Study Title for Study Participants: **Testing MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer**

Official Study Title for Internet Search on

http://www.ClinicalTrials.gov:

S1418/BR006, A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN1mi, ypN1-3) After Neoadjuvant Chemotherapy.

What is the usual approach to my breast cancer?

You are being asked to take part in this study because you have "triple-negative" breast cancer. This means that your type of breast cancer doesn't have receptors for estrogen, progesterone, or the protein HER2, that are found in some other types of breast cancer, so that your doctor feels you are not a candidate for those targeted therapies. Additionally, you have already had preoperative chemotherapy (also called "neoadjuvant" chemotherapy) and your breast cancer has at least partly survived that treatment.

Patients in your situation, who are not in a study, may not receive any more treatment after surgery, or your doctor may recommend further chemotherapy and/or radiation therapy as part of the usual treatment for this 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:

- **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**

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 usual approach (no more treatment or additional chemotherapy and radiation therapy after surgery or radiation therapy alone after surgery), with any effects (good or bad) of receiving one year of therapy with the experimental drug MK-3475 (also called pembrolizumab) after surgery. This study will allow the researchers to know whether treatment with MK-3475 (pembrolizumab) is better, the same, or worse than the usual approach alone. There will be about 1,000 people taking part in this study.

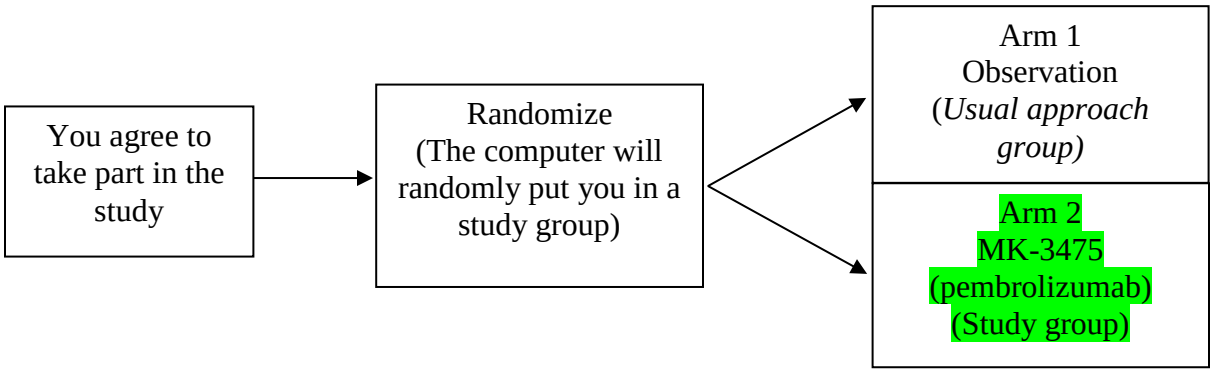
What are the study groups?

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 get observation with close clinical monitoring. Your doctors may recommend postoperative radiotherapy, or more post-operative chemotherapy, as part of your usual treatment. This treatment plan must be determined by you and your physician before entering the trial. If you are assigned to Arm 1, you may not receive any other treatment that is not part of the study. During the study, radiation therapy are allowed as part of your treatment plan. You will have visits with your physician every 12 weeks for one year.

If you are in Arm 2, you will receive MK-3475 (pembrolizumab) by intravenous infusion over a 30-minute period. You will not have to be hospitalized for this infusion unless your doctor feels it is needed. You will receive MK-3475 (pembrolizumab) infusions every three weeks for one year and will be seen by your physician every six weeks during treatment. If your doctor recommends additional therapy after surgery as part of your routine care, you may also receive radiation therapy and at the same time as you receive MK-3475 (pembrolizumab).

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?

If you get randomized to the MK-3475 (pembrolizumab) treatment group (Arm 2), you will receive the study drug for one year. After you are finished with study treatment, the study doctor will ask you to visit the office for follow-up exams. The first visit will be 6 weeks (-/+ 1 week) after the last dose of the study drug. The visits will then be every 6 months (+/- 4 weeks) after the last dose of study drug until five years from the start of treatment, then every 12 months for the next 5 years.

