

**Kansas City Clinical Oncology Program**

**Z1071: A Phase II Study Evaluating the Role of Sentinel Lymph Node Surgery and Axillary Lymph Node Dissection Following Preoperative Chemotherapy in Women with Node Positive Breast Cancer (T0-4, N1-2, M0) at Initial Diagnosis**

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have breast cancer that appears to have spread to your lymph nodes, and you will receive chemotherapy before you have surgery.

**Who is conducting this study?**

This study is being conducted by the American College of Surgeons Oncology Group (ACOSOG), a cancer research group sponsored by the National Cancer Institute (NCI).

**Why is this study being done?**

The purpose of this study is to evaluate the role of sentinel lymph node dissection (SLND) surgery and axillary lymph node dissection (ALND) surgery after chemotherapy in patients with breast cancer that has spread to the lymph nodes in the breast area. These are called the axillary (underarm) lymph nodes.

Sentinel lymph node dissection (SLND) is a procedure that locates and removes just the first few lymph nodes that drain lymphatic fluid from the area around the breast and are therefore most likely to contain cancer cells. These lymph nodes are called the sentinel nodes. A patient will usually have from 1 to 4 sentinel nodes. SLND is commonly used in patients who have surgery before receiving any chemotherapy.

Axillary lymph node dissection (ALND) is a procedure that removes all of the axillary lymph nodes. If positive sentinel nodes are identified after chemotherapy, then it is standard practice to remove all the axillary nodes.

We would like to find out if SLND is effective in identifying cancer remaining in the lymph nodes after chemotherapy and therefore can be used to determine which patients would benefit from an ALND procedure, and which patients might not need an ALND procedure. Before you take part in this study, you should call your health insurer to find out if the cost of the SLND procedure will be paid for by your insurance plan. Some health insurers may not pay for these costs. You will have to pay for any costs not covered by your health insurer.

In addition, this study will evaluate the effectiveness of an axillary ultrasound examination in identifying cancer remaining in the lymph nodes after chemotherapy and if it can be used to identify patients who would benefit from a SLND procedure.

The goals of this study are:

- To provide further understanding of the best method for evaluating how axillary lymph node metastases are affected by preoperative chemotherapy
- To examine the effects of preoperative chemotherapy on axillary lymph node metastases.
- To evaluate the role of axillary ultrasound to guide the use of SLND surgery in patients with node positive disease.
- To evaluate the impact of SLN and ALND surgery on arm function and quality of life.

### **How many people will take part in the study?**

About 660 people will take part in this study.

### **What will happen if I take part in this research study?**

#### **Before you begin the study...**

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Physical exam and medical history
- A breast biopsy to confirm your diagnosis
- An ultrasound of the axillary nodes (underarm lymph nodes)
- A biopsy of the axillary nodes

#### **During the study...**

If you agree, you will have the following exams, tests or procedures. These tests are optional and are for research purposes only. They will be done at no cost to you. These tests are being done to find out more about how your cancer and your treatment affect your body. Specifically, we would like to find out how your surgery will affect your arm function and your quality of life. You may still participate in the study if you do not want to have these tests done.

- You will have arm measurements done with a tape measure before surgery, one to two weeks after surgery, then every six months for 2 years and again at 3 years.
- You will complete questionnaires about your quality of life, your arm function, and other health-related questions (including baseline smoking history) before surgery, one to two weeks after surgery and then every six months for 2 years and again at 3 years. The questionnaires will take 20-40 minutes to complete.

If you are participating in another study of how surgery affects arm function, you will not be able to take part in the arm function portion of this study. You may still take part in the main

treatment study. If you are not sure whether or not you are participating in another study, please ask your study doctor or nurse.

### Making Your Choice

Please read the sentence below and think about your choice. After reading the sentence, circle "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at 816-823-0560.

No matter what you decide to do, it will not affect your care.

Even if you agree to have these tests done now, you may change your mind at any time. Just contact us and let us know that you do not want to continue with these tests.

1. I agree to have arm measurements and complete quality of life questionnaires for the research study.

Yes

No

### Chemotherapy

You will receive the chemotherapy recommended by your doctor if you have not already received it.

### After chemotherapy...

At the completion of chemotherapy and within four weeks before surgery, you will need the following tests and procedures. They are part of regular cancer care. If you received chemotherapy before entering the study, then you may not need to repeat these tests.

