Study Title for Study Participants: **Testing MK-3475 (Pembrolizumab) Compared to Standard Treatment for High Risk Resected Melanoma**

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: ***S1404*** *A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma.*

What is the usual approach to high risk melanoma?

You are being asked to take part in this study because you have melanoma, which, although it has been successfully treated with surgery, has a high probability of coming back.

There are several treatment options for high risk resected melanoma. These include: 1) high dose interferon alfa-2b, 2) a different version of interferon (called "pegylated" interferon), and 3) ipilimumab which was recently approved by the FDA. However, only some patients benefit from these treatments. Though a choice of either high dose interferon alfa-2b or ipilimumab has been selected as the standard treatment option for this study, please talk with your doctor about alternatives before finalizing your decision to take part in this study. We hope to find a more effective and long-lasting treatment for your type of cancer.

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

Your other choices may include:

- **You may choose to have the usual approach, described above**
- **You may choose to take part in a different study, if one is available**
- **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 compare the effects, good and/or bad, of the experimental drug MK-3475 (also called pembrolizumab) to the usual treatment of either interferon alfa-2b or ipilimumab. This study will allow the researchers to know whether treatment with MK-3475 (pembrolizumab) is better, the same, or worse than usual treatment. In this study, you will get either MK-3475 or a choice of either interferon alfa-2b or ipilimumab. There will be about 1,378 people taking part in this study.

What are the study groups?

This study has two study groups (also called study "arms"). A computer will by chance assign you to one of the two study arms. This is called randomization. This is done by chance because no one knows if one study arm is better, the same, or worse than the other arm. Once you are put on one arm, you cannot switch to the other arm. Neither you nor your doctor can choose which arm you will be in.

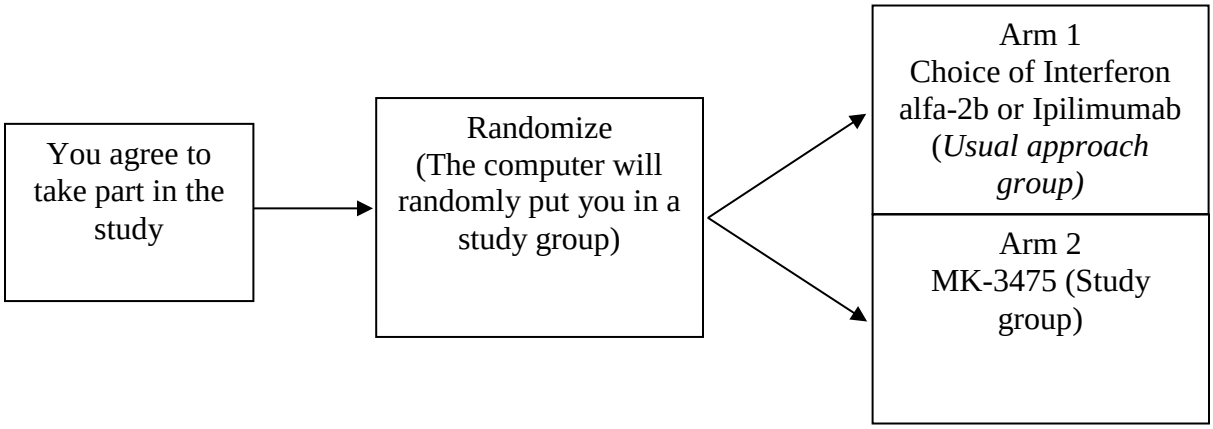
If you are in Arm 1, you will receive either interferon alfa-2b or ipilimumab in two stages, called the induction phase and the maintenance phase.

If you choose to get interferon alfa-2b, in the induction phase you will receive interferon alfa-2b for 5 consecutive days (Mon-Fri) out of 7 days, for four weeks. This will be done by intravenous infusion (given through a vein in your arm) over a 20 minute period. These infusions will be given in an outpatient setting. In the maintenance phase, you will receive interferon alfa-2b three times weekly, every other day (Mon, Wed, Fri) for 48 weeks. This will be done by subcutaneous injection (just below the skin). You will be taught how to self administer the interferon subcutaneous injections. You will be asked to keep track of your injections with a written interferon calendar which will be reviewed during visits to your doctor's office or clinic.

