Study Title for Study Participants: Testing the Addition of the Study Drug Olaparib to the Usual Radiotherapy in Inflammatory Breast Cancer Patients

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

S1706, "A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy alone for Inflammatory Breast Cancer," (NCT TBD)

What am I being asked to do?

We are asking you to take part in a research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this study because you have inflammatory breast cancer and you have already had chemotherapy and surgery to remove the cancer.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It is important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question: Can we lower the chance of your cancer returning by adding the drug olaparib to the usual radiation therapy for your cancer?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your inflammatory breast cancer. The usual approach is defined as care most people get for inflammatory breast cancer when they have already received chemotherapy and had surgery to remove the cancer.

What is the usual approach to my inflammatory breast cancer?

The usual approach for patients who are not in a study is treatment with radiation therapy to the chest, which has been approved by the Food and Drug Administration (FDA). For patients who receive the usual approach for this cancer, about 20-40 out of 100 are free of cancer at five years.

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.
- You may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will get either the usual radiation therapy plus the study drug olaparib (Group 1) for up to 6 weeks, or you will get the usual radiation therapy alone (Group 2) for up to 6 weeks.

After you finish the study treatment, your doctor will continue to follow your condition until 8 years after you started the study and watch you for side effects. You will be seen about 5 weeks after you finish the study treatment, then about every 3 months for up to 3 years after you started taking part in this study or until your disease comes back. Then, from 3 years after you started taking part in this study or from the time that your disease comes back, you will be seen about every 6 months until up to 8 years after you started taking part in this study. Your doctor will run blood tests and check your disease status at these visits.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that the addition of the study drug olaparib to the usual approach may not be as good as the usual approach for your cancer at preventing your cancer from coming back.

There is also a risk that you could have side effects from the study drug. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

Some of the most common side effects from the study drug or from the radiation therapy to the chest wall and lymph nodes around the tumor that the study doctors know about are:

- Anemia, which may require transfusion
- Infection, especially when white blood cell count is low
- Reddening, tanning, or peeling of the skin
- Hair loss in the radiation treatment area under the arm
- Mild pain

- Tiredness
- Nausea, vomiting, diarrhea, loss of appetite

There may be some risks that the study doctors do not yet know about.

Benefits
There is evidence that adding the study drug olaparib to the usual approach is effective in stabilizing your type of cancer. It is not possible to know now if the study drug will extend your time without disease compared to the usual approach. This study will help the study doctors learn things that will help people in the future.

If I decide to take part in this study, can I stop later?
Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your 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.

Are there other reasons why I might stop being in the study?
Yes. The study doctor may take you off the study if

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor the National Cancer Institute (NCI). The study sponsor is the organization that oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

MAIN CONSENT FORM

What is the purpose of this study?

The purpose of this study is to compare the usual treatment alone to using the study drug (olaparib) plus the usual treatment. The addition of olaparib to the usual treatment may or may not prevent your cancer from returning. But it could also cause side effects, which are described in the risks section below.
This study will help the study doctors find out if this different approach is better, the same, or worse than the usual approach. To decide if it is better, the study doctors will be looking to see if the study approach increases the life of patients by 8 months or more compared to the usual approach.

The drug olaparib is already approved by the Food and Drug Administration (FDA) for use in ovarian, fallopian tube, peritoneal cancer, and gBRCA mutated her2-negative metastatic breast cancer, however olaparib is not approved for inflammatory breast cancer.

There will be about 300 people taking part in this study.

What are the study groups?

This study has 2 study groups.

Group 1 will receive the usual radiation therapy plus the study drug olaparib. Olaparib will be taken during radiation. Olaparib is taken twice daily with water, swallowed whole and not chewed or crushed. Olaparib may be taken with or without food. You should avoid grapefruit, grapefruit juice and Seville oranges while taking olaparib. You should also not receive live viruses or live bacterial vaccines while receiving olaparib and during the 30-day follow-up. If you are assigned to Group 1, you will keep a medication diary. This helps you keep track of when you take your olaparib tablets. The study doctor will show you how to use this diary. Each time you visit the clinic, you must bring the pill diary, any remaining tablets, and the olaparib bottles.

