

Study Title for Study Participants:

Testing Treatment with Ipilimumab and Nivolumab compared to Treatment with Ipilimumab Alone In Advanced Melanoma

**Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>:
S1616, “A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) or Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD-1 or Anti-PD-L1 Agent.”**

What is the usual approach to my cancer?

You are being asked to take part in this study because you have melanoma that cannot be removed by surgery. Also, you received an immunotherapy drug (a drug that helps the body's immune system destroy cancer cells), and your cancer got worse while receiving that. People who are not in a study are usually treated with another type of immunotherapy or targeted therapy if there is a mutation in the cancer.

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.

Why is this study being done?

The purpose of this study is to compare any good and bad effects of using ipilimumab in combination with nivolumab to the usual approach of using ipilimumab alone. The combination treatment of ipilimumab and nivolumab could stop your melanoma from getting worse, but it could also cause side effects. This study will allow the researchers to know whether this different approach is better, the same, or worse than the usual approach. To be better, the drug combination should stop your melanoma from getting worse for 3 or more months longer than the usual approach. Both ipilimumab and nivolumab have already been FDA-approved to treat other cancers. However, ipilimumab and nivolumab in this setting are investigational and not FDA-approved for use in combination in treating melanoma, except in people who have not received any previous PD-1 agents such as nivolumab or pembrolizumab. Up to about 94 people are expected to take part in this study.

What are the study groups?

This study has two study groups (also called study “arms”).

Group 1

If you are in **Group 1**, you will receive ipilimumab once every three weeks for up to four times. Ipilimumab is given through a vein over a 90 minute period.

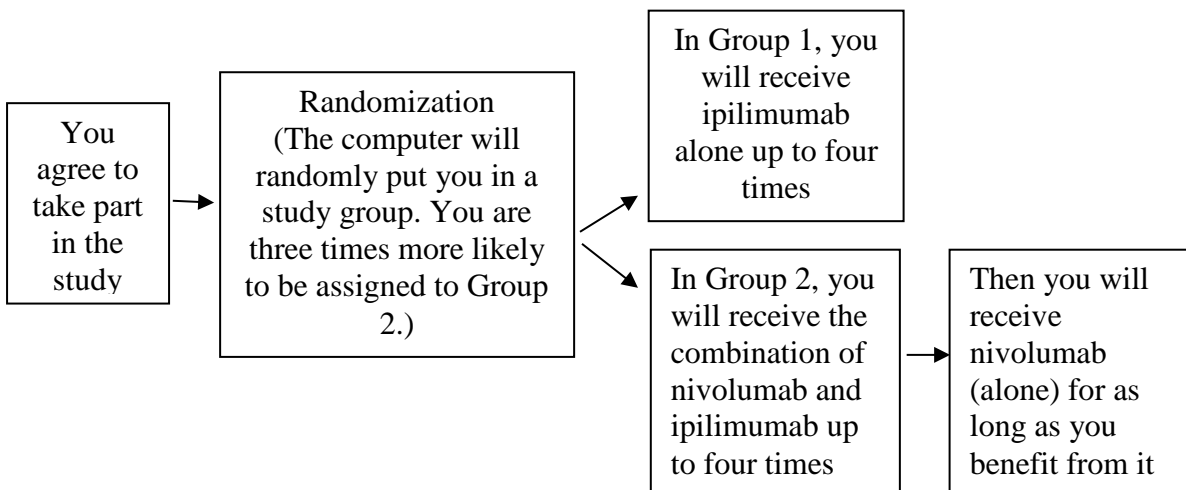
Group 2

If you are in **Group 2**, you will receive nivolumab and ipilimumab once every three weeks for up to four times. Both drugs are given through a vein. Nivolumab will be given over a 60 minute period. Then ipilimumab will be given over a 90 minute period.

After four treatments of this drug combination, you will receive nivolumab by itself once every four weeks. Again, it will be given through a vein over a 60 minute period.

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. For every patient assigned to Group 1, the computer will assign three patients to Group 2. In other words, there is a greater chance you will be assigned to Group 2 than Group 1.

Another way to find out what will happen to you during this study is to read the chart below.



How long will I be in this study?

If you are in Group 1, you will receive the study drug for 12 weeks.

If you are in Group 2, you will receive ipilimumab and nivolumab for 12 weeks. Then you will receive nivolumab alone for as long as your cancer does not get worse, the side effects are tolerable, and you agree to stay on study.

After you finish the study treatment in either group (Group 1 or Group 2), your doctor will continue to watch you for side effects and follow your condition for 3 years from the time you started the study. The doctor will ask you to visit the office for follow-up exams at least once every 6 months for 2 years from the time you started the study, then once more at the end of the third year.

