COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL/SMILOW CANCER HOSPITAL CARE CENTERS/SAINT FRANCIS HOSPITAL

Study Title for Study Participants: Testing platinum-based chemotherapy after surgery in triple-negative breast cancers
Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
EA1131: A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Capecitabine in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy
Principal Investigator: Andrea Silber, MD
Principal Investigator's Phone Number: (203) 785-2876
24-Hour Phone Number: (203) 785-4191
Principal Investigator's Mailing Address: 300 George St, Suite 120, New Haven, CT 06511

WHAT IS THE USUAL APPROACH TO MY BREAST CANCER?

You are being asked to take part in this study because you:

- Have a breast cancer that does not have the estrogen, progesterone or HER2 receptor, and is called triple-negative breast cancer
- Have completed all your chemotherapy prior to your surgery
- Had ≥ 1 cm worth of cancer in the breast at the time of your surgery
- Have completed your radiation treatment after surgery, if indicated

People in your situation, who are not in a study, have two options:

1. Receive no more treatment: For patients who receive no other treatment, about 50 out of 100 are free of cancer at four years.
2. Receive more chemotherapy with a drug called capecitabine (also known as Xeloda®) for about 18 weeks. Capecitabine is FDA approved in treating patients with metastatic triple-negative breast cancer. Recently, a big clinical trial in Japan showed that for patients who receive capecitabine, about 67 out of 100 are free of cancer at four 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 (i.e. no other treatment or more chemotherapy with capecitabine for 18 weeks)
- you may choose to take part in a different study, if one is available
- or you may choose not to be treated for cancer

WHY IS THIS STUDY BEING DONE?

The main purpose of this study is to compare getting more treatment with capecitabine (i.e. one of the usual approaches), to any good and bad effects of getting more treatment with a platinum-based chemotherapy (cisplatin or carboplatin), after surgery.

Platinum agents (cisplatin or carboplatin) are already FDA-approved to be used in patients with stage IV breast cancers, but are usually not used in patients with early forms of breast cancer. Getting a platinum-based chemotherapy after surgery could prevent the cancer from returning (metastatic recurrence), but it could also cause side effects.

Because recent studies have shown that capecitabine chemotherapy is a better treatment than receiving no other treatment, a new study group has been added to replace the current no other treatment group. This study will allow the researchers to know whether this different approach is better, the same, or worse than using capecitabine chemotherapy. To be better, the study approach (platinum agents) should improve the number or patients that are free of cancer at four years to 77 out of 100, compared to capecitabine (with which about 67 out of 100 are free of cancer at four years).

There will be about 750 people taking part in this research study.

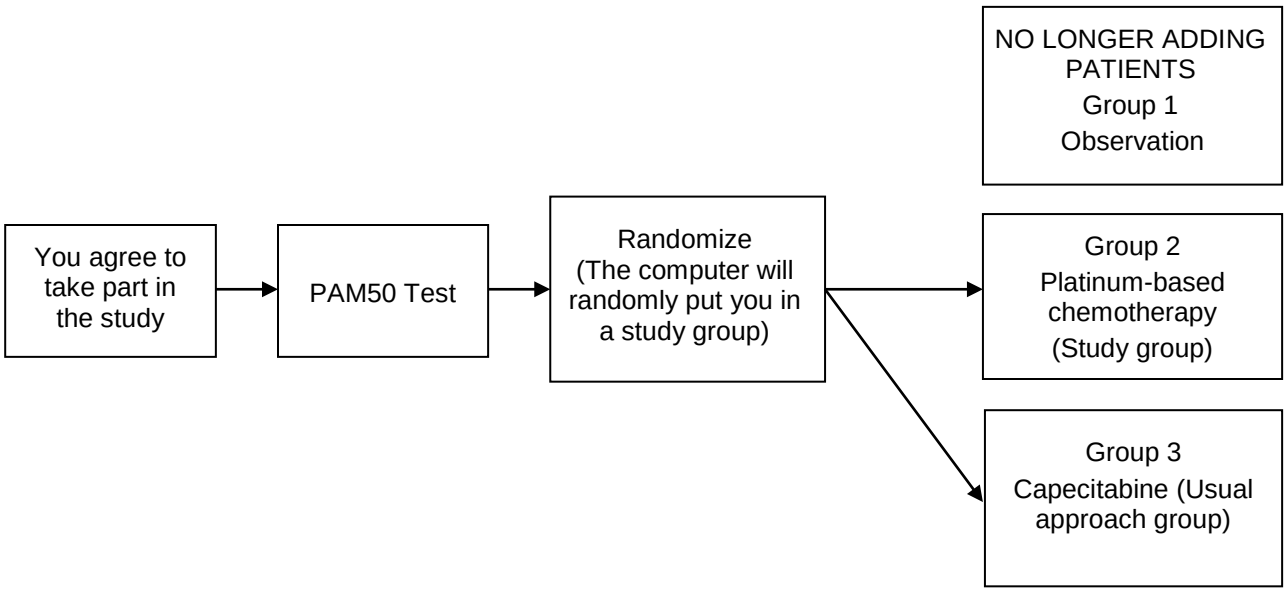
WHAT ARE THE STUDY GROUPS?

