assess this tumor tissue for expression of the PD-L1 protein and evaluate the effect it may have on your type of cancer. You and your study doctor will not get the results of this testing.

Any residual material from this analysis will be requested for banking for future unknown research. To permit the use of your leftover material, please refer to the consent questions below under the "Optional Studies" section of this document.

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 nivolumab may not be as good as observation at preventing your cancer from coming back.

You also may have the following discomforts:

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

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.

The nivolumab 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 for at least one week prior to the start of treatment, during treatment, and continue for 5 months after the last dose of protocol treatment for women of childbearing potential and 7 months after the last dose of protocol treatment for males who are sexually active with a women of childbearing potential.

Side Effect Risks

The chemotherapy, radiation therapy, and immunotherapy 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.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.

3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

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

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

Drug Risks

The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects of Nivolumab

(Table Version 2.4: December 2, 2020)

Special precautions
Side effects of Nivolumab may happen anytime during treatment or even after your treatment has ended. Some of these problems may happen more often when Nivolumab is used in combination with ipilimumab. **Call or see your healthcare provider right away if you develop any problems listed below or the symptoms get worse.**

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

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving Nivolumab, from 4 to 20 may have:
• Anemia which may require blood transfusion • Swelling and redness of the eye • Pain • Diarrhea, nausea • Dry mouth • Fever • Swelling and redness at the site of the medication injection • Bruising, bleeding

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving Nivolumab, from 4 to 20 may have:

- Pain or swelling of the joints
- Loss of appetite
- Reaction during or following a drug infusion which may cause fever, chills, rash

Nivolumab 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:

- Lung problems (pneumonitis and pleural effusion). Symptoms may include: new or worsening cough, chest pain, shortness of breath.
- 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.
- Skin: itching; rash, blisters including inside the mouth; loss of skin pigment
- 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
- 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 urination; dizziness or fainting.

RARE, AND SERIOUS

In 100 people receiving Nivolumab, 3 or fewer may have:

- Dry eyes
- Sores in the mouth which may cause difficulty swallowing
- A syndrome starting with flu-like symptoms and followed by swelling, tenderness which may cause blurred vision, ringing in the ears, changes in hair or hair loss
- Swelling of the bowels

Nivolumab 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:

- Visual disturbances which may cause double vision, blurred vision, or loss of vision with a chance of blindness
- A condition with high blood sugar which leads to tiredness, frequent urination, excessive thirst, headache, nausea and vomiting, and can result in coma
- 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.

RARE, AND SERIOUS In 100 people receiving Nivolumab, 3 or fewer may have:
• Heart problems including swelling and heart failure. Symptoms and signs of heart problem may include: Shortness of breath, swelling of the ankle and body. • Problem of the muscle, including swelling, which can cause muscle pain and severe muscle weakness sometimes with dark urine • Swelling of the brain (meningitis/encephalitis) which may cause: headache, stiff neck confusion, sleepiness, seizures or injury to the brain which may cause headache, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome) • 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 • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Complications associated with stem cell transplant using donor stem cells (allogeneic stem cell transplant). These complications are caused by attack of donor cells on the host organs (inducing liver, skin and gut damage), and can lead to death. If you are considering an allogeneic stem transplant after participating in this study, please tell your doctor that you have received Nivolumab therapy, since the risk and severity of transplant-associated complications may be increased.

Additional Drug Risks

The study drug could interact with other drugs. Please talk to your study doctor about the possible interactions.

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

Risks with Providing Tissue for Research

There is a small risk that when this tissue sample is submitted to the biobank for the PD-L1 research study, your tissue could be used up.

The risk associated with allowing your left over tissue to be kept for future unknown research is described in the "Optional Studies" section below.

What are my responsibilities in this study?

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

- Keep your study appointments and follow the treatment schedule provided by your doctor.

- 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 28 days after your last dose of study drug.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your cancer. This includes:

- The costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- Your insurance co-pays and deductibles.
- Cost of giving standard therapies – chemotherapy and radiation therapy.
- Cost of preparing and administering the nivolumab.

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

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

You or your insurance provider will not have to pay for the nivolumab 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 or your insurance will not be billed for the research test of PD-L1 on your tissue.

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.

The ECOG-ACRIN Cancer Research Group is conducting this study. ECOG-ACRIN is a cancer research group that conducts studies for the National Cancer Institute. Your doctor is a member of ECOG-ACRIN or another group that is participating in this study.

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, ECOG-ACRIN, and Bristol-Myers Squibb, or any drug company supporting 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 works with to review research.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research, including the Imaging and Radiation Oncology Core (IROC).
- Alliance for Clinical Trials in Oncology
- NRG Oncology
- SWOG Cancer Research Network

- Canadian Cancer Trials Group
- The biobank and researchers approved to study your samples or health data.

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 website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website 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 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.

Optional sample collections for bio-banking for possible future studies

Researchers are trying to learn more about cancer and other health problems using tissue, blood and saliva 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.

At this time, we are requesting that you allow the collection and submission of some of your tumor tissue, blood and saliva for research studies that may be done at a later date. Additionally, we would like to retain the leftover material that was sent by your doctor as part of the mandatory pre-trial tissue submission.

If you choose to take part in this optional study, any tissue, blood or saliva will be stored for future research. Storing samples for future studies is called "bio-banking." The biobank is being run by ECOG-ACRIN and is supported by the NCI. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

We don't know what research may be done in the future using your tissue, blood or saliva samples. This means that:

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

What is involved in this optional sample collection?

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

1. If you agree to allow your samples to be used for the optional planned research studies, a salivary rinse and about two (2) tablespoons of blood from a vein in your arm will be collected at the following time points: Before you start treatment, 3 months post

completion of chemotherapy/radiation, and 9 months post completion of chemotherapy/radiation. If, as part of your care, a procedure is performed to collect tumor tissue if your cancer becomes worse, samples of the tissue will be sent for research. No additional procedures will be done to obtain the tissue for research.

2. If you agree, any samples leftover after the planned research studies will be stored for future research.
3. If they were collected for one of the planned research studies, they will be distributed to the appropriate researchers. If your samples will be kept for future research, they 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. 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:

May we keep any leftover material from the tissue submitted for the mandatory PD-L1 research study?

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

YES NO

May we have samples of your tissue, blood and saliva for use in future research studies?

I agree to provide additional specimens for research

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)