Informed Consent Model for S1609

Study Title for Study Participants: Treatment with Ipilimumab and Nivolumab for Rare Cancers

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors

What is the usual approach to my cancer?

You are being asked to take part in this study because you have a type of rare cancer for which there is no standard of care treatment, or for which you have already received standard of care therapy options and your cancer has become worse. People who are not in a study are usually treated with either surgery, radiation, or with drugs. Sometimes, combinations of these are used and your doctor can explain which may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for several months or more.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above
- you may choose to take part in a different study, if one is available
- or you may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

Who is doing this study?

SWOG is sponsoring this trial. SWOG is an adult cancer clinical trials organization. SWOG is funded through the National Cancer Institute, and its network consists of about four thousand physicians at almost three hundred institutions throughout the United States.

Why is this study being done?

The purpose of this study is to test any good and bad effects of the combination of study drugs called ipilimumab and nivolumab in treating rare cancers and cancers of unknown primary origin. This study is also testing the good and bad effects of treating cancers that have a protein called PD-L1 with the study drug nivolumab alone. The study drugs (either the combination treatment of ipilimumab and nivolumab or treatment with nivolumab alone) could shrink your cancer but the study drugs could also cause side effects. Researchers hope to learn if the study drugs will shrink the cancer by at least one-quarter compared to its present size. Both ipilimumab and nivolumab have already been FDA-approved to treat other cancers. However, ipilimumab and nivolumab are investigational and not FDA-approved for use in combination in treating rare cancers or cancers of unknown primary origin. Nivolumab is not FDA-approved for

treating all cancers that have the protein called PD-L1. There will be about 818 people taking part in this study.

What are the study groups?

One group of study participants will get two study drugs (nivolumab and ipilimumab). Another small group of participants will only get nivolumab. Both study drugs are given through a vein.

If you are in the group that gets both drugs, then you will get both study drugs (nivolumab and ipilimumab) every 6 weeks (on the first day of each cycle), and you will get nivolumab every 2 weeks.

If you are in the group that only gets nivolumab, you will get nivolumab every two weeks.

For all patients:

- After completing 17 cycles of treatment (or about 2 years after agreeing to take part in this study), you and your study doctor will discuss your treatment options (described below) and decide which treatment option to continue.

For patients who are in the group that gets both study drugs (nivolumab and ipilimumab):

- If you are still receiving both study drugs after 17 cycles of treatment (or about 2 years after agreeing to take part in this study), and
- If your study doctor deems that it may benefit you to switch to taking nivolumab alone.

Then (after completing 17 cycles of treatment with both study drugs or after about 2 years of receiving both study drugs), you will have the option to: (1) get nivolumab alone (at a higher dose) once every 4 weeks, (2) get nivolumab alone (at the same dose as before) once every two weeks, (3) continue to get both study drugs (nivolumab and ipilimumab) at the same time (every 6 weeks on the first day of each cycle and nivolumab every 2 weeks) and the same dose as before – no change in treatment.

For patients 1) in the group that only gets nivolumab and 2) who were in the group that received both study drugs where ipilimumab was permanently stopped due to side effects prior to completion of 17 cycles (or about 2 years):

- At the time of completing 17 cycles of treatment (or about 2 years after agreeing to take part in this study), you will have the option to: (1) get nivolumab alone (at a higher dose) once every 4 weeks, or (2) continue to get nivolumab alone (at the same dose as before) once every two weeks – no change in treatment.

You will continue to receive study drugs until your disease gets worse or you experience bad side effects from the study drugs or your study doctor decides that you are not benefiting from the study drugs.

How long will I be in this study?

You will receive the study drugs as long as your cancer does not get worse, the side effects are not too great, you agree to stay on study, your study doctor believes you are benefitting from the study drugs, and you do not have a treatment delay of more than 56 days that the doctors think is related to the study drugs. When you finish taking the study drug(s) (either the combination of nivolumab and ipilimumab or nivolumab alone), your doctor will watch you for side effects and follow your condition with visits to the office at least every 3 months for 3 years, from your enrollment in the study. Your treating physician (or someone from your physician's office) may also continue to contact you via phone or mail to follow-up on your status until 10 years after the time of your enrollment to the study.

If your disease gets worse, and your study doctor believes that you are still benefiting from the study drug or drugs (including review of laboratory test results), your study doctor may discuss whether you would like to continue receive study treatment. Since some patients have delayed responses to immunotherapy (the study drugs), you can continue to receive the study drug or drugs for as long as you do not have any additional or new symptoms of your disease getting worse and your study doctor continues to believe that you are still benefiting from the study drugs. You may also decide not to continue treatment after your disease gets worse and your study doctor will discuss other options (such as other clinical trials, palliative care, or hospice care) with you.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra tests that you will need to have if you take part in this study.

Before you begin the study:

You will need to have the following extra tests to find out if you can be in the study:

- If you are a female who can have children: pregnancy test (For most patients this will be a blood or urine test. If you have gestational trophoblastic disease, germ cell tumor, or other rare cancer types for which a blood or urine test may give an incorrect result (false positive), then you may need an ultrasound to rule out pregnancy.)