This study has three study groups.

- Group 1 will receive observation. However, this group is no longer adding patients.
- Group 2 will get a platinum-based chemotherapy treatment for 12 weeks. You and your doctor will get to choose between cisplatin or carboplatin.
- Group 3 will get the usual approach used for this type of cancer: capecitabine for 18 weeks.

A computer will by chance assign you to treatment groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the others.

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.



HOW LONG WILL I BE IN THIS STUDY?

If you get randomized to the platinum-based chemotherapy group (Group 2), you will receive a 30-minute intravenous infusion (IV through the vein) of either cisplatin or carboplatin once, every 3 weeks, for 4 doses (total of 12 weeks). After you finish the platinum-based chemotherapy, your doctor will continue to watch you for side effects and follow your condition for about 10 years (every 3 months if you are less than 2 years from study entry, every 6 months if you are 2-5 years from study entry, every 12 months if you are 5-10 years from study entry).

If you get randomized to the usual approach group (Group 3), you will receive capecitabine pills for a total of 6 cycles (total of 18 weeks). Each cycle is 3 weeks long. In these cycles you will take the pills twice a day for 2 weeks and then get one week off. Capecitabine pills should be taken within 30 minutes after a meal. You will be required to complete a medication diary and bring it to each medication visit along with any unused pills in the pill bottle. After you finish the capecitabine chemotherapy, your doctor will continue to watch you for side effects and follow your condition for about 10 years (every 3 months if you are less than 2 years from study entry, every 6 months if you are 2-5 years from study entry, every 12 months if you are 5-10 years from study entry).

WHAT EXTRA TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY?

Most of the exams, tests, and procedures you will have are part of the usual care for your cancer. However, there are some extra procedures that you will need to have if you take part in this study.

Before you begin the study:

You will need to have the following extra tests to find out if you can be in the study:

- Pregnancy test 2 weeks prior to randomization.
- Tissue from your surgery, which will be tested with the **PAM50 biomarker**, will be sent to a central laboratory to find out if your breast cancer is basal-like triple-negative. This biomarker test is still investigational in this treatment setting.

Small pieces of tissue from your tumor will be sent to a central laboratory to be reviewed. This review is simply to confirm your breast cancer subtype following treatment.

These samples are required during screening in order for you to take part in this study because the research on the samples is an important part of the study.

This biomarker test called PAM50 will determine if you have a type of triple-negative breast cancer called “basal-like triple-negative breast cancer”. Basal-like triple-negative breast cancers are biologically aggressive. They sometimes return in other parts of the body (metastatic recurrence) after 2-3 years from the initial diagnosis.

Your privacy is very important, and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information.

Neither you nor your health care plan/insurance carrier will be billed for sending tissue for PAM50 testing, nor for the cost of performing the PAM50 biomarker test itself that will be used for this study.

If you agree, any leftover tissue will be stored for Biobanking (see Section on optional studies).

