# 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:** NRG-BR003: A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer

**Principal Investigator:** Debra Brandt, DO
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**Principal Investigator's Mailing Address:** 200 Kennedy Drive, Torrington, CT 06790

## What is the usual approach to my breast cancer?

You are being asked to take part in this research study because you have a type of breast cancer that is HER2-negative and is not sensitive to hormone treatment. You have already been treated with surgery. People who are not in a study usually have chemotherapy after surgery, and if needed, radiation therapy. For patients who receive the usual approach for this cancer, about 70 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
- or you may choose not to be treated for cancer

## Why is this study being done?

The purpose of this study is to compare the good and bad effects of the chemotherapy drug, carboplatin, given with the usual chemotherapy drugs after surgery, compared to the usual chemotherapy drugs given without carboplatin. The addition of carboplatin to the usual chemotherapy could prevent your cancer from returning, but it could also cause side effects. This study will allow the researchers to know whether giving carboplatin with the usual chemotherapy is better, the same, or worse than giving the usual chemotherapy. If giving carboplatin with the usual chemotherapy drugs is better, there should be a higher chance that your breast cancer will not return. Carboplatin is FDA-approved for the treatment of cancer and is used for the treatment of breast cancer that has spread, but it has not yet been proven useful in earlier stages of breast cancer. There will be about 990 people taking part in this study.

## What are the study groups?

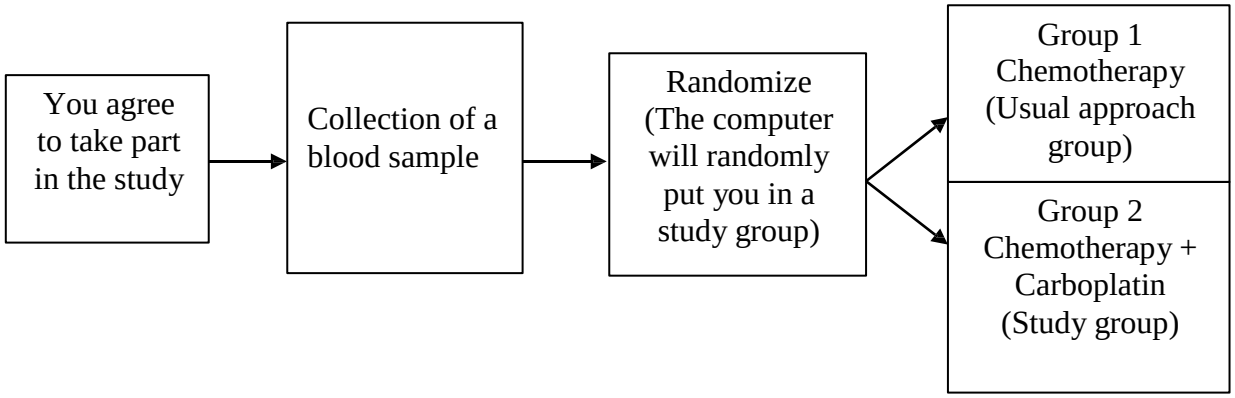
This study has two study groups.

- Group 1 will get the usual chemotherapy drugs used for this type of cancer: doxorubicin and cyclophosphamide, followed by paclitaxel.
  - Doxorubicin and cyclophosphamide will be given into a vein. This will take up to 1 hour.
  - This schedule will be repeated once every 2 weeks (called a cycle) for 4 cycles. About 2-3 weeks after you finish doxorubicin and cyclophosphamide, you will begin paclitaxel.
  - Paclitaxel will be given into a vein. This will take about 1 hour.
  - This schedule will be repeated once a week for 12 weeks.
- Group 2 will get the usual chemotherapy drugs used for this type of cancer: doxorubicin and cyclophosphamide, followed by paclitaxel plus the chemotherapy drug called carboplatin.
  - You will receive the same chemotherapy and follow the same schedule as Group 1.
  - You will begin carboplatin when you begin paclitaxel.
  - Carboplatin will be given into a vein after you receive the paclitaxel. This will take about 1 hour. It will take up to 2 hours to receive both chemotherapy drugs.
  - This schedule will be repeated once every 3 weeks (called a cycle) for 4 cycles.

The place where receive your chemotherapy drugs will have its procedures for giving chemotherapy drugs. This means that the time it takes to receive your chemotherapy drugs may be different than the times just described.

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




Should you choose to take part in this study you will need to:

- Keep your study appointments, and
- Tell your study doctor or study staff about any medications you are taking; any side effects, doctors' visits, or hospitalization that you may have whether or not you think they are related to the study therapy; and if you have been in a research study in the last 30 days or are in another research study now.

