

Study Title for Study Participants: **Testing MK-3475 (Pembrolizumab) in  
Desmoplastic Melanoma**

Official Study Title for Internet Search on

<http://www.ClinicalTrials.gov>: **S1512** *A Phase II and Pilot Trial of PD-1 Blockade with MK-3475 (Pembrolizumab) in Patients with Resectable or Unresectable Desmoplastic Melanoma (DM)*

**What is the usual approach to desmoplastic melanoma?**

You are being asked to take part in this study because you have desmoplastic melanoma that is surgically removable in the best judgment of the surgeon, or you have desmoplastic melanoma that is not surgically removable in the best judgment of the surgeon.

There are several treatment options for high risk melanoma, but nothing that is specifically approved for desmoplastic melanoma. Patients whose melanoma is surgically removable will normally have surgery either before or after getting other treatment. However, only some patients benefit from these treatments. Patients whose melanoma is not surgically removable will normally receive the same or similar treatment as is offered in this study. Your doctor can explain which may be best for you.

**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 have treatment at this time, but continue to have your disease checked periodically.

**Talk to your doctor about your choices before you decide if you will take part in this study.**

**Why is this study being done?**

The purpose of this study is to test any good and bad effects of the study drug MK-3475 (also called pembrolizumab). MK-3475 (pembrolizumab) could shrink your cancer but it could also cause side effects. Researchers hope to learn if the study drug will cause the cancer to at least temporarily disappear in more than twenty percent of patients with melanoma that is not surgically removable. In patients with melanoma that is surgically removable, researchers also hope to learn if the study drug will cause the surgery to be more effective and avoid repeated surgery. MK-3475 (pembrolizumab) has already been FDA-approved as an initial treatment of

unresectable or metastatic melanoma and to treat melanoma after treatment with ipilimumab, but is experimental as used in this study in Group 1. There will be about 56 people taking part in this study.

## **What are the study groups?**

This study has two study groups. Your study doctor will let you know what group you will be assigned to before you start the study. All study participants will get the same study drug treatment. You will receive MK-3475 (pembrolizumab) into a vein over a 30 minute period. This will be given in the outpatient setting. You will receive MK-3475 (pembrolizumab) every three weeks. This three week period is called a “cycle”.

If your melanoma is surgically removable before beginning study treatment, you will be assigned to Group 1. After 3 cycles of MK-3475 (pembrolizumab), your study doctor will decide if your melanoma is still surgically removable. If it is, you will have surgery. Even if it appears your disease has disappeared, you will still undergo surgery to remove any disease that might remain. If it is not removable, you will have one more cycle of MK-3475 and your study doctor will decide if your melanoma is surgically removable. If it is, you will have surgery and if it is not you will not receive any additional treatment as part of this study.

If your melanoma is not surgically removable before beginning study treatment, you will be assigned to Group 2. Every 3 cycles, your study doctor will decide if your melanoma is surgically removable. If it is, you have the option to have surgery or to continue taking MK-3475 (pembrolizumab) for up to two years from starting the study. If your melanoma is not surgically removable, but has not gotten worse you will take MK-3475 for another 3 cycles. This process will continue for up to two years from starting the study.

## **How long will I be in the study?**

If you are in the group that has melanoma that is surgically removable (Group 1), you will receive up to 4 cycles of treatment before getting surgery (as long as your melanoma has not become too difficult to remove by surgery).

If you are in the group that has melanoma that is not surgically removable (Group 2), you will continue to receive treatment until the treatment is no longer effective (or until the melanoma becomes surgically removable) or for up to two years.

After you are finished with the study treatment in either group (Group 1 or Group 2), the doctor will ask you to visit the office for follow-up exams once every 6 months for 2 years from starting the study and then once a year for up to 5 years from starting the study.

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

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

Before you begin and while on the study

### **Tissue Biopsies**

This study requires that small samples of cancer tissue be sent to a central laboratory for testing of a biomarker called “CD8 T cells”. (A biomarker can be a genetic feature or specific protein or cells found in the tumor sample.) 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 “CD8 T cells” will be compared over time. Therefore, small pieces of cancer tissue removed by biopsy will be taken for the study before you begin the study drugs and again between 3-5 weeks after starting the study drugs.

The researchers will also request an optional biopsy (see “Additional Studies” section below) if your disease gets worse (progresses) within 5 years after you start the study treatment. This will be used to compare to the required tissue samples.

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 biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place.

If there is any leftover tissue after testing, with your consent, the sample will be stored for biobanking. This will be discussed in the section about optional studies.

### **Blood draws**

A blood sample will be taken for the study before you begin 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. This sample is required in order for you to take part in this study because the research on the sample is an important part of the study. The sample will be tested to see how your immune system is working. If there is any leftover blood after testing, with your consent, the sample will be stored for biobanking. This will be discussed in the section about optional studies.

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 tissue (at the beginning of the study and 3-5 weeks after beginning treatment) and blood that will be used for this study. You and/or your health care plan/insurance carrier will be responsible for the cost of your surgery.