During the study:

If you choose to take part, then you may need the following extra procedures if you are randomized to Group 2 (platinum-based chemotherapy). They are not part of the usual care for your type of cancer. Please note that capecitabine-based chemotherapy for Group 3 patients only is part of the usual care for your type of cancer.

STUDY CALENDAR

Parameter	Pre-Randomization			Post-Randomization				
	All patients			All patients	For Group 2	For Group 3	For Groups 2 and 3	For Groups 1, 2, and 3
	Within 8 weeks prior to Screening	Within 2 Weeks prior to Screening	Up to 1 week after Screening	Within 2 weeks prior to randomization	Every 3 weeks, 4 times	Every 3 weeks, 6 times	28 days after completing treatment	Every 3 months x 2 years, then every 6 months x 3 years, then every 12 months x 5 years
CLINICAL VISITS								
History and Physical EXAM	X			X	X	X	X	X
LABORATORY/IMAGING TEST								
Blood tests	X			X	X	X	X	X
Pregnancy Test				X				
Imaging Tests			Imaging tests may be done at any time during study if a recurrence is suspected					
TREATMENT								
Chemotherapy Administration for Group 2 and 3 patients					X	X		
TISSUE SAMPLE COLLECTION								
Mandatory Tumor Tissue Collection (PAM 50)	X							

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
- You could have side effects from the study drug if you are randomized to Group 2.
- The study approach may not be better, and could possibly be worse, than the usual approach for your cancer (due to possible side effects from study drug).
- There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back 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. In some cases, this information could be used to make it harder for you to get or keep a job. There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

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.

RISKS ASSOCIATED WITH RADIATION

This research study involves exposure to radiation from extra imaging tests to exclude presence of recurrent disease. Please note that this radiation exposure is not necessary for your medical care and is for research purposes only. Although each organ will receive a different dose, the amount of radiation exposure will receive from this study is equal to a uniform whole-body exposure of 20 rem. This calculated value is known as the "effective dose" and is used to relate the dose received by each organ to a single value.

This amount of radiation is well below the dose guidelines established by the federal government and adhered to by the Yale-New Haven Hospital Radiation Safety Committee for research subjects. To give you an idea about how much radiation you will get, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives your body the equivalent of about 6 extra years' worth of this natural radiation.

(Note: average natural exposure is 300mrem or 0.3rem, so compare 20 to 0.3rem)

SIDE EFFECTS POSSIBLY ASSOCIATED WITH CHEMOTHERAPY

The chemotherapy 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.

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

Possible Side Effects of Capecitabine

COMMON, SOME MAY BE SERIOUS In 100 people receiving Capecitabine, more than 20 and up to 100 may have:
• Swelling of the body • Blisters on the skin • Redness, pain or peeling of palms and soles • Pain • Diarrhea, loss of appetite, nausea, vomiting • Sores in mouth which may cause difficulty swallowing • Anemia which may require blood transfusions • Infection, especially when white blood cell count is low • Bruising, bleeding • Feeling of “pins and needles” in arms and legs • Tiredness • Fevers

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Capecitabine, from 4 to 20 may have:

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving Capecitabine, from 4 to 20 may have:

- Blurred vision, dry or itchy eyes
- Muscle spasms, body aches
- Abnormal heartbeat
- Restlessness, irritability
- Swelling of face fingers and lower legs
- Constipation
- Difficulty with balancing

RARE, AND SERIOUS

In 100 people receiving Capecitabine, 3 or fewer may have:

- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face and throat
- Difficulty speaking, walking or seeing
- Internal bleeding which may cause blood in vomit or black tarry stools
- Damage to the heart

Possible Side Effects of Cisplatin

COMMON, SOME MAY BE SERIOUS

In 100 people receiving Cisplatin, more than 20 and up to 100 may have:

- Nausea, vomiting
- Infection, especially when white blood cell count is low
- Anemia which may cause tiredness, or may require blood transfusions
- Bruising, bleeding
- Kidney damage which may cause swelling, may require dialysis
- Hearing loss including ringing in ears
- Numbness and tingling of fingers and toes