- Physical examination
- An ultrasound of the axillary nodes (the lymph nodes in the underarm area)
- A pregnancy test (if you are of childbearing potential and have not already had a pregnancy test)

Images and reports from your ultrasound exams will be sent to the Quality Assurance Review Center for review by the study radiologist. This will help us to standardize the evaluation of your lymph nodes before and after your chemotherapy. The images and reports will not contain any of your identifying information (e.g., your initials, birthdate or medical record number). The accompanying paperwork will contain your initials and a study identification number.

After chemotherapy and within four weeks before surgery, you also will have the following tests and procedures, if you agreed to the optional tests:

- Questionnaires about your quality of life and arm function
- Arm measurement

## Surgery

Within 12 weeks of completing chemotherapy, you will have surgery to remove your breast tumor. The two most common types of breast surgery are mastectomy and lumpectomy. You and your doctor will decide what type of surgery to have. Your surgery will include a sentinel lymph node dissection procedure.

During the sentinel lymph node dissection (SLND), radioactive tracing material with or without blue dye is injected into the breast by your doctor. The tracer and/or dye travels through your lymph system and collects in the first draining lymph nodes (called the sentinel nodes). Your surgeon will make an incision under your arm and remove the nodes that contain tracing material.

After the SLND, you also will receive an axillary lymph node dissection (ALND), where all or most of the underarm nodes are removed.

After surgery, a pathologist will examine the lymph nodes that were removed. Samples from these lymph nodes may need to be submitted for central review by the study pathologist. This is done for quality control purposes. The samples will not contain any of your identifying information (e.g., your initials, birthdate or medical record number). The accompanying paperwork will contain your initials and a study identification number.

## Optional Bone Marrow Collection During Surgery

You may choose to donate a sample of bone marrow collected at the time of your surgery for a correlative science study. Correlative science studies are related studies being done as part of the main study. You may still take part in the main treatment study even if you say 'no' to taking part in the correlative science study.

Breast cancer cells are sometimes found in the bone marrow of women with early stage breast cancer. The bone marrow may serve as a sanctuary site or reservoir for these cells. It is thought that some of these breast cancer cells in the bone marrow may eventually travel to other organs and form cancer at these sites (called metastases). We would like to study the tumor cells that are present in bone marrow to determine whether chemotherapy kills these cells as it does the breast cancer cells in the breast and lymph nodes. We will also study these cells to try to identify markers which will predict which of these cells will go on to form metastatic disease.

In this study, researchers will use a test called immunocytochemical staining or ICC to see if there are any breast cancer cells in your bone marrow. A sample of your bone marrow will be sent to a special laboratory where the ICC test will be performed. The test results will not be given to you or your doctor since this new test has no proven benefit to you.

The bone marrow will be collected using a procedure called a bone marrow aspiration. The bone marrow aspiration will be performed during the same operation as your breast surgery. Your doctor will insert a needle into your right and left hip bones to remove a small amount of bone marrow (about 4 teaspoons total).

The samples will be placed in vials and submitted to ACOSOG. The samples will not contain any of your identifying information (e.g., your initials, birthdate or medical record number). The accompanying paperwork will contain your initials and a study identification number.

### Making Your Choice

Please read the sentence below and think about your choice. After reading the sentence, circle "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at 816-823-0560.

No matter what you decide to do, it will not affect your care.

Even if you agree to have these tests done now, you may change your mind at any time. Just contact us and let us know that you do not want to continue with these tests.

1. I agree to have bone marrow collected and used for the research study.

Yes

No

### Optional Sample Donation for Future Studies

You also may donate left over tissue samples from your diagnostic breast biopsy and your surgery, and left over bone marrow samples from the correlative science studies, for use in future studies. More information about contributing left over samples for future research is included in a later section of this form.

### After surgery...

You will see your doctor at one to two weeks, then every 6 months for 2 years, every year for 2 years, and every other year for 6 years. At those visits, you will have the following tests and procedures that are being done to see how the study is affecting your body. Only the physical exam is required. All other tests are optional.

#### Within 1-2 weeks after surgery:

- Physical exam (required)
- Questionnaires about your quality of life and arm function
- Arm measurement

#### Every 6 months for 2 years:

- Physical exam (required)
- Questionnaires about your quality of life and arm function
- Arm measurement

#### Every year for 2 years then every other year for 6 years:

- Physical exam (required)
- Questionnaires about your quality of life and arm function (at Year 3 only)
- Arm measurement (at Year 3 only)