Before you begin the study, small pieces of your cancer tissue (that was collected at the time of your surgery) and about 5 teaspoons of blood will be submitted for testing and studies about genes and markers that might predict how the body will respond to cancer and the study treatment. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment During the study (prior to Week 9) and if your cancer gets worse, about 4 teaspoons of blood will also be submitted for the same testing. Unless you have gestational trophoblastic disease (a type of rare cancer), these samples are required for you to take part in this study because the research on the samples is an important part of the study. If you have gestational

trophoblastic disease, you will only be required to submit tissue if it is available, and you will still be required to submit blood samples.

- Your samples will be sent to and stored in the Biobank, along with samples and information from other people who take part. The Biobank is being run by SWOG and is supported by the National Cancer Institute. Your blood samples will be kept until they are used up. Your tissue samples will be kept at the biobank and then will be sent to Circulogene, Biodesix, NCI CIMAC (Cancer Immune Monitoring and Analysis Centers) at MD Anderson Cancer Center, Stanford University, and/or Icahn School of Medicine at Mount Sinai), or other planned future research locations for testing. Neither you/nor your insurance company will be billed for the collection of the blood samples or the studies on your tissue or blood samples. The results will not be added to your medical records and you or your study doctor will not know the results.

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

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

You may also have the following discomforts:

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

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

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

Here are important points about side effects:

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

The tables below show the most common and the 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.

For All Patients:

Possible Side Effects of BMS-936558 (Nivolumab).

Special precautions:
Side effects of BMS-936558 (nivolumab, MDS-1106) may happen anytime during treatment or even after your treatment has ended. Some of these problems may happen more often when BMS-936558 (nivolumab, MDS-1106) 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 BMS-936558 (nivolumab, MDS-1106), more than 20 and up to 100 may have:

- **Tiredness**

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving BMS-936558 (nivolumab, MDS-1106), 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**
- **Pain or swelling of the joints**
- **Loss of appetite**
- **Reaction during or following a drug infusion which may cause fever, chills, rash**

BMS-936558 (nivolumab, MDS-1106) 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.**

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving BMS-936558 (nivolumab, MDS-1106), from 4 to 20 may have:

- **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 urine; dizziness or fainting.**

RARE, AND SERIOUS

In 100 people receiving BMS-936558 (nivolumab, MDX-1106), 3 or fewer may have:

- **Dry eyes**
- **Sores in the mouth which may cause difficulty swallowing**

BMS-936558 (nivolumab, MDS-1106) 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.**
- **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, seizure, 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**

RARE, AND SERIOUS

In 100 people receiving BMS-936558 (nivolumab, MDX-1106), 3 or fewer may have:

- **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 BMS-936558 therapy, since the risk and severity of transplant-associated complications may be increased.**

For Patients Receiving Both Study Drugs (Combination of Nivolumab and Ipilimumab):

Possible Side Effects of Ipilimumab

Special precautions:
Side effects of ipilimumab (MDX-010) may happen anytime during treatment or even after your treatment has ended. Some of these problems may happen more often when ipilimumab (MDX-010) is used in combination with BMS-936558 (nivolumab). **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 ipilimumab (MDX-010), more than 20 and up to 100 may have:

- **Diarrhea, nausea**
- **Tiredness**

Ipilimumab (MDX-010) 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:

- **Skin: itching; rash, blisters including inside the mouth (can be severe); hives**

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving ipilimumab (MDX-010), from 4 to 20 may have:

- **Abnormal heartbeat**
- **Hearing loss**
- **Swelling and redness of the eye**
- **Pain**
- **Difficulty swallowing, eating**
- **Constipation, vomiting**
- **Weight loss, loss of appetite**
- **Fever**
- **Dehydration**
- **Pain or swelling of the joints**

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving ipilimumab (MDX-010), from 4 to 20 may have:

- **Reaction during or following a drug infusion which may cause fever, chills, rash**
- **Low blood pressure which may cause feeling faint**

Ipilimumab (MDX-010) 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). 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.**
- **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.**
- **Problem of the muscle, including swelling, which can cause muscle pain and severe muscle weakness sometimes with dark urine.**
- **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.**
- **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 urine; dizziness or fainting.**

RARE, AND SERIOUS

In 100 people receiving ipilimumab (MDX-010), 3 or fewer may have:

- **Bleeding**
- **Blockage of the bowels which may cause constipation**
- **Fluid around heart**
- **Severe illness with multiorgan failure**
- **Confusion**

Ipilimumab (MDX-010) 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:

- **A condition with high blood sugar which leads to tiredness, frequent urination, excessive thirst, headache, nausea and vomiting, and can result in coma**
- **Heart problems including swelling and heart failure. Symptoms and signs of heart problem may include: Shortness of breath, swelling of the ankle and body.**
- **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), 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 ipilimumab therapy, since the risk and severity of transplant-associated complications may be increased.**
- **Swelling of the brain (meningitis/encephalitis), which may cause: headache, confusion, sleepiness, seizures, and stiff neck.**

Risks of combined treatment with both BMS-936558 (Nivolumab) and Ipilimumab:
Recent studies looking at use of both of the study drugs together show that the side effects of both study drugs may occur more often and may be worse (more severe) when the drugs are taken together than when the drugs are taken alone. This means that all of the risks indicated in the BMS-936558 (Nivolumab) and Ipilimumab tables above could be worse or more common than if either BMS-936558 (Nivolumab) or Ipilimumab were taken by itself.

