

**Consent Addendum B: Optional A011202 Biobanking**

**A RANDOMIZED PHASE III TRIAL COMPARING AXILLARY LYMPH NODE  
DISSECTION TO AXILLARY RADIATION IN BREAST CANCER PATIENTS (CT1-3  
N1) WHO HAVE POSITIVE SENTINEL LYMPH NODE DISEASE AFTER  
NEOADJUVANT CHEMOTHERAPY**

This consent addendum is about an optional study that you can choose to take part in. It is separate from the main study described in the main consent form. This optional study will not benefit your health. 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 this optional study is your choice. You can still take part in the main study even if you say “no” to this study. There is no penalty for saying “no.” You and your insurance company will not be billed for this optional study. If you sign up for, but cannot complete this study for any reason, you can still take part in the main study.

Circle your choice of “yes” or “no” for the following study.

**Optional sample collections for known laboratory studies and/or storage for possible future studies**

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person’s response to treatment. Genes carry information about traits that are found in you and your family. 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, your blood and tissue samples will also be stored. Storing samples for future studies is called “biobanking.” The biobank is being run by Alliance for Clinical Trials in Oncology and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people’s health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request

identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what additional research may be done in the future using your blood and tissue 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.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes. If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

### **What is involved in this optional sample collection?**

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

1. About 3 ½ tablespoons of blood will be collected from a vein in your arm at the time you agree to have samples collected, 5-6 years after surgery and 8 years after you complete radiation therapy. A sample from the tissue that was collected at the time of your breast cancer diagnosis and a sample collected at the time of surgery will be sent to the biobank.
2. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

### **What are the risks in this optional sample collection?**

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- 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.
- 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.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health 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 study researchers and biobank. 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 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 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 biobank 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. 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 doctor. Contact information for your study doctor is listed on the consent cover page.

**My signature agreeing to take part in the biobanking**

I have been given a copy of all 4 pages of this consent addendum. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES            NO

Participant Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of Person Obtaining Consent: \_\_\_\_\_

Date: \_\_\_\_\_

Time of consent: \_\_\_\_\_ (AM) (PM)

(Required for initial consent only)