If you get randomized to the usual approach group (Arm 1), you will have visits with your study doctor every 12 weeks for one year. You will then have an "end of year" assessment at the end of the first year (at Week 55). The visits will then be every 6 months (for 4 years), then every 12 months for the next 5 years.

If you are in either the usual approach group (Arm 1) or the MK-3475 (pembrolizumab) treatment group (Arm 2) and your breast cancer comes back at any time during the study, then your study doctor will ask you to come in for a follow-up visit every 6 months until 5 years after the time that you were assigned to one of the study groups, and then every year until 10 years after the time that you were assigned to one of the study groups. Your doctor will see you more often as clinically necessary.

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 (Arm 1 and Arm 2):

- You will need to have a blood test to check your thyroid function.

- If you are a female who can have children, you will need to have a pregnancy test to find out if you can be in the study. If you are in Arm 2, this pregnancy test must be done within 72 hours (3 days) prior to your starting to receive the study drug (MK-3475 (pembrolizumab)).

- You will need to have an extra laboratory test performed on a piece of the cancer tissue that was removed during your surgery. You will not have another surgery. The test is being performed to see if your cancer has the protein called PD-L1, which is the target of MK-3475 (pembrolizumab). Since your breast cancer was removed with surgery it is customary for the breast cancer 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 PD-L1. Submission of these slides is required because the research on the tissue sample is an important part of the study. Neither you nor your health plan/insurance company will be billed for this PD-L1 testing.

- In addition to the slides submitted to the central lab for testing, you will be given the option to have tissue block and/or blood submitted for banking for future studies. This is described in the section called "Optional Research Studies Involving Specimens". You can indicate whether you will allow your specimens to be banked for future studies in that section.

If you are assigned to Arm 1 (Observation):

During the study:

- Even if you are not receiving any treatment, you will be asked to come in for more frequent follow-up visits every 12 weeks (84 days) for the first year, then about every 6 months for the next 4 years. At these visits, you will have a physical exam and your blood will be drawn to check your blood counts and liver and kidney functions. These tests are not standard for people who are not receiving any treatment after surgery. There may be additional tests and more frequent blood draws if you receive chemotherapy after surgery as part of routine care recommended by your doctor. Those tests will be determined by your doctor.

If you are assigned to Arm 2 (MK-3475 (pembrolizumab)):

While you are receiving study treatment:

- It is expected that all tests will be covered by your health plan/insurance due to the need to check for side-effects while you are receiving treatment.
- Your thyroid function will be checked while you are taking the study drug (MK-2475 (pembrolizumab). Blood tests to check your thyroid function will also be done at Cycle 3 (Week 13), Cycle 5 (Week 25), Cycle 7 (Week 37), and your end of treatment visit.

For the next 4 years after completion of MK-3475 treatment on Arm 2:

- You will be seen in the clinic for physical examination and blood tests to determine blood counts and liver and kidney function about every 6 months. These tests are not standard for people who are not participating in a study.

After 5 years after you are assigned to a study group (for both Arms 1 and 2), there will be no more blood tests.

All other exams, tests, and procedures that your doctor may order before you begin the study and while you are on the study are part of the usual approach for your cancer.

Quality of Life Study

The first 510 patients who read or speak English enrolled in the main study will participate in the Quality of Life Study, as all patients who join the main study are not needed by the researchers to answer the Quality of Life research questions and the questionnaires are only available in English.

You will be asked to fill out a form with questions about your physical and emotional well-being. Researchers will use this information to learn more about how cancer and cancer treatment affects people. Most patients have a number of symptoms that last after their chemotherapy and surgery. We would like to know if you have any symptoms before you join the study so we can follow them during your participation in the study. You will be asked to fill out this form at 8 times while you are on the study:

- when you join the study
- at 3, 12, and 18 months after joining the study

- at 2, 3, 4, and 5 years after joining the study

Each form will take about 20-30 minutes to complete. The form will ask about things like fatigue, constipation, diarrhea, and pain.

You will also be asked to fill out a form with questions about your health and certain health behaviors, such as use of tobacco and alcohol. You will be asked to fill out this form at 4 times while you are on the study:

- when you join the study
- at 3, 12, and 18 months after joining the study

Each form will take about 5-10 minutes to complete.