## How long will I be in this study?

You will receive the study drugs for about 6 months. After you finish the study drugs, your doctor will continue to watch you for side effects and follow your condition for 10 years.

## 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 approach for your cancer. However, there are extra blood samples and a tumor sample submission that not part of the usual approach for your cancer.

You will need to have:

- blood samples (about 1 tablespoon) will be taken for the study before you begin the study drugs, after you complete doxorubicin and cyclophosphamide but before you begin paclitaxel or paclitaxel and carboplatin, after the last paclitaxel or paclitaxel and carboplatin dose, 12 months after you join the study, and if your cancer returns.
- a sample of tumor tissue that was removed during your breast surgery will be sent to the NRG Oncology Division of Pathology.

These blood and tumor samples will be used for research purposes of the NRG-BR003 study. All of these samples are required in order for you to take part in this study because the research on the samples is an important part of the study. The tissue and blood samples will be used to learn more about certain features of cancer tumors and how they respond to treatment. The researchers may also use your samples to decide the best methods, both new and existing, to evaluate the NRG-BR003 tumor samples.

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.

## What is involved with storing samples for BR003 use for the purposes of the study?

If you take part in this study, the researchers will store and use your samples and health information for medical research. Some of the research that may be done for the NRG-BR003 study is unknown at this time. Storing samples for future studies is called "biobanking." The BR003 biobanking is for studies done at a later time related to the BR003 study purposes. The Biobanks are being run by NRG Oncology and are supported by the National Cancer Institute.

Your samples and some related information will be sent to researchers for use in the study. Remaining samples may be stored in the Biobank, along with samples from other people who take part. The samples will be kept until they are used up, returned, or destroyed.

Qualified researchers can submit a request to use the materials stored in the Biobank for BR003 related studies. The National Cancer Institute and/or a science committee at the clinical trials organization 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.

## 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
- Be asked sensitive or private questions which you normally do not discuss
- The addition of carboplatin may not be better, and could possibly be worse, than receiving the usual chemotherapy drugs alone.

The carboplatin used in this study may affect how different parts of your body work such as your liver, kidneys, 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 other chemotherapy drugs in this study.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

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

Study Group 1 and Group 2 – Possible side effects of doxorubicin, cyclophosphamide, and paclitaxel, which are the usual approach for this type of cancer:

Possible Side Effects of **Doxorubicin**

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving **doxorubicin**, more than 20 and up to 100 may have: |
|---|
| • Hair loss<br>• Vomiting<br>• Red colored urine, saliva, or sweat |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving **doxorubicin**, from 4 to 20 may have: |
|---|
| • Heart failure or heart attack which may cause shortness of breath, swelling of ankles, cough or tiredness which may occur years after the dose<br>• Swelling of the body which may cause shortness of breath<br>• Swelling and redness at the site of the medication injection or area of previous radiation<br>• Belly pain<br>• Sores in the mouth, throat or stomach |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving **doxorubicin**, from 4 to 20 may have: |
|---|
| • Nausea, diarrhea<br>• Hepatitis which may cause yellow eyes and skin<br>• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat<br>• Cancer of the bone marrow (leukemia) caused by chemotherapy<br>• Damage to organs which may cause infection, bleeding, may require transfusions<br>• Darkening of the nail beds or skin or hands and feet<br>• Loss of nails |

| **RARE, AND SERIOUS**<br>In 100 people receiving **doxorubicin**, 3 or fewer may have: |
|---|
| • Infection, especially when white blood cell count is low<br>• Bruising, bleeding<br>• Severe blood infection |

Possible Side Effects of **Cyclophosphamide**

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving **cyclophosphamide**, more than 20 and up to 100 may have: |
|---|
| • Hair loss<br>• Nausea, vomiting, loss of appetite<br>• Sores in mouth<br>• Infection, especially when white blood cell count is low<br>• Absence of menstrual period which may decrease the ability to have children<br>• Blood in urine |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving c**yclophosphamide**, from 4 to 20 may have: |
|---|
| • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions<br>• Loss or absence of sperm which may lead to an inability to father children<br>• Stuffy nose<br>• Fluid around the heart |

| **RARE, AND SERIOUS**<br>In 100 people receiving **cyclophosphamide**, 3 or fewer may have: |
|---|
| • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body<br>• Damage to the heart or heart failure which may cause shortness of breath, swelling of ankles, cough or tiredness<br>• A new cancer including cancer of bone marrow (leukemia) caused by chemotherapy<br>• Swelling of the body including the brain which may cause dizziness, confusion<br>• Scarring of the lungs |

