Official Title:	A Phase 2 trial of Liposomal Doxorubicin and Carboplatin in Patients with ER,PR, HER2 Negative Breast Cancer (TNBC)
NCT number:	NCT023151196
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[redacted]

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: A Phase 2 trial of liposomal doxorubicin and carboplatin in patients with ER, PR, HER2 negative breast cancer (TNBC)

Principal Investigator: [redacted]

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor (the principal investigator) or another member of the study team (an investigator) will also be asked to sign this informed consent form. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

[redacted].

The costs that are usually covered include things such as research laboratory tests required by the study, and the costs of collecting all of the information required by the study.

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Why is this study being done?
The purpose of this study is to determine the activity and safety of a combination chemotherapy regimen for early stage breast cancers that do not express estrogen receptor (A protein found inside the cells of the female reproductive tissue, some other types of tissue, and some cancer cells. The hormone estrogen will bind to the receptors inside the cells and may cause the cells to grow. Also called ER), progesterone receptor (A protein found inside the cells of the female reproductive tissue, some other types of tissue, and some cancer cells. The hormone progesterone will bind to the receptors inside the cells and may cause the cells to grow. Also called PR), or HER2 protein (A protein involved in normal cell growth. It is found on some types of cancer cells, including breast and ovarian. Cancer cells removed from the body may be tested for the presence of HER2 to help decide the best type of treatment). The two drugs doxorubicin and carboplatin will be given together and then paclitaxel will be given alone. In addition, this study will determine if there are changes in the DNA (deoxyribonucleic acid, a self-replicating material present in nearly all living organisms as the main constituent of chromosomes. It is the carrier of genetic information) of the cancer itself that predict which breast cancers will have the best response and for which breast cancers we need to identify other effective treatments. Laboratory evaluations will be done to identify potentially effective alternatives.

Drugs used as part of our standard of care to treat early stage breast cancer include doxorubicin and paclitaxel. Liposomal doxorubicin is another formulation of doxorubicin that is FDA approved and is part of our national oncology guidelines for treating metastatic breast cancer. Carboplatin is FDA-approved and is part of our national oncology guidelines for treating metastatic breast cancer. Carboplatin is approved for treating early stage, HER2-expressing breast cancers in combination with other chemotherapies.

Liposomal doxorubicin and carboplatin have proven benefit in the treatment of metastatic breast cancer. Their combination has been tested in a clinical trial at the Cancer Institute for safety, tolerability, and benefit for treatment of breast cancers that do not express estrogen receptor, progesterone receptor or HER2 protein. The combination of liposomal doxorubicin and carboplatin has not yet been tested for treatment of early stage breast cancer. Therefore, the goal of this study is to determine the response rate of early stage breast cancers that do not express estrogen receptor, progesterone receptor or HER2 protein to the combination of liposomal doxorubicin and carboplatin. All laboratory correlates are for research purposes only.

Why have you been asked to take part in this study?
You have been asked to participate in this study because you have been diagnosed with an early stage breast cancer that does not express estrogen receptor, progesterone receptor or the HER2 protein for which chemotherapy is a recommended treatment.

Who may take part in this study? And who may not?
You may be included in this study if:

- You have been diagnosed with stage II-III breast cancer that does not express estrogen receptor, progesterone receptor, or HER2 protein.

- You are at least 18 years of age.
- You are not pregnant.
- You have an adequate contraceptive method during treatment and for three months after completing treatment.
- You have a sufficient level of daily activity.
- You meet specific criteria on bloodwork for blood counts, kidney, and liver function.
- You have adequate heart function.
- You have had imaging to exclude metastatic (the spread of cancer from the place where it started to other places in the body) breast cancer, i.e. breast cancer in other organs.
- You are not receiving other treatments for your breast cancer.
- You have signed consent for this study.
- You are eligible to undergo surgery, either lumpectomy ((the spread of cancer from the place where it started to other places in the body),
  or mastectomy (surgery to remove part or all of the breast. There are different types of mastectomy that differ in the amount of tissue and lymph nodes removed) for local treatment of the breast cancer.
- Your cancer tissue is provided for laboratory analysis.