You may be uncomfortable answering some of the questions on these forms, and you can skip any you do not want to answer.

In addition to the questionnaires, researchers would like to try to understand whether or not any of the symptoms that patients experience after breast cancer treatment with MK-3475 (pembrolizumab) are being caused by higher blood levels of inflammation proteins called cytokines or with variations in genes that affect inflammation. Researchers may also look at variations in genes that affect other symptoms. To measure these, a small sample of blood will be taken from your vein (1-2 teaspoons) at 4 visits at the same time that blood is already being drawn for the main study. Blood for this test will be collected when you join the study, and at 3, 12, and 18 months after joining the study. 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. Side effects of the blood draws are generally mild pain, bleeding, and/or bruising at the site of the draw. The tests done on these samples will be examined in a research laboratory and then compared to responses on the questionnaires to see if they can explain whether or not a patient experiences fatigue and other symptoms that may be reported at study entry and over time.

The information from the questionnaires and the results from the blood sample marker tests along with other information collected for the **S1418** treatment study will be examined by the researchers for the Quality of Life study. 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 being done using these samples.

Neither you nor your health care plan/insurance carrier will be billed for the collection and storage of blood that will be used for the treatment and Quality of Life 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:

- **You may lose time at work or home and spend more time in the hospital or doctor's office than usual**
- **You may be asked sensitive or private questions which you normally do not discuss**

- **The study approach may not be better, and could possibly be worse, than the usual approach for your cancer.**

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.

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.

Arm 2: MK-3475 (pembrolizumab) treatment group

Possible Side Effects of 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 (fluid buildup around the heart (pericarditis)) 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 Radiotherapy with MK-3475 (pembrolizumab) (Arm 2):

Receiving radiation together with MK-3475 may increase the efficacy of the radiation therapy but it may also cause more side effects including fatigue, skin damage, autoimmune reactions described for MK-3475. Currently, not all side effects of combined, concurrent therapy with radiation and MK-3475 are known and therefore unexpected side effects can also occur.

Risks of Venipuncture/Intravenous Needle Insertion (Arms 1 and 2):

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 must have a pregnancy test within 72 hours (3 days) prior to beginning study drug (MK-3475 (pembrolizumab)). Women of childbearing potential and must agree to use adequate contraception (abstinence or barrier method of birth control plus hormonal methods or intrauterine device) prior to study entry and for the duration of study participation through 120 days after receiving the last dose of MK-3475 (pembrolizumab). Two birth control methods are required for MK-3475 (pembrolizumab). 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?

There is some evidence that treatment with the study drug, MK-3475 (also called pembrolizumab), for one year after surgery may delay or prevent your cancer from coming back (in your breast or other parts of your body). It is not possible to know now if the study drug will extend your time without disease or prevent your disease from coming back as compared to the usual approach. This study will help the study doctors 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, Institutional Review Board (IRB) or Federal Drug Administration (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.

The cost of getting 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.

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.

The cost of some blood tests, where those tests are not part of your usual care, may be paid by the study. For Arm 1, the cost of some blood tests, where those tests are not part of your usual care throughout the duration of the study and follow-up visits, may be paid by the study. For Arm 2, the cost of some blood tests done at your follow-up visits may be paid by the study. 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. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

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

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

Some of these organizations are:

- Montana Cancer Consortium
- The study sponsor, SWOG, and any drug company supporting the study.
- National Clinical Trials Network groups that conduct clinical trials (and the groups it works with to conduct research), including: Alliance, ECOG-ACRIN, NRG, CCTG
- 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 (FDA) and the groups it works with to review research.
- The National Cancer Institute in the U.S. (and the groups it works with to review research), and similar ones if other countries are involved in the study.
- Health Canada and the groups it works with to review research.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact information for your study doctor is listed on the consent cover page.

ADDITIONAL STUDIES SECTION:

This section is about optional studies 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 take part in the additional studies.

1. <u>Optional Sample collections for Laboratory Studies and/or Biobanking for Possible Future Studies</u>

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 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) The risks of the blood draw are generally mild pain, bleeding and/or bruising at the site of the blood draw.
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 in optional banking (blood and tissue). 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 for optional banking. 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)