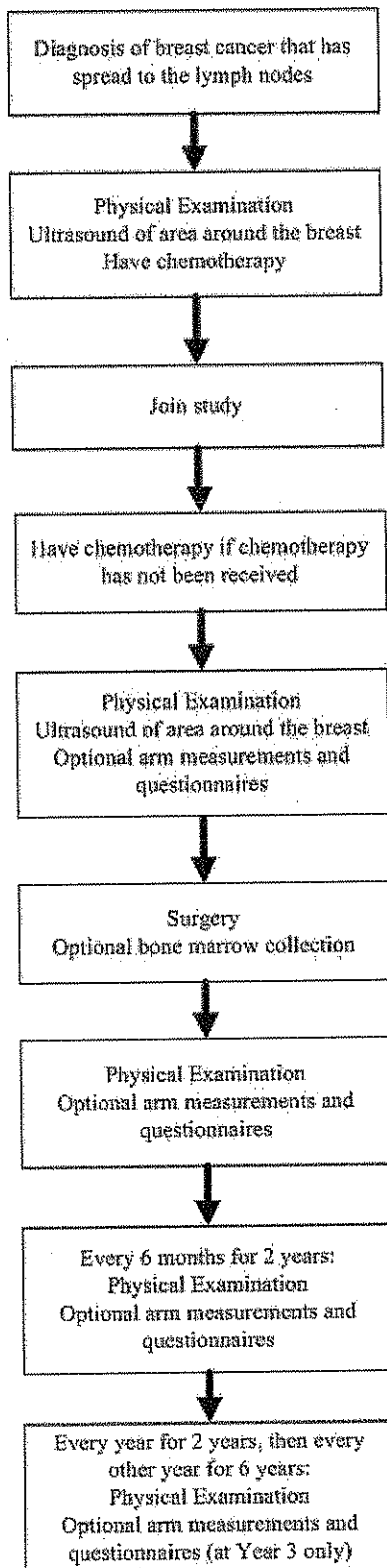
## Study Chart

Another way to tell what will happen in the study is to review the chart below. The left-hand column shows the day in the study and the right-hand column tells you what to do on that day.

Study time period	What you do
Before starting study	<ul style="list-style-type: none"> <li>Physical exam including medical history</li> <li>Breast biopsy to confirm your diagnosis</li> <li>Ultrasound of the axillary nodes (the lymph nodes in the underarm area)</li> <li>Biopsy of the axillary nodes</li> <li>Receive chemotherapy</li> </ul>
After starting study	<ul style="list-style-type: none"> <li>Receive chemotherapy (if chemotherapy was not received before beginning the study)</li> </ul>
After chemotherapy and within 4 weeks before surgery	<ul style="list-style-type: none"> <li>Physical exam (required)</li> <li>An ultrasound of the axillary nodes (the lymph nodes in the underarm area) (required)</li> <li>Pregnancy test (required, if you are of childbearing potential and have not already had a pregnancy test)</li> <li>Questionnaires about your quality of life and arm function</li> <li>Arm measurement</li> </ul>
Within 12 weeks after chemotherapy	<ul style="list-style-type: none"> <li>Surgery to remove tumor, including SLN and ALND</li> <li>Bone marrow collection (optional)</li> </ul>
1-2 weeks after surgery	<ul style="list-style-type: none"> <li>Physical exam (required)</li> <li>Questionnaires about your quality of life and arm function</li> <li>Arm measurement</li> </ul>
Every 6 months for 2 years	<ul style="list-style-type: none"> <li>Physical exam (required)</li> <li>Questionnaires about your quality of life and arm function</li> <li>Arm measurement</li> </ul>
Every year for 2 years, then every other year for 6 years	<ul style="list-style-type: none"> <li>Physical exam (required)</li> <li>Questionnaires about your quality of life and arm function (at Year 3 only)</li> <li>Arm measurement (at Year 3 only)</li> </ul>

### Study Plan

Another way to find out what will happen to you during the study is to read the study plan below. Start reading at the top and read down the list, following the lines and arrows.



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

You will be in the study for a little over ten years. After your surgery, the study doctor will ask you to visit the office for follow-up exams at 1-2 weeks, then every 6 months for 2 years, every year for 2 years, and every other year for 6 years.

### **Can I stop being in the study?**

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the surgery can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped by ACOSOG.