Possible Side Effects of **Paclitaxel**

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving **paclitaxel**, more than 20 and up to 100 may have: |
|---|
| • Anemia which may cause tiredness, or may require blood transfusions<br>• Infection, especially when white blood cell count is low<br>• Diarrhea, nausea, vomiting<br>• Sores in mouth which may cause difficulty swallowing<br>• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat<br>• Bruising, bleeding<br>• Pain<br>• Muscle weakness<br>• Numbness, tingling or pain of the arms and legs<br>• Hair loss |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving **paclitaxel**, from 4 to 20 may have: |
|---|
| • Abnormal heartbeat<br>• Damage to the lungs which may cause shortness of breath<br>• Blood clot which may cause swelling, pain, shortness of breath |

| **RARE, AND SERIOUS**<br>In 100 people receiving **paclitaxel**, 3 or fewer may have: |
|---|
| • Heart attack or heart failure which may cause shortness of breath, swelling of ankles, and tiredness<br>• A tear or a hole in the stomach which may cause belly pain or that may require surgery |

Study Group 2 – In addition to side effects outlined above, people who are in Group 2 may also experience the possible side effects of **carboplatin** listed below.

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving **carboplatin**, more than 20 and up to 100 may have: |
|---|
| • Hair loss<br>• Vomiting, nausea<br>• Infection, especially when white blood cell count is low<br>• Anemia which may cause tiredness, or may require blood transfusions<br>• Bruising, bleeding<br>• Belly pain |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving **carboplatin**, from 4 to 20 may have: |
|---|
| • Diarrhea, Constipation<br>• Numbness and tingling in fingers and toes<br>• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat<br>• Changes in taste<br>• Changes in vision |

| **RARE, AND SERIOUS**<br>In 100 people receiving **carboplatin**, 3 or fewer may have: |
|---|
| • Damage to organs which may cause hearing and balance problems |

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study and for at least 3 months after your last dose of study therapy. The drugs used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

## What are the risks for the extra procedures?

Extra blood draw risks:

The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. Rarely, an infection can occur.

## What are the risks of Biobanking?

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.

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

It is not possible to know at this time if the addition of carboplatin to chemotherapy drugs is better than chemotherapy drugs alone so this study may or may not help you. This study will help researchers learn things that will help people in the future.

## Can I stop taking part in this study?

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

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

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

If you decide you no longer want your samples to be used, you can call the study doctor, Dr. Debra Brandt, at (203) 785-5811, who will let the researchers know. Then, any sample that remains in the bank will no longer be used. (You will still be able to take part in the BR003 study.) Samples or related information that have already been given to or used by researchers will not be returned.

## 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 Human Investigation Committee at (203) 785-4688.

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

You and/or your health plan/insurance company will need to pay for all of the costs of treating your cancer while in this study, including the cost of managing any side effects. 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.

There are no costs to you or your insurance for the collection of the blood and tumor tissue samples for research or the biobanking. The cost of the blood and tumor tissue collection and banking will be the responsibility of NRG Oncology. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

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.

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, MRI scans, CT scans, ECHOs, pregnancy tests, blood samples for research purposes, information recorded in study questionnaires, survival follow-up information and records about any study drug(s) that you received.

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 specimens from this study will be kept in a central database for research. Your name or contact information will not be put in the database. If you previously had a test done to determine if you carry a *BRCA1* or *BRCA2* mutation in your genes, NRG Oncology will collect the information as part of the BR003 study.

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, NRG Oncology
- Alliance for Clinical Trials in Oncology
- ECOG-ACRIN Cancer Research Group
- SWOG
- 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 Cancer Trials Support Unit (CTSU), a service sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar organizations if other countries are involved in the study.
- The U.S. Department of Health and Human Services
- 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
- 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.
- Drug regulatory agencies in other countries
- Governmental agencies to whom certain disease (reportable diseases) need to be reported
- Health care providers who provide services to you in connection with this study

- Laboratories and other individuals that analyze your health information in connection with this study, according to the study plan
- Those individuals at Yale who are responsible for the financial oversight of research including billing and payments
- The study doctor, Dr. Debra Brandt, and the Yale study team
- Data and Safety Monitoring Boards and other 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 Debra Brandt, DO, at 200 Kennedy Drive, Torrington, CT 06790.

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.

## How will information about my blood and tissues 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. All staff supported by NRG Oncology with access to the list/any information identifying you must sign an agreement to keep your identity confidential.
3) Researchers to whom NRG Oncology 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 identified 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.

Neither you nor your doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.

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.

## 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, about the use of your samples for research, or to report side effects or injuries. Contact the study doctor, Dr. Debra Brandt, at (203) 785-5811.

## Optional Biobanking For Possible Future Studies Not Related To NRG-BR003

Researchers are trying to learn more about cancer. Much of this research is done using samples from your tissue and blood. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure cancer.