You may Not be included in this study if:

- You are pregnant or breastfeeding.
- Have another cancer except specific limited cancers or other cancers treated at least 5 years previously with no evidence of recurrence.
- Have evidence of metastatic disease.
- Have a diagnosis of inflammatory breast cancer.
- Have a history of hypersensitivity reaction attributed to the drugs used in this study, i.e. doxorubicin, paclitaxel, or carboplatin.
- Have another serious medical disorder that would compromise your safety or your ability to complete the study.
- Have had a heart attack or unstable angina in the past 6 months, significant heart failure, uncontrolled abnormal heart rhythms, structural heart disease causing significant heart dysfunction or significant EKG abnormality.
- Have had prior treatment with the study drugs for any cancer.
- Have known or active hepatitis B or C with abnormal liver function tests.
- Have significant vascular disease.
- Have evidence of bleeding or clotting disorder.
- Have lung disease resulting in moderate to severe breathing difficulty.
- Have history of a major organ transplant requiring chronic immunosuppression, e.g., kidney, liver, lung, heart, bone marrow transplant, or autoimmune diseases. Patients who have received corneal transplants, cadaver skin, or bone transplants are eligible.
- Have moderate/significant nervous system disorder.
- Have a condition that would prohibit administration of steroids.

The study doctor and/or research team will also ask you other questions about your medical history in order to make sure you qualify to be in this study.

How long will the study take and how many subjects will participate?
A total of 60 subjects will be enrolled study wide. Approximately 60 subjects will take part in this study from the [redacted]. We expect accrual over four years but participants will be evaluated for a minimum of five years after enrollment.

What will you be asked to do if you take part in this research study?
Before you may take part in this study, you will need to answer questions and have the following tests and examinations to see if you are eligible. This is called screening. It is important to answer all questions honestly and completely. If anything changes before or during the study, you must tell the study doctor. Depending on the answers to these questions and the results of the tests and examination, it is possible that you may not be able to take part in this study.

In some instances, certain tests or procedures conducted during the study may have to be repeated. This can happen if some or all of the results or tissue are unusable. Also, you may be asked to have additional tests or examinations. This can happen if an unexpected medical event occurs during the study. Before you begin treatment, you will need to have the following tests and procedures done:

- A prior biopsy confirming your diagnosis of breast cancer and that it does not express three proteins: estrogen receptor, progesterone receptor, and HER2. This tissue will also be used for laboratory testing to evaluate DNA/genetic changes and expression of tissue cancer markers.
- A new biopsy for research purposes
- A blood specimen for research purposes
- Signed consent
- Completing a Quality of Life questionnaire at three time points during treatment that can be completed in five minutes

A medical history and physical exam will be done by the study doctor prior to starting the study and prior to each cycle during the study.

In addition, you will be required to have:

- Blood tests done before treatment and before each cycle during the study. You will have blood drawn using a small needle to check your blood counts, your blood chemistry, and how your liver and kidneys are working.
- a urine test to evaluate your kidney function.
- Answered questions about the extent of your physical activity, how you are generally feeling informally and using a brief survey.
- Scans may be done before the study and as necessary for evaluation of any new symptoms.
- You will also need to have an ECG (electrocardiogram, also known as an "EKG"- a painless paper tracing of the heart's normal electrical activity).
- If you are able to conceive, you will have a pregnancy test within one week of the start of the

study. If you are pregnant, you cannot take part.

- An additional biopsy may be needed to obtain adequate tissue for testing and/or placement of a clip, a small marker to designate the location of the breast cancer, in the breast prior to start of treatment.
- If you have low numbers of white blood cells (what helps you fight infection) you may be given G-CSF. G-CSF is a special type of protein called a growth factor. It stimulates bone marrow to make white blood cells and is given as an injection. Your study doctor will tell you if you need G-CSF along with study drug administration.

Patients participating in this study will receive the following chemotherapy prior to undergoing breast surgery. Two drugs, carboplatin and liposomal doxorubicin, will be given together every 28 days. Twenty-eight days is considered a cycle. The combination of carboplatin and liposomal doxorubicin will be given for four cycles. Patients will then have their breast surgery followed by 12 weekly doses of paclitaxel, another type of chemotherapy. Patients will only receive additional therapy, such as radiation therapy, if determined to be necessary by their treating physician.

Cancerous tissue from the breast biopsy will be sent for a test that looks for genetic abnormalities within the cancer cells. This is called genomic analysis. These types of abnormalities are not the kind the parents pass to their offspring. These are abnormalities that arise within normal cells of the breast that then result in the breast cells behaving as a cancer. Some of these genetic abnormalities in the cancer cells may tell your doctors if any additional therapies may be useful in the treatment of your breast cancer in the future. In the event that testing of your cancer identifies an abnormality or mutation that could be inherited, that is, passed from parents to their children, your treating physician would be notified so that they can discuss with you whether or not testing to confirm the presence of an inherited genetic mutation is appropriate. You will be able to decide whether or not this testing is right for you based on that discussion with your physician and/or meeting with one of our genetic counselors. This study does not require you to undergo that specific type of genetic testing.