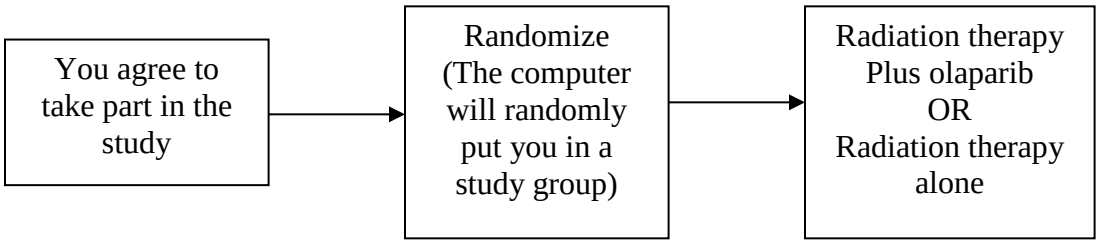
Group 2 will receive the usual radiation therapy alone, which will be given 5 days per week for 6 weeks.

For both Groups 1 and 2, if you have HER2 positive tumors, chemotherapy (such as, trastuzumab) will be held during the radiation treatment phase.

For both groups: After you have received 6 weeks of protocol treatment, you will be asked to come in for a follow-up visit 5 weeks after your last radiation treatment, then about every 3 months for up to 3 years after you started taking part in this study or until your disease comes back. Then, beginning at 3 years after you started taking part in this study or beginning at the

time that your disease comes back, you will be asked to come in for a follow-up visit every 6 months until up to 8 years after you started taking part in this study.

We will use a computer to assign you to one of the study groups. This process is called "randomization." It means that your doctor will not choose and you cannot choose which study group you are in. You will be put into a group by chance. You will have an equal chance of being in Group 1 or Group 2.
Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



What exams, tests and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Before you begin the study, these exams, tests, and procedures will also be done:

- If you are a woman, a pregnancy test.
- Blood tests to check your liver and kidney function.

During the study, these exams, tests, and procedures will be done about every 12 weeks (at follow-up visits) to monitor your safety and health:

- Physical exam.
- Blood tests to check your liver and kidney function.

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

General Risks

If you choose to take part in this study, there is a risk that the study approach may not be as good as the usual approach for your cancer at preventing your cancer from coming back.

You also may have the following discomforts:

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

Reproductive Risks: The study drug olaparib and radiation used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study. Women who are able to get pregnant and their partners should agree to use 2 highly effective forms of contraception while on study (both Group 1 and Group 2) and for at least 6 months after the last dose of olaparib (Group 1). If you are using hormonal contraception, it is important to tell your study doctor. Hormonal contraception may not work as well while taking olaparib. Male study participants must use a condom while on study (both Group 1 and Group 2) and for at least 6 months after the last dose of olaparib (Group 1) and should avoid fathering a child or donating sperm during this time period.

<u>Side Effect Risks</u>

The drug used in this study, olaparib, 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.**

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- **If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.**
- **Your study doctor will work with you to treat your side effects.**
- **Your study doctor may adjust the study drugs to try to reduce side effects.**

The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Drug Risks (Group 1 Only)

This study is looking at the usual radiation therapy to treat this type of cancer plus a study drug.

Possible Side Effects of Olaparib

COMMON, SOME MAY BE SERIOUS **In 100 people receiving olaparib, more than 20 and up to 100 may have:**
• **Anemia which may require blood transfusion** • **Diarrhea, Nausea, vomiting** • **Tiredness** • **Loss of appetite**

OCCASIONAL, SOME MAY BE SERIOUS **In 100 people receiving olaparib, from 4 to 20 may have:**
• **Bloating, constipation, heartburn** • **Pain** • **Swelling of arms, legs** • **Fever** • **Bruising, bleeding** • **Infection, especially when white blood cell count is low** • **Dizziness, headache** • **Changes in taste** • **Cough, shortness of breath**

RARE, AND SERIOUS **In 100 people receiving olaparib, 3 or fewer may have:**
• **Cancer of bone marrow caused by chemotherapy** • **Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions** • **Damage to the lungs which may cause shortness of breath**

The study drug olaparib could interact with other drugs. Your study doctor will give you a drug information handout and wallet card that lists these possible interactions. Share this information with your family members, caregivers, other health care providers, and pharmacists.

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

Receiving the study medication, olaparib, in combination with radiation may increase the normal expected reactions with radiation that are described below.