### **What side effects or risks can I expect from being in the study?**

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

**You should talk to your study doctor about any side effects that you have while taking part in the study.**

**Risks and side effects related to the *radioactive tracer injection* associated with SLND include those which are:**

#### **Likely**

- Exposure to radiation (equal to 1/10<sup>th</sup> to 1/20<sup>th</sup> of the annual exposure the average person receives from the sun)
- Tenderness, redness, and pain in the area of the injection site

#### **Less Likely**

- Infection at the injection site
- Allergic reaction to the injected solution

**Risks and side effects related to the *blue dye injection* associated with SLND include those which are:**

**Likely**

- Slight blue coloring of the skin around the area of the injection (usually temporary, may be permanent)
- Tenderness and pain in the area of the injection site
- Bluish or greenish discoloration of your urine for several hours after injection

**Less Likely**

- Infection at the injection site
- Allergic reaction to the injected solution
- Death of skin (necrosis) at the injection site

**Risks and side effects related to the *sentinel lymph node dissection (SLND)* and *axillary lymph node dissection (ALND)* include those which are:**

**Likely**

- Time away from work
- Pain
- Mild edema or swelling in your breast and arm that is temporary
- Loss of feeling or touch at the incision site and in areas of the upper arm (may be permanent)
- Scarring and/or indentation of your skin in the area of the incision (may be permanent)
- Bleeding or development of a hematoma (a localized blood-filled swelling) or seroma (mass caused by accumulation of fluid within a tissue or organ) in the armpit on the side of the surgery (rarely serious)

**Less Likely**

- Breast or axillary wound infection (may be serious). If this occurs, it usually happens within 2 weeks after surgery.
- Chronic lymphedema (may be serious). This is swelling of the arm on the side of the surgery that does not go away.
- Injury to motor nerves that help control shoulder function, which can result in difficulty raising or lowering your arm.
- Increased susceptibility to infection in the arm on the side of the surgery if that arm is injured in the future

**Risks and side effects related to the *bone marrow aspiration* include those which are:**

**Likely**

- Slight discomfort and/or pain
- Bruising at the site of the bone marrow aspiration

- Bleeding
- Swelling and/or redness at the site of the bone marrow aspiration

### **Less Likely**

- Infection at the site of the bone marrow aspiration

**Reproductive risks:** You should not become pregnant while on this study because the chemotherapy you have received or will receive can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. Women of childbearing potential will require a pregnancy test before having surgery, if they have not already had a negative pregnancy test.

For more information about risks and side effects, ask your study doctor.

### **Are there benefits to taking part in the study?**

There may or may not be direct medical benefits to you from your taking part in this study, other than removal of your cancer and lymph nodes. We hope that information learned from this study will help patients with breast cancer in the future.

### **What other choices do I have if I do not take part in this study?**

Your other choices may include:

- Having surgery for your cancer without being in a study
- Taking part in another study
- Having no surgery

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

### **Will my medical information be kept private?**

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The American College of Surgeons Oncology Group (ACOSOG)
- The ACOSOG Data Monitoring Committee, a group of experts who regularly review the progress of the study
- The local IRB (a group of people who review the research to protect your rights) of this institution
- The Quality Assurance Review Center (QARC). QARC is an organization funded by the National Cancer Institute (NCI) to provide expert review of diagnostic imaging data.

- The National Cancer Institute (NCI)
- The Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
- Other government agencies, like the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), involved in keeping research safe for people
- Other oncology research groups who have endorsed this study

### What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

You will not be paid for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://www.cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

### What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, \_\_\_\_\_ [*investigator's name(s)*], if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at \_\_\_\_\_ [*telephone number*].

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

### What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

## Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor \_\_\_\_\_ [name(s)] at \_\_\_\_\_ [telephone number].

For questions about your rights while taking part in this study, call the Kansas City Clinical Oncology Program Institutional Review Board (a group of people who review the research to protect your rights) at 816-823-0560.

## Optional Banking of Specimens for Future Research

This section of the informed consent form is about contributing any leftover tissue samples from your diagnostic breast biopsy and your surgery for future studies, if samples are available. You can still be a part of the main study even if you say 'no' to contributing left over tissue samples for future studies.

### About Contributing Specimens for Future Research

As a part of your treatment for breast cancer, your doctor will biopsy and then remove your breast tumor. If there are tissue samples left over from your diagnostic biopsy and surgery, we would like to have the tissue that is left over for future research. If you agree, these samples will be stored (or "banked") by ACOSOG and may be used in future research to learn more about cancer and other diseases. If all the tissue is needed by your doctor for current or future treatment decisions, then no tissue will be sent for banking.

If you agree to have bone marrow collected as part of the study, we also would like to keep any bone marrow left over from the correlative science studies for future research.

Your tissue samples and bone marrow samples are called "specimens". You can learn more about how biological specimens are used for research at <http://biospecimens.cancer.gov/patientcorner/>.

The research that may be done with your specimens is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your specimens will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

### Things to Think About

The choice to let us keep the specimens for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your specimens can be used for future research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your specimens. Then any specimens that remain will no longer be used for research and will be discarded.