Cancerous breast tissue that is removed during a procedure is normally sent to the pathology department where it is processed. Pathologists typically examine the tissue under a microscope to confirm a diagnosis and provide information to the treating physician as to possible stage of your breast cancer and whether specific proteins are expressed which help determine treatment recommendations. A portion of the cancerous tissue that is not used by the pathologist will be requested for evaluation in the laboratory to help determine sensitivity of the cancer to various other drug therapies. The response to these drug therapies and how you do on the clinical trial will be correlated with the genomic analysis. This will help determine if there are specific genetic alterations in the breast cancer that make it more (or less) sensitive to each of the drugs tested.

What are the risks and/or discomforts you might experience if you take part in this study?

If you participate in this study, you must understand that you take the risk of treatment not being effective against your cancer. The drugs used in this study may cause all, some or none of the side effects listed. In addition, there is always the risk of developing very uncommon or previously unknown side

[redacted] carboplatin and liposomal doxorubicin has been previously evaluated in a clinical trial at [redacted]. Paclitaxel is a standard chemotherapy given for the treatment of breast cancer. However, some side effects from any chemotherapy drug may be serious enough to result in hospitalization and/or death.

During a CT scan, you will be exposed to small amounts of radiation, which are equal to 3 years of exposure from the air around us. There is also a rare risk of a serious allergic reaction to the dye used in the test.

When your blood is drawn, there is the possibility of developing a bruise, bleeding or (rarely) infection at the place where your blood is drawn. Techniques used to draw blood will minimize these risks.

Common side effects observed with almost any chemotherapy include:

Bone marrow suppression: The drugs used to kill cancer cells also kill some normal body cells, especially those that grow rapidly (blood cells, hair, cells that line the mouth, stomach and intestines). Blood cells are made in the bone marrow and are responsible for fighting infections (white blood cells), carrying oxygen (red blood cells), and causing blood to clot (platelets). A reduction in the number of these blood cells (marrow suppression) can lead to an increased risk of infection, weakness, or bleeding. Should these effects occur, they can be treated with blood products (transfusions) and antibiotics. Reduced white blood cells may be treated with an injection the day after chemotherapy.

Hair loss: This may be partial or complete and more likely with paclitaxel than the combination of liposomal doxorubicin with carboplatin. Hair growth usually returns when the drug is stopped. Hair color will not change, but hair is sometimes curlier.

Nausea, vomiting and temporary loss of appetite: This does not usually last for more than a day after the administration of chemotherapy. Anti-nausea medication will be prescribed before and during treatment with chemotherapy.

Irregular menstrual cycle: Women may experience temporarily an irregular cycle or it may cease permanently resulting in an inability to conceive.

Extravastion: A leakage or escape of medication from a vein into the tissues resulting in pain and possible tissue damage.

Secondary leukemia: Some patients may develop leukemia or a second cancer.

Blood clots: They occur frequently in patients with cancer and have occurred in patients on similar studies.

In the past few years, liposomal doxorubicin has experienced drug shortages for which measures have been taken to reduce this occurrence. However, should another shortage occur, epirubicin (a drug with action similar to liposomal doxorubicin) would be given as a substitute.

[redacted]

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Toxicities (The extent to which something is harmful) associated with the specific chemotherapies used in this study are listed below:

CARBOPLATIN

Common side effects from carboplatin include:

- hair loss
- loss of appetite or weight
- stomach pain
- diarrhea
- constipation
- nausea and vomiting
- changes in vision or hearing
- numbness or tingling in the fingertips
- irritation or sores in the lining of the mouth and throat and possible change in taste

Less common side effects from carboplatin include:

- Rash or allergic reaction with change in blood pressure or shortness or breath
- Swelling of the feet or ankles
- Abnormalities in electrolytes (measured on bloodwork)
- Reduced kidney function
- Abnormalities in liver tests

LIPOSOMAL DOXORUBICIN

Common side effects from liposomal doxorubicin include:

- hair loss
- loss of appetite or weight
- diarrhea
- nausea and vomiting
- irritation or sores in the lining of the mouth and throat and possible change in taste

Less common side effects from liposomal doxorubicin include:

- Rash or allergic reaction with change in blood pressure or shortness or breath
- Infusion reaction
- red rash with peeling, swelling and/or discomfort on the palms or soles of the feet
- reduced heart function
- second malignancy

PACLITAXEL

Common side effects from paclitaxel include:

- hair loss
- loss of appetite or weight
- diarrhea

- nausea and vomiting
- muscle/joint discomfort and weakness
- numbness or tingling in the fingertips
- irritation or sores in the lining of the mouth and throat

Less common side effects from paclitaxel include:

- Rash or allergic reaction with change in blood pressure or shortness or breath

EPIRUBICIN

Common side effects from epirubicin include:

- hair loss
- loss of appetite or weight
- fatigue
- diarrhea
- nausea and vomiting
- irritation or sores in the lining of the mouth and throat

Less common side effects from epirubicin include:

- Rash or allergic reaction with change in blood pressure or shortness or breath
- Infusion reaction
- red rash with peeling, swelling and/or discomfort on the palms or soles of the feet
- reduced heart function
- second malignancy

Unrelated to the drug therapy are other potential risks. For instance, since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family economic stress. However, the genetic information gained through testing of your cancer cells does not confirm the presence of an inherited genetic abnormality. Only blood testing, done only with your knowledge and permission through your treating physician can confirm the presence of an inherited genetic abnormality.