If you choose to get ipilimumab, in the induction phase you will get ipilimumab by an infusion into your vein over 90 minutes. This infusion will be given as an outpatient. During the induction phase you will get the infusion once every three weeks for four doses. In the maintenance phase, you will get ipilimumab by an infusion into your vein over 90 minutes. This infusion will be given as an outpatient. During the maintenance phase you will get the infusion once every twelve weeks for about twelve doses (total treatment time will be a maximum of three years).

If you are in Arm 2 you will receive MK-3475 (pembrolizumab) by intravenous infusion over a 30 minute period. This infusion will be in the outpatient setting. You will receive MK-3475 (pembrolizumab) infusions every three weeks for eighteen doses (approximately one year).

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



How long will I be in the study?

You will receive study drugs for one year if you get interferon alfa-2b or MK-3475 (pembrolizumab) or three years if you get ipilimumab. After you are finished with study treatment, the doctor will ask you to visit the office for follow-up exams. For interferon alfa-2b or MK-3475 (pembrolizumab), the first visit will be 6 weeks (-/+ 1 week) after the last dose of the study drug. The next visit will be 12 weeks (-/+ 1 week) after the last dose of the study drug, then there will be a visit every 3 months for the first two years, then every 6 months for Years 2-5, then every 12 months for the next 5 years. For ipilimumab, the first visit will be 6 weeks after the last dose of the study drug, then every 6 months for Years 4-5, then every 12 months for the next 5 years. Follow-up exams will take place for up to 10 years as long as your disease does not reoccur. If you come off of study treatment because your disease comes back, your overall condition will be followed every 6 months for 1 year, then annually until 10 years from the date you began the study. We would like to keep track of your medical condition for 10 years from the date the study started to look at the long-term effects of the study treatment.

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

Before you begin the study:

All of the exams, tests, and procedures you will have before you begin the study are part of the usual approach for your cancer. The one test that is not standard is a test to determine a biomarker* called PD-L1.

It is likely that your melanoma was removed through surgery and it is customary for the melanoma tissue to be preserved in a paraffin embedded block. This study requires that a minimum of five slides, made from the tissue block, be sent to a central laboratory for staining and determination of a biomarker called PD-L1. (*A biomarker can be a genetic feature or

specific protein found in the tumor sample). Submission of these slides is required because the research on the tissue sample is an important part of the study.

In addition to the slides submitted to the central lab for testing, you will be given the option to submit slides for banking for future studies. You can indicate whether you will allow your specimens to be banked for future studies in the section called "Optional Studies".

Neither you nor your health care plan/insurance carrier will be billed for the collection of the tissue that will be used for this study.

During the study:

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

- If you are on Arm 2 (MK-3475), you will be required to provide blood samples for additional testing to measure the amount of study drug that is in it and for antibody testing. These blood samples will be collected before you receive your study treatment the day of your infusion before the infusion at Week 1, Week 4, Week 10, Week 19, Week 25, and Week 49. Additionally, a sample will be obtained 30 days after you are off protocol treatment. The total amount of blood taken each time for this testing is about two teaspoons. This is not part of regular cancer care, but is being done as part of this research study.
- Questionnaires – You will complete three questionnaires (which will take about 10 minutes to complete) to collect information about how you are feeling physically and emotionally during your treatment and how you are performing your daily activities. These questionnaires are required for patients who can fill out the questionnaires in English, Spanish or French. The questionnaires will be given to you at the beginning of the study (before you start treatment), Weeks 1, 4, 13, 25, 37 and 48 then 24 and 48 weeks after the date of your last treatment. If any questions make you feel uncomfortable, you may skip those questions and not give an answer. We will do our best to make sure that your personal information will be kept private. This is not part of regular cancer care, but is being done as part of this research study.

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.**
- **You may be asked sensitive or private questions which you normally do not discuss**

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 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.