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.

For All Patients:

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study as the drugs used in this study could be very damaging to an unborn baby. Women who receive these drugs should use effective contraception during the period of the trial and for at least 23 weeks (5 months) after completion of treatment. Men who receive these drugs should use effective contraception during the period of the trial and for at least 31 weeks (7 months) after completion of treatment. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

Risks of continuing treatment after your cancer gets worse: It is possible that patients taking the study drug or drugs will have a delayed response within the first 24 weeks of taking the study drugs. This means that your cancer might get better after it gets worse. If you are continuing to show clinical benefit after your disease progresses (as shown by CT or MRI images), your study doctor may ask you if you would like to continue treatment with the study drugs. The risks of continuing treatment after your cancer gets worse include all of the risks above and the risk that there may be no benefit to receiving the study drugs. It is not known if the study drugs will provide any benefit after your cancer gets worse. Even if you and your doctor decide to continue treatment with the study drugs after your disease gets worse, you may need to stop treatment later due to side effects. These side effects may include results of laboratory tests if the test results show that your cancer has continued to get worse while taking the study drugs.

Risks of blood draws: The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.

Risks of studies on your blood and tissue samples:
There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with 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. There can also be a risk in finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study. There is additional information on risks of genetic testing included in the optional consent below.

What possible benefits can I expect from taking part in this study?

This study has only a small chance of helping you because we do not know at this time if the study drugs/study approach is effective. This study may help researchers learn things that may help other people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The 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.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available

- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

If you consent to allow your blood and/or tissue samples to be kept in a bank for additional and/or future research, please see the "What if I change my mind?" section below if you decide that you no longer want your samples to be used.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

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.

What are the costs of taking part in this study?

For patients receiving both study drugs: The nivolumab and ipilimumab will be supplied at no charge while you take part in this study. If you and your study doctor decide that you will continue taking the study drugs after your cancer gets worse, the nivolumab and ipilimumab will still be supplied at no charge for as long as you take part in the study.

For patients receiving nivolumab alone: The nivolumab will be supplied at no charge while you take part in this study. If you and your study doctor decide that you will continue taking the study drug after your cancer gets worse, the nivolumab will still be supplied at no charge for as long as you take part in the study.

For all patients: The cost of getting the study drugs (nivolumab and ipilimumab) or study drug (nivolumab alone) ready and giving it to you is not paid by the study sponsor so you or your insurance company may have to pay for this. It is possible that the study drugs (combination of nivolumab and ipilimumab or nivolumab alone) may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

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

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. Contact information for your study doctor is listed on the consent

cover page. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

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 and the researchers 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 that goes out to others will not identify you.

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

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

- Montana Cancer Consortium
- The study sponsor, SWOG, and any company supporting the study or the study treatment now or in the future. This would include any organization helping the company with the study. The Institutional Review Board (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 Food and Drug Administration (FDA) and the groups it works with to review research.
- The National Cancer Institute (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.

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.

Who can answer my questions about this study?

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.

This section is about optional studies 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. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records, and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say 'no' to any or all of these studies. If you sign up for but cannot complete any of the 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.

Future Contact

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

Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part in this part of the study, the study doctor for the main study would also like to ask your permission to collect additional blood and tissue (at time of a regular standard of care procedure), and to store and use your blood samples and health information for future medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by SWOG and supported by the National Cancer Institute.

WHAT IS INVOLVED?

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

1) Your sample and some related health information may be stored in the Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record will be updated from time to time. Your samples may include:
2) About 1 extra teaspoon of blood will be collected from a vein in your arm (at the same time as other study blood tests) prior to your beginning study treatment. Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
3) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
4) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
2) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
   There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
3) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information.
4) There are laws against misuse of genetic information, but they may not give full protection. The Genetic Information Nondiscrimination Act of 2008, also referred to

as GINA, was passed by Congress to protect Americans from such discrimination. The law prevents discrimination from health insurers and employers. This law does not cover life insurance, disability insurance and long-term care insurance. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

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

1) When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and SWOG staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom SWOG sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

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?

Neither you nor your health care plan/insurance carrier will be billed for the collection or testing of the tumor tissue or blood samples that will be used for this study. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

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

WHAT IF I HAVE MORE QUESTIONS?

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 to show whether or not you would like to take part in each option:

SAMPLES FOR FUTURE RESEARCH STUDIES:

1. **I agree to the additional blood sample collection (collected prior to beginning study treatment).**

   YES NO

2. **My blood 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.

My Signature Agreeing to Take Part in the Main 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 copy of this form. I agree to take part in the main study and 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)