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.

The researchers ask your permission to store and use your samples and health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. Some of the research that may be done on your samples for the NRG-BR003 study is unknown at this time but may be planned and started at a later date. Storing samples for future studies is called "biobanking." The Biobank for the optional blood and tissue samples is being run by NRG Oncology and supported by the National Cancer Institute.

### What is involved?

If you agree to take part in the optional sample study, here is what will happen next:

1) Your samples and some related 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, destroyed, or returned. Information from your medical record will be updated from time to time.
2) Qualified researchers can submit a request to use the materials stored in the Biobank. 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.
3) 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.
4) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

### What are the possible risks associated with the optional biobanking?

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.

## 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 NRG Oncology staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom NRG Oncology sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

## What are the possible benefits?

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

## Are there any costs or payments?

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

## What if I change my mind?

If you decide you no longer want your samples to be used, you can call the study doctor, Dr. Debra Brandt at (203) 785-5811, who will let the researchers know. Then, any sample that remains in the bank will no longer be used. Samples or related information that have already been given to or used by researchers will not be returned.

## What if I have more questions?

If you have questions about the use of your samples for research, contact the study doctor, Dr. Debra Brandt, at (203) 785-5811.

## SAMPLES FOR FUTURE STUDIES

***The researchers would like your permission to use all your samples collected for the study for future health research not related to the purposes of the NRG-BR003 study.***

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

YES NO

## ADDITIONAL STUDIES SECTION

## This section is about optional contact for future studies you can choose to take part in.

**CONTACT FOR FUTURE RESEARCH STUDIES:**
I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

**YES** **NO**

This is the end of the sections about optional and additional studies.

**Reproductive risks for Saint Francis Hospital and Medical Center**

## IMPORTANT INFORMATION ABOUT REPRODUCTIVE RISKS

### MEN

Study drugs such as the ones offered as part of this clinical trial can affect an unborn child. If you are a man able to have children, it is important that you do not father a child while you are taking part in this study, and perhaps even for some time after you stop taking the study drugs. Your doctor will discuss this in detail with you.

Saint Francis Hospital and Medical Center is dedicated to your health and well being. While abstinence is the most effective way of preventing a pregnancy, we understand that you may consider other methods of pregnancy prevention. Saint Francis Hospital and Medical Center will not provide contraception products as part of this study, nor does it endorse, approve, or intend contraception, other than abstinence, by complying with the requirements of this study.

Study drugs such as the ones offered as part of this clinical trial may affect your ability to father a child in the future. Your doctor will discuss this in detail with you.

You are encouraged to ask your study doctor or research nurse for more information about reproductive risks and pregnancy prevention.

As a Catholic institution, Saint Francis Hospital and Medical Center abides by the Ethical and Religious Directives for Catholic Health Care Services, as determined by the United States Conference of Catholic Bishops. As such, Saint Francis Hospital and Medical Center neither endorses nor provides medical practices and/or procedures that contradict the moral teachings of the Roman Catholic Church.

Patient Initials _____

## IMPORTANT INFORMATION ABOUT REPRODUCTIVE RISKS

### WOMEN

Study drugs such as the ones offered as part of this clinical trial can affect an unborn child. If you are a woman able to have children, it is important that you do not become pregnant while you are taking part in this study, and perhaps even for some time after you stop taking the study drugs. Your doctor will discuss this in detail with you. Women who are breast feeding should stop breast feeding while taking part in this study.

Saint Francis Hospital and Medical Center is dedicated to your health and well being. While abstinence is the most effective way of preventing a pregnancy, we understand that women may also decide to use other methods of pregnancy prevention. Saint Francis Hospital and Medical Center will not provide contraception products as part of this study, nor does it endorse, approve, or intend contraception, other than abstinence, by complying with the requirements of this study.

You are encouraged to ask your study doctor or research nurse for more information about reproductive risks and pregnancy prevention.

As a Catholic institution, Saint Francis Hospital and Medical Center abides by the Ethical and Religious Directives for Catholic Health Care Services, as determined by the United States Conference of Catholic Bishops. As such, Saint Francis Hospital and Medical Center neither endorses nor provides medical practices and/or procedures that contradict the moral teachings of the Roman Catholic Church.

Patient Initials _____

## 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'.

Print patient's name_____

Patient's signature_____

Date of signature_____

Print name of person(s) conducting the informed consent discussion_____

Signature of person(s) conducting the informed consent discussion_____

Date of signature_____

| Interpreter/ Witness -only if applicable, otherwise blank | Signature | Date |
|---|---|---|

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 Debra Brandt at (203) 785-5811. 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.