In the future, people who do research may need to know more about your health. While the ACOSOG may give those people reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Your specimens will be used only for research and will not be sold. The research done with your specimens may help to develop new products in the future, but you will not be able to benefit financially from the new products.

### Genetic Research

Sometimes specimens are used for genetic (DNA) research.

The purpose of doing genetic research is to discover changes in genes (or DNA) associated with the development or outcome of cancer. This could lead to better ways to prevent, detect, and treat cancer and, perhaps, other diseases as well. Due to advances in the techniques and tests used to analyze genetic material in specimens (DNA), it is likely that your specimens could be used for this type of research, if you allow it.

Body tissues are made up of cells. Cells contain DNA, which is part of your unique genetic material that carries the instructions for your body's development and function. DNA can be analyzed so that your unique, exact genetic code or the altered genetic code of your tumor cells can be identified and compared to other patients. Cancer can result from changes in a person's genetic material (DNA) that causes cells to divide in an uncontrolled way and, sometimes, to travel to other organs. Currently, researchers and doctors know some of the genetic changes that can cause cancer, but they do not know all of the genetic changes that can cause cancer.

By studying the genetic code of cancer cells and the people who have cancer, scientists expect to identify most of the genetic changes associated with different kinds of cancer. ACOSOG and scientists who work with ACOSOG members, such as your doctor, would also like to compare genetic information obtained from you biological specimens with information available from your progress on the ACOSOG study, such as the response to treatment and your long term health. With this knowledge, future treatments for cancer could become customized to a patient's unique genetic make-up (this is known as personalized medicine).

Your specimens and medical information collected as part of the ACOSOG study will be labeled with a code.

Only ACOSOG will have the information that matches the code to traditionally-used identifying information, such as your initials, birthdate or medical record number. ACOSOG will keep the information that matches the code to this traditionally-used identifying information in a safeguarded database. Only very few, authorized people, who have specifically agreed to protect your identity, will have access to this database. All other researchers and personnel, including those who will be working with your samples and medical information, will not have access to any of the traditionally-used identifying information about you.

Information from analyses of your coded specimens and your coded medical information will be put into databases along with information from other research participants. These databases will be accessible by the Internet. The purpose of making sequence and medical information available is so that they can be used by scientific researchers throughout the world to study cancer and other diseases.

Please note that traditionally-used identifying information about you, such as your initials, birthdate or medical record number would NOT be put into the databases.

Even if your specimens are used for this kind of research, the results will not be put in your health records and although you can learn more about this type of research, individual information about your genetic code or your tumor will not be available to you.

### Benefits

The benefits of research using specimens include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

### Risks

- Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measures that we use, it is impossible to guarantee that links between you and the genetic information we would obtain will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other relatives. Consequently, it may be possible that genetic information from them could be used to try and identify your sample from the publicly available information. Similarly, it may be possible that genetic information from you could be used to help identify them.
- While the databases used to store your genetic information would not contain information that is traditionally used to identify you, such as your initials, birthdate or medical record number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you.

We would like to emphasize that we will do everything we can to protect your private information. However because of the nature of the issues, we feel that we should explain these issues to you carefully.

- An additional risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

### Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at 816-823-0560.

No matter what you decide to do, it will not affect your care.

1. My tissue (if available) may be kept for use in future research to learn about, prevent, or treat cancer.

Yes No

2. My tissue (if available) may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

Yes No

3. My tissue (if available) may be kept for use in future genetic research.

Yes No

**If I have agreed to donate bone marrow for the correlative science studies:**

4. My bone marrow may be kept for use in future research to learn about, prevent, or treat cancer.

Yes No

5. My bone marrow may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

Yes No

6. My bone marrow may be kept for use in future genetic research.

Yes No

**Where can I get more information?**

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at <http://www.cancer.gov/>

- For NCI's clinical trials information, go to: <http://www.cancer.gov/clinicaltrials/>
- For NCI's general information about cancer, go to <http://www.cancer.gov/cancertopics/>

You will get a copy of this form. If you want more information about this study, ask your study doctor.

**Release**

By signing this form you authorize KCCOP to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

CTSU ACOSOG Z1071  
Approval Date: 11/13/11 to 8/18/11  
Assurance #: FWA00003582

You will get a copy of this form. If you want more information about this study, ask your study doctor.

**Signature**

I have been given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

**Participant Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

**Signature of Person Obtaining Consent** \_\_\_\_\_

**Date** \_\_\_\_\_