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving Cisplatin, from 4 to 20 may have:

- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Confusion
- Difficulty with balance

RARE, AND SERIOUS

In 100 people receiving Cisplatin, 3 or fewer may have:

- Cancer of bone marrow later in life caused by chemotherapy
- Seizure

Possible Side Effects of Carboplatin

COMMON, SOME MAY BE SERIOUS

In 100 people receiving Carboplatin, more than 20 and up to 100 may have:

- Hair loss
- Vomiting, nausea
- Infection, especially when white blood cell count is low
- Anemia which may cause tiredness, or may require blood transfusions
- Bruising, bleeding
- Belly pain
- Numbness and tingling of fingers and toes

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving Carboplatin, from 4 to 20 may have:

- Diarrhea, Constipation
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Changes in taste

RARE, AND SERIOUS

In 100 people receiving Carboplatin, 3 or fewer may have:

- Changes in vision

RARE, AND SERIOUS
In 100 people receiving Carboplatin, 3 or fewer may have:
• Damage to organs which may cause hearing and balance problems

There are side effects of Capecitabine, Cisplatin and Carboplatin that can be initiated or made worse if they are taken with certain other medicines or supplements. This may include, but are not limited to, certain antibiotics and diuretics (water-pills), higher doses of anti-inflammatory medications such as aspirin or ibuprofen, and certain drugs that interfere with blood clotting (vitamin E, anti-inflammatories, coumadin, etc.). Make sure you give your doctor a complete list of all the medications you are on, even the over the counter ones. Your doctor will make sure that the medications you are on are safe to take with the platinum-based chemotherapy.

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 participating in this study. The chemotherapies 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.

You should not become pregnant or father a baby while on this research study because the drugs in this study can affect a fetus.

Women should not breastfeed a baby while on this research study.

It is important that you understand that you need to either practice “abstinence” (that is avoiding sexual activity) or use birth control while on this research study. Check with your doctor about what kind of birth control methods to use and how long to use them.

Avoiding sexual activity is the only certain method to prevent pregnancy. However, if you choose to be sexually active, you must agree to use an appropriate double barrier method of birth control (such as female use of a diaphragm, intrauterine device (IUD), sponge and spermicide, in addition to the male use of a condom) or involve female use of prescribed “birth control pills” or a prescribed birth control implant. Both double barrier contraception and birth control pills or implants must be used for at least one week prior to the start of the research study and continuing for up to 26 weeks after the last dose of the study drugs. If you choose to be sexually active during the study, you must accept that pregnancy could still result, exposing you or your sexual partner to potential loss of pregnancy as well as other unknown effects on the developing fetus. You should contact your doctor immediately if you or your partner suspect a pregnancy.

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

Early research shows that basal-like triple-negative breast cancers are sensitive to the effects of platinum-based chemotherapy. Using platinum-based chemotherapy after surgery may possibly help further prevent a recurrence of your type of breast cancer. But it is not possible

to know at this time if this study approach is better, worse, or no better than the usual care for this cancer, so this study may or may not help you.

CAN I STOP TAKING PART IN THIS STUDY?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

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

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.
- If you become pregnant

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, call the Yale University Institutional Review Board at (203) 785-4688.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

The PAM50 biomarker test will be done at no charge for you to take part in this study. The cost of capecitabine, cisplatin or the carboplatin are (as well as the cost of getting these drugs ready and giving one of the other to you) not paid for by the study sponsor, so you or your insurance company may have to pay for these costs.

You and/or your health plan/insurance company will need to pay for all of the other costs of caring for you 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 being supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

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

WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS STUDY?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. 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.

CONFIDENTIALITY

Information about your study participation will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g. health insurance company, disability provider.)

WHO WILL SEE MY MEDICAL INFORMATION?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

The protected health information that will be collected in this study includes demographics, medical history, physical examinations, routine lab tests, review of adverse events and medications you take (past and present), vital signs, CT scans, pregnancy tests, tissue samples for research purposes follow-up information and records about any study drug(s) that you received.