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

If the exams, tests, and procedures show that you can take part in the study, and you choose to take part, then you will need the following extra procedures. They are not part of the usual approach for your type of cancer.

- Before you begin the study:
A small piece of cancer tissue that was removed from a previous biopsy will be taken at the beginning of the study if this cancer tissue is available to your treating physician. Since this biopsy has already been performed, there are no physical risks related to this “archival” tissue submission. Neither you nor your health care plan/insurance carrier will be billed for the collection or submission of the tissue that will be used for this study. If there is leftover, tissue it will be banked in a central laboratory. This will be discussed in the section on optional studies.
- Biopsies. You will have two additional biopsies while on this study; the first before beginning study treatment and the second around Day 28 of your study treatment. The research biopsy is done in a similar way to biopsies done for diagnosis. Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, which can be treated with regular pain medications, and bruising. Rarely, an infection can occur. You will sign a separate consent form before the biopsies are taken. This will be a standard surgical consent form from the institution where the biopsy procedures take place. Small pieces of cancer tissue removed during a biopsy before the study and between 3-5 weeks into the study will be submitted to a central lab for research. These samples are required in order for you to take part in this study because the research on the samples is an important part of the study. The research will see if any biomarkers are associated with treatment outcomes. (A biomarker can be a genetic feature or specific protein found in the tumor sample.). Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. Results of testing done with your sample will not be shared with you or your doctor. Neither you nor your health care plan/insurance carrier will be billed for the biopsies or for the collection of the tissue samples that will be used for this study. Any tissue leftover from the biopsy and testing may, with your consent, be stored for biobanking. This will be discussed in the section on optional studies.
- You will give a blood sample within 28 days of beginning study treatment and again around Day 28 of your study treatment. The blood sample will be collected before you

begin to receive your study treatment but at the same time you have blood taken for laboratory tests. About 5 teaspoons of blood will be taken at each of these timepoints and sent to a central lab for research. These blood samples are required in order for you to take part in this study because the research on the samples is an important part of the study. The research will see if any biomarkers are associated with treatment outcomes. (A biomarker can be a genetic feature or specific protein found in the tumor sample). Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. The results of this testing will not be available to you or your study doctor. Neither you nor your health care plan/insurance carrier will be billed for the collection of the blood (at the beginning of the study and 28 days after beginning treatment). Any tissue leftover from the blood draw and testing may, with your consent, be stored for biobanking. This will be discussed in the section on optional studies.

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 nivolumab (MDX-1106) and ipilimumab (MDX-010) together 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 than usual**
- **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. The study doctor will be testing 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 interfere with your ability to have children.**
- **Some side effects may be 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.**

- The study doctor will work with you to treat your side effects.
- The 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.

Possible Side Effects of Ipilimumab (Arms 1 and 2)

<p>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 nivolumab. Call or see your healthcare provider right away if you develop any problems listed below or the symptoms get worse.</p>
<p style="text-align: center;">COMMON, SOME MAY BE SERIOUS</p> <p>In 100 people receiving ipilimumab (MDX-010), more than 20 and up to 100 may have:</p> <ul style="list-style-type: none">• Diarrhea, nausea• Tiredness <p>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:</p> <ul style="list-style-type: none">• Skin: itching; rash, blisters including inside the mouth (can be severe); hives
<p style="text-align: center;">OCCASIONAL, SOME MAY BE SERIOUS</p> <p>In 100 people receiving ipilimumab (MDX-010), from 4 to 20 may have:</p> <ul style="list-style-type: none">• 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• Reaction during or following a drug infusion which may cause fever, chills, rash• Low blood pressure which may cause feeling faint <p>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:</p>

- **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.**

Possible Side Effects of Nivolumab (ARM 2 only)

Special precautions

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

- **Tiredness**

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving nivolumab (MDX-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**

Nivolumab (MDX-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.**
- **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 nivolumab (MDX-1106), 3 or fewer may have:

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

Nivolumab (MDX-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**
- **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.**

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.

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 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 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.

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

It is not possible to know at this time if the study drug/study approach is better than the usual approach, so this study may or may not help you. This study will help researchers learn things that will help 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.

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, you may contact 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?

The ipilimumab (Groups 1 and 2) and nivolumab (Group 2 only) will be supplied at no charge while you take part in this study. The cost of getting the ipilimumab (Groups 1 and 2) and nivolumab (Group 2 only) 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 nivolumab and ipilimumab 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. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- Montana Cancer Consortium
- The study sponsor, SWOG, and the drug company supporting the treatment study you are on.
- The NCI Central Institutional Review Board (CIRB) and the Institutional Review Board, (IRB) that oversees the institution where you are taking part in the study. An IRB 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 National Cancer Institute (NCI) in the U.S., and similar ones if other countries are involved in the study.