Groups 1 and 2 (Radiation Therapy Risks):

Possible Side Effects of Radiation Therapy to the Chest Wall and the Lymph Nodes Around the Tumor

COMMON, SOME MAY BE SERIOUS **In 100 people receiving radiation therapy, 20 to 100 may have:**
• **Reddening, tanning, or peeling of the skin** • **Mild pain** • **Hair loss in the treatment area (under the arm, not on the head)** • **Tiredness** • **Nausea** • **Anemia, which may require transfusion** • **Infection, especially when white blood cell count is low**
OCCASIONAL, SOME MAY BE SERIOUS **In 100 people receiving radiation therapy, 4 to 20 may have:**
• **Thickening and numbness of the skin** • **Sores or ulcers on the skin or near the cancer location** • **Permanent hair loss in the treatment area (not the head)** • **Bleeding from the skin**

RARE, AND SERIOUS **In 100 people receiving radiation therapy, 3 or fewer may have:**
• **Damage to internal organs** • **Abnormal opening in internal organs which may cause pain and bleeding**

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.

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

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

What are my responsibilities in this study?

If you choose to take part in this study, you will need to

- Keep your study appointments.
- Tell your doctor about:
    - all medications and supplements you are taking
    - any side effects
    - any doctors' visits or hospital stays outside of this study
    - if you have been or are currently in another research study.

- If you are in Group 1, write down in your medication diary when you take the study drug at home.

For women: Do not get pregnant or breastfeed while taking part in this study.
For men: Do not father a baby while taking part in this study.
For all: Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 3 months after your last dose of study drug (Group 1) or radiation treatment (Group 2).

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your inflammatory breast cancer. This includes:

- The costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety and prevent and treat side effects.
- Your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include

- The olaparib will be supplied at no charge while you take part in this study.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

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. Ask them if they will pay. If you have no insurance, you would be responsible for any costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

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 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
- 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.
- The National Cancer Institute (NCI) and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research.

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

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.

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.

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.

ADDITIONAL STUDIES SECTION:
(This section is about optional studies you can choose to take part in)

Optional studies that 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. They are separate from the main study described above. These optional studies will not benefit your health. 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.

Taking part in these optional studies is your choice. You can still take part in the main study even if you say "no" to any or all of these studies. There is no penalty for saying "no."

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

Circle your choice of "yes" or "no" for each of the following studies.

1. **FUTURE CONTACT:**
   I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

   YES NO

2. **OPTIONAL SAMPLE COLLECTIONS FOR BIOBANKING FOR POSSIBLE FUTURE STUDIES**:

Researchers are trying to learn more about cancer, diabetes, and other health problems using samples from your tissue, blood, urine, or other fluids. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about genes. Other studies may look at how genes affect a person's response to treatment. Genes carry information about features that are found in you and in people who are related to you. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Unknown future studies

If you choose to take part in this optional study, tissue from your surgery that was collected at the time of diagnosis of your original cancer (or, if applicable, at the time that your cancer came back) will be stored. Additional blood will also be collected for this optional study. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) 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 Nationwide Children's Hospital and supported by the National Cancer Institute.

We don't know what research may be done in the future using your tissue and blood samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- Future research studies may include sequencing of all or part of your DNA called genomic sequencing. All your genetic information makes up your genome. Genomic sequencing is a test that records all or part of the pieces of DNA that are in your genes, piece by piece. This is usually done to look for changes in your genome that may cause health problems.
- You will not get reports or other information about any research that is done using your samples.

What is involved in this optional sample collection?

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

1) Before you start treatment, a sample from the tissue that was previously collected at the time of your surgery (at time of diagnosis of your cancer or your cancer coming back) will be sent to the biobank. If your disease comes back or gets worse, a small amount of extra tissue will also be collected (at the time you have a biopsy for regular cancer care) and submitted to the biobank.
2) About 4 teaspoons of blood will be collected from a vein in your arm and submitted to the biobank at four times: 1) on or before your first day of treatment, 2) on or around your last day of treatment, 3) at your first follow-up visit after completion of treatment, and 4) when you return for your yearly visit.
3) Your sample and some related health information may be stored in the biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
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 risks in this optional sample collection?

1) **The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.**
2) **Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.**
3) **Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find 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. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/.**

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) They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2) Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3) Your personal information will not be given to anyone unless it is required by law.
4) If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

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 about this optional sample collection?

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 biobank will be destroyed or returned to your study doctor if requested. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study. Contact information for your study doctor is listed on the consent cover page.

Please circle your answer to show whether or not you would like to take part in each option.

SAMPLES FOR FUTURE RESEARCH STUDIES:

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

YES NO

This is the end of the section about optional studies.

Signature:

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

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

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

Specimen Consent Supplemental Sheets

How are Specimens Used for Research?

Where do specimens come from?

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

Why do people do research with specimens?

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

What type of research will be done with my specimen?

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

How do researchers get the specimen?

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

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

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

Why do you need information from my health records?

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

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

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

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

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

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

How am I protected?

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

What if I have more questions?

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