Possible Side Effects of interferon alfa-2b

COMMON, SOME MAY BE SERIOUS In 100 people receiving interferon alfa-2b, more than 20 and up to 100 may have:
• **Infection, especially when white blood cell count is low** • **Diarrhea, nausea, vomiting** • **Flu-like symptoms including body aches, muscle pain** • **Tiredness** • **Weight loss** • **Loss of appetite** • **Anemia which may require blood transfusions** • **Headache** • **Depression, thoughts of suicide** • **Hair loss** • **Pain** • **Fever, Chills**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving interferon alfa-2b, from 4 to 20 may have:
• **Heart failure or attack which may cause shortness of breath, swelling of ankles, cough or tiredness**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving interferon alfa-2b, from 4 to 20 may have:
• **Abnormal heartbeat** • **Low blood pressure** • **Change in skin color, numbness or pain in fingers and toes** • **Diabetes** • **Internal bleeding, which may cause black tarry stool, blood in vomit** • **Liver damage which may cause yellowing of eyes and skin, or confusion** • **Bruising, bleeding** • **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat** • **Damage to organs** • **Swelling of the body** • **Confusion** • **Stroke, coma** • **Blurred vision with chance of blindness, visual loss** • **Bleeding of the eye** • **Blockage of the lungs or lung collapse** • **Damage to the blood vessel in lungs** • **Blood clot**

RARE, AND SERIOUS In 100 people receiving interferon alfa-2b, 3 or fewer may have:
• **None**

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**
- **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.**

*This is applicable for patients who have undergone a stem cell transplant.

You should tell your doctor if you develop any diarrhea, constipation, any change in your bowel movements, have blood in your stool, or have abdominal pain or pain when swallowing. Your doctor may want to perform tests to better understand why you have these symptoms. These tests will allow your doctor to look at your intestine for damage. It may also help determine the type of treatment you might need, which may include the use of steroids. You may have to go into the hospital for doctors to investigate and treat the diarrhea or other stomach/intestinal symptoms.

Ipilimumab may increase your chance of bowel perforation. A bowel perforation means that your bowel has developed a hole which allows the contents of your intestine to leak into the abdomen. This is considered a medical emergency as it causes a severe infection which can result in death. It has also been reported that patients with bowel metastasis of melanoma (melanoma cancer which has spread to the bowel) might be at higher risk of bowel perforation, which could also result in death. If you know you have diverticulum

(protrusion of soft tissue through the colonic wall) and/or diverticulitis (inflammation in the diverticulum), you need to tell your doctor and your doctor will evaluate whether it is appropriate to treat you with ipilimumab.

Contact your doctor if you experience weakness of your limbs with or without numbness or tingling. Some patients may experience a sensation of tingling, tickling, prickling or burning of a person's skin with unknown long-term physical effect. In rare cases, the immune system may attack skeletal muscles (myasthenia gravis) or the nerves that control muscles (Guillain-Barre Syndrome), which could be life-threatening if not treated appropriately.

Risk Profile for MK-3475 (pembrolizumab)

COMMON, SOME MAY BE SERIOUS **In 100 people receiving MK-3475 (pembrolizumab), more than 20 and up to 100 may have:**
• **Tiredness**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving MK-3475 (pembrolizumab), from 4 to 20 may have:
• **Nausea** • **Infection** • **Loss of appetite** • **Pain in back** • **Joint stiffness** • **Cough** • **Swelling and redness of the skin** **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:** • **Anemia which may require blood transfusion** • **Pain in lymph nodes** • **Blood clot which may cause bleeding, confusion, paralysis, seizures and blindness** • **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** • **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** • **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:

- **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**

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. With regard to interferon alfa-2b, ipilimumab or MK-3475, 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. Two birth control methods are required for MK-3475 (two barrier methods, barrier method plus hormonal method, or barrier method plus IUD).

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

This study may or may not help you because it is not possible to know at this time if the study drug is better than the usual approach. 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. 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 MK-3475 (pembrolizumab) will be supplied at no charge while you take part in this study. 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. Interferon alfa-2b and ipilimumab are commercially available and will not be supplied for this study.
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, Alliance, ECOG-ACRIN, CCTG, NRG and any drug company supporting the study.
- 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.
- IROC - Your medical images will be transferred to the Ohio State University in Columbus, Ohio. Your medical images will be reviewed by investigators at this organization as part of the quality control for this 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, nor will you or your study doctor 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 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) A sample from the tissue that was collected at the time of your surgery or biopsy will be sent to the Biobank for use in future studies. A sample of tissue will also be sent at the time of relapse should this occur. Blood samples will also be collected at the following times: Before you begin study treatment, at the start of Cycle 3 (Weeks 13 if there are no dose delays), at the start of Cycle 4 (Week 25 if there are no dose delays), at the time you are removed from study treatment for any reason and at relapse.
2) 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.
3) 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.

4) 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.
5) 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:

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

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.