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.

ADDITIONAL STUDIES SECTION

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.

1. Future Contact

Occasionally, researchers working with SWOG may have another research idea that relates to people who were on a SWOG study. In some cases, to carry out the new research, we would need to contact participants in a particular study. You can agree or not agree to future contact.

Please circle your answer: 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

2. Optional Research Studies that Involve Specimens

Please note: This section of the Informed Consent Form is about additional research studies that are being done with people who are taking part in the main study. You may take part in these additional studies if you want to. You can still be part of the main study even if you say “no” to taking part in the additional 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, samples of your tissue and blood will be stored. The researchers ask your permission to store and use your samples and health information for 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 the Ribas Laboratory.

What is involved?

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

- 1) Any leftover tissue or blood from the samples that were sent to the Ribas Laboratory for testing will be stored for future studies.
- 2) Your samples will be stored in the Ribas Laboratory, along with samples and information from other people who take part. The samples will be kept until they are used up.
- 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) 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.
- 2) 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. 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 sample(s) is 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. Your samples may be helpful to research. 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?

There are no costs to you or your insurance. 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.

If you decide to withdraw your specimens from a SWOG Specimen Repository in the future, a written withdrawal of consent should be submitted through your study doctor to the SWOG Operations Office. Please designate in the written withdrawal whether you would prefer to have the specimens destroyed or returned to the study doctor.

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

My samples and related information may be kept in the Ribas Laboratory for use in future health research.

Yes No

THIS IS THE END OF THE SECTION ABOUT OPTIONAL STUDIES

Signature:

This study has been explained to me, and I have been told what my enrollment in the study involves. I have read all pages of this consent and have had my questions answered to my satisfaction at this time. I consent to participate in this study and any additional studies where I circled 'yes'. I understand that by signing this form I have not given up any of my legal rights. I will be given a copy of this consent form. I may also request a copy of the protocol (full study plan).

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)
(Required for initial consent only)

Specimen Consent Supplemental Sheets

How are Specimens Used for Research?

Where do specimens come from?

A specimen may be from a blood sample or from bone marrow, skin, toenails or other body materials. People who are trained to handle specimens and protect donors' rights make sure that the highest standards of quality control are followed by SWOG. Your doctor does not work for SWOG, but has agreed to help collect specimens from many patients. Many doctors across the country are helping in the same way.

Why do people do research with specimens?

Research with specimens can help to find out more about what causes cancer, how to prevent it, how to treat it, and how to cure it. Research using specimens can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

What type of research will be done with my specimen?

Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen may look for genetic causes and signs of disease.

How do researchers get the specimen?

Researchers from universities, hospitals, and other health organizations conduct research using specimens. They contact SWOG and request samples for their studies. SWOG reviews the way that these studies will be done, and decides if any of the samples can be used. SWOG gets the specimen and information about you from your hospital, and sends the specimen samples and some information about you to the researcher. SWOG will not send your name, address, phone number, social security number or any other identifying information to the researcher.

Will I find out the results of the research using my specimen?

You will not receive the results of research done with your specimen. This is because research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future.

Why do you need information from my health records?

In order to do research with your specimen, researchers may need to know some things about you. (For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked?) This helps researchers answer questions about diseases. The information that will be given to the researcher may include your age, sex, race, diagnosis, treatments and family history. This information is collected by your hospital from your health record and sent to SWOG. If more information is needed, SWOG will send it to the researcher.

Will my name be attached to the records that are given to the researcher?

No. Your name, address, phone number and anything else that could identify you will be removed before they go to the researcher. The researcher will not know who you are.

How could the records be used in ways that might be harmful to me?

If your confidential genetic information is discovered, you may suffer from genetic discrimination. Genetic discrimination occurs if people are treated unfairly because of differences in their genes that increase their chances of getting a certain disease. In the past, this could have resulted in the loss of health insurance or employment. Because of this, The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, was passed by Congress to protect Americans from such discrimination. The new law prevents discrimination from health insurers and employers. This act was signed into federal law on May 21, 2008, and went into effect May 2009. This law does not cover life insurance, disability insurance and long-term care insurance.

While this study has safeguards in place to protect your confidential genetic information and to make it extremely unlikely that your identity would be connected with any special studies that are performed on your tissue, it is possible that this information could be discovered by someone who is unauthorized to have access to it.

How am I protected?

SWOG is in charge of making sure that information about you is kept private. SWOG will take careful steps to prevent misuse of records. Your name, address, phone number and any other identifying information will be taken off anything associated with your specimen before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person which will help to protect your privacy.

What if I have more questions?

If you have any questions, please talk to your doctor or nurse, or call our research review board at 888-657-3711.