### **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:**

- **You may lose time at work or home and spend more time in the hospital or doctor's office than usual**
- **The study approach may not be better, and could possibly be worse, than the usual approach for your cancer.**
- **The research-related biopsy may cause a small amount of bleeding or in rare occasions infection can occur. You may have pain and bruising at the biopsy site, which can be treated with regular pain medication.**
- **You may be asked sensitive or private questions which you normally do not discuss.**

**The MK-3475 (pembrolizumab) 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 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 are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.**

**There is also a risk that you could have side effects from the study drug (s)/study approach.**

**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.**

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some 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 that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

### Risk Profile for MK-3475 (pembrolizumab)

(CAEPR Version 2.5, December 27, 2019)

<b>COMMON, SOME MAY BE SERIOUS</b>
In 100 people receiving MK-3475 (pembrolizumab), more than 20 and up to 100 may have:
<ul style="list-style-type: none"><li>• <b>Tiredness</b></li></ul>

<b>OCCASIONAL, SOME MAY BE SERIOUS</b>
In 100 people receiving MK-3475 (pembrolizumab), from 4 to 20 may have:
<ul style="list-style-type: none"><li>• <b>Nausea</b></li><li>• <b>Infection</b></li><li>• <b>Loss of appetite</b></li><li>• <b>Pain in back</b></li><li>• <b>Joint stiffness</b></li><li>• <b>Cough</b></li><li>• <b>Swelling and redness of the skin</b></li></ul>
<p><b>MK-3475 (pembrolizumab) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:</b></p> <ul style="list-style-type: none"><li>• <b>Anemia which may require blood transfusion</b></li><li>• <b>Pain in lymph nodes</b></li><li>• <b>Blood clot which may cause bleeding, confusion, paralysis, seizures and blindness</b></li><li>• <b>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</b></li><li>• <b>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</b></li></ul>

**bowel movements, blood in your stools or dark, tarry, sticky stools, severe belly pain or tenderness**

- **Diarrhea**
- **Sores in the mouth which may cause difficulty swallowing**
- **Pain in belly**
- **Sores in the bowels**
- **Chills, fever**
- **Liver problems (hepatitis) which can cause liver failure. Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes, severe nausea or vomiting; drowsiness; pain in the right upper belly**
- **Pain or swelling of the joints**
- **Problem of the muscle, including swelling, which can cause muscle pain and severe muscle weakness sometimes with dark urine**
- **Fluid in the joints**
- **Pain in chest**
- **Lung problems (pneumonitis and other conditions). Symptoms may include: new or worsening cough, chest pain, shortness of breath.**
- **Skin: itching; acne; rash (can be severe); blisters and peeling on the skin, mouth; skin changes; hives**

#### **RARE, AND SERIOUS**

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

- **A syndrome starting with flu-like symptoms and followed by swelling, tenderness which may cause flu-like symptoms, blurred vision, ringing in the ears, changes in hair or hair loss**
- **Swelling of the spinal cord**
- **Feeling of "pins and needles" in arms and legs**
- **Redness, pain or peeling of palms and soles**

**MK-3475 (pembrolizumab) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:**

- **Heart problems including swelling and heart failure. Symptoms and signs of heart problems may include: Shortness of breath, swelling of the ankles and body**
- **Swelling and redness of the eye**
- **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat**
- **Reaction during or following a drug infusion which may cause fever, chills, rash**
- **Damage to organs in the body when donor cells attack host organs which may cause yellowing of eyes and skin, itchy dry skin**

- **Damage to organs in the body when the body produces too many white cells**
- **A condition with high blood sugar which leads to tiredness, frequent urination, excessive thirst, headache, nausea and vomiting, and can result in a coma**
- **Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs**
- **Swelling of the brain (encephalitis/meningitis) which may cause headache, confusion, sleepiness, seizures, and stiff neck**
- **Kidney problems, including nephritis and kidney failure requiring dialysis. Signs of kidney problems may include: decrease in the amount of urine, blood in your urine, ankle swelling**
- **Swelling or tenderness of blood vessels**

Pembrolizumab works by helping your immune system to fight your cancer. However, pembrolizumab can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects. These side effects may be serious (i.e. causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time.

#### **Risks of Venipuncture/Intravenous Needle Insertion:**

**Occasional, some may be serious: Mild pain and discomfort at the injection or needle insertion site as well as possible infection, bleeding, bruising, and soreness.**

**Rare: Severe pain, swelling, infection from the actual injection, and fainting.**

**Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.**

**Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study. The drugs used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study. Women of child bearing potential and men must agree to use adequate contraception (barrier method of birth control or abstinence) prior to study entry and for the duration of study participation through 120 days after receiving the last dose of treatment. If you become pregnant while receiving treatment on this study, you should inform your doctor immediately and stop the study drug.**

#### **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 if the study drug/approach is effective. This study may help researchers learn things that may 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. Contact information for your study doctor is listed on the consent cover page. 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, 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?**

The MK-3475 (pembrolizumab) will be supplied at no charge while you take part in this study. The cost of getting the MK-3475 (pembrolizumab) 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 drug 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 will not be charged for the research biopsy or blood draw required before you begin the study treatment.

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 any drug company supporting the study.
- Other participating National Clinical Trials Network groups; Alliance, ECOG-ACRIN, and NRG Oncology.
- The Institutional Review Board, 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 and the National Cancer Institute 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.

### **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 used. 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 located at the University of California, Los Angeles.

## **What is involved?**

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

- 1) If your disease gets worse (progresses) within 5 years after you start the study treatment, the researchers would like to collect about ½ inch of tissue. This would be collected at the time of a standard of care biopsy. It would be used for “CD8 T cells” testing.
- 2) If there is any remaining after the “CD8 T cells” studies are done, the tissue that was collected at the time of your surgeries or biopsies will be kept at a Biobank for use in future studies. Also, if there is any remaining after the immune studies are done, the blood that was collected before you started study treatment will be sent to a Biobank for use in future studies.
- 3) Your samples will 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.
- 4) 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.
- 5) 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.
- 6) 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) 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. You will sign a separate consent form before the biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place.
- 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.
- 3) 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.

- 4) 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:**

**1. 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

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

Yes                  No

## **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)

## **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.