The ECOG-ACRIN Cancer Research Group is conducting this study. ECOG-ACRIN is a cancer research group that conducts studies for the National Cancer Institute. Your doctor is a member of ECOG-ACRIN or another group that is participating in this study, such as SWOG, NRG, and Alliance. To help protect your privacy, ECOG-ACRIN has obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, ECOG-ACRIN cannot be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state or local civil, criminal, administrative, legislative or other proceeding. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

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:

- The study sponsor, ECOG-ACRIN Cancer Research Group
- 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.
- Molecular Diagnostics Laboratory (MDL) at MD Anderson Cancer Center
- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University and the Human Investigation Committee (the committee or Institutional Review Board that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential
- Your providers who are participants in the Electronic Medical Record (EMR) system
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The study doctor, Dr. Andrea Silber, and the Yale study team
- The U.S. Food and Drug Administration (FDA). This is done so that the FDA can review information about the new drug product involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- The study sponsor or manufacturer of study drug, ECOG-ACRIN and/ or their representatives
- Drug regulatory agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale-New Haven Hospital, are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However to better protect your health information, agreements are in

place with these individuals and/or companies that require that they keep your information confidential.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

Withdrawing Your Authorization to Use and Disclose Your Health Information
You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Andrea Silber, at the Yale University, 300 George Street, Suite 120, New Haven, CT 06511.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

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 the study doctor, Dr. Andrea Silber, at (203) 785-2876.

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Andrea Silber, at (203) 785-2876. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

ADDITIONAL STUDIES SECTION:

This section is about optional studies you can choose to take part in.

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading these optional studies hope the results will help other people with cancer in the future.

The results will not be added to your medical records, and you and 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.

Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer and other health problems. Much of this research is done using samples of 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.

At this time, we are requesting that you allow the storage of samples of your tumor tissue for research projects that may be done at a later date. Storing samples for future studies is called "Biobanking." The Biobanks are run by ECOG-ACRIN staff and researchers and they are financially supported by the National Cancer Institute.

A) What is involved?

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

1. Tumor tissue leftover from the PAM50 biomarker test (described above) and central review will be sent to the Biobank.
2. Your samples and some related information will be stored in the Biobank, along with samples and information from people who took part in this or other research studies. The samples will be kept until they are used up.
3. Only qualified researchers can submit a request to use the materials stored in the Biobanks. A committee of experts at ECOG-ACRIN, and/or the National Cancer Institute, will review each request to use the samples for research. All research projects using these samples will also be reviewed by an ethics or institutional review board 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. Results from the research may be placed in centralized storage systems called databases. It is possible that some of your genetic information and your health information may be

placed in these databases. It is also possible that some of these databases may be public.

B) What are the possible risks?

1. There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
2. There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
3. In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

C) 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 ECOG-ACRIN staff with access to the list must sign an agreement to keep your identity confidential.
3. Researchers to whom ECOG-ACRIN 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.

D) What are the Possible Benefits?

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.

E) Are there any costs or payments?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

F) What if I change my mind?

If you decide you no longer want your samples to be used, you can call the study doctor, Dr.

Andrea Silber, at (203) 785-2876, who will let the researchers know. Then, any sample that remains in the Biobank will no longer be used and related health information will no longer be collected. Tissue samples may be retained for documentation purposes, and then will be returned to the site that sent them. Samples or related information that have already been given to or used by researchers will not be returned.

G) What if I have more questions?

If you have questions about the use of your samples for research, contact the study doctor, Dr. Andrea Silber, at (203) 785-2876.

SAMPLES FOR FUTURE RESEARCH STUDIES:

May we keep any tissue leftover after the biomarker test and central review for future research?

- **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.

MY SIGNATURE AGREEING TO TAKE PART IN THE MAIN STUDY

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional studies where I circled 'yes'.

Participant's signature _____

Date of signature _____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature _____

Person obtaining consent (print name)	Signature	Date
Interpreter/ Witness (print name) – only if applicable, otherwise blank	Signature	Date