There are state and federal laws that protect against genetic discrimination. A federal law, the Genetic Information Nondiscrimination Act makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will
protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when

[redacted], it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

A federal law (Genetic Information Non-Discrimination Act, GINA) will help lower the risk from health insurance or employment discrimination on the basis of genetic information. The federal law does not include other types of misuse by life insurance, long-term care or disability insurance. If you want to learn more about the GINA Law, you can find information about it on the internet or ask the study staff. In addition to the federal law, some states have laws that also help protect against genetic discrimination. There are state and federal laws that protect against genetic discrimination.

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REPRODUCTIVE RISKS

Females will be included in this study. If you are pregnant, you cannot participate in this study. You should not become pregnant or father a baby while participating in this study because the drugs in this study can be associated with unknown risks that could affect you or an unborn baby.

All subjects and their spouses or partners must use an effective birth control method. Some examples of birth control are the following: have had a prior history of surgically-induced sterility (i.e., tubes tied, vasectomy), avoiding any activity that could cause you to become pregnant (no sexual intercourse), or using birth control pills, IUD, condom, or double-barrier contraception diaphragm with spermicidal jelly, transdermal (through your skin) or injectable contraceptives.

You must practice birth control during the study and for at least six months after you receive the last dose of the study drug. Before entering the study, you and the study doctor must agree on the birth control method you will use during the entire study.

A counselor and more information about preventing pregnancy will be made available to you if you have any questions.

If you are capable of becoming pregnant, a pregnancy test (using a urine and/or blood sample) will be done and the results must be negative before you are permitted to enroll in this study. A repeat pregnancy test must be done if you miss any periods or your menstrual cycle becomes irregular.

If you are currently breast feeding a child and agree to participate in this study, you must stop breast feeding before receiving the first dose of study drug. You must agree to discontinue breast feeding for the entire time you are participating in the study to prevent any potential health risk or injury to the child.

If you become pregnant while in this study, you must tell the study doctor as soon as possible. The study doctor will advise you of the possible risks to your unborn child and options available to you. Because of the possible risks to an unborn child, the study drug will be stopped. You may be asked to receive medical follow-up services for yourself during the pregnancy and for the baby after birth. You may be

[redacted]

[redacted]

asked to provide more information about the pregnancy and its outcome.

Can you take other medicines while on this study?

You should not take any over-the-counter medicines, herbal products, vitamins or food supplements while taking part in this study, unless you tell the study doctor and get permission from the study doctor to go on taking these medicines. You will follow the instructions of the study doctor about the use of any of these products.

You should also tell the study doctor about all medicines that other doctors may have prescribed for you to take.

Are there any benefits for you if you choose to take part in this research study?

There may or may not be direct medical benefit to you from taking part in this study. If the treatment is successful, it is hoped that your breast cancer will become smaller in size or disappear, reducing the risk of your breast cancer coming back in the future. It is hoped that the information learned from this study will also benefit other patients with breast cancer in the future. However, it is possible that information learned from your particular breast cancer may be helpful to your care in the future.

What are your alternatives if you don't want to take part in this study?

The following alternative treatments are available if you choose not to take part in this study, and you have been given the chance to ask questions about them:

- You may choose not to receive the medication designated in this study to treat your breast cancer.
- You may receive non-experimental treatments and can ask the study doctor about these treatments.
- You may choose to participate in an alternative experimental treatment and can ask your study doctor about other treatment studies that are available.

Talk to your doctor about your choices before you decide if you will take part in this study. You are under no obligation to take part in this research study. If you decide that you do not wish to take part in this study, you are free to leave the study at any time.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to go on taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

You and/or your insurance company will be billed for the costs of your treatment that are considered standard of care (for example, doctor/ Advanced Practice Nurse (APN) visits, nursing care to administer the treatments, routine lab tests, restaging scans, etc.) as you would have received these services even if

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you were not participating in this study. You will be responsible for any co-payments due for office visits, co-insurances and deductibles due on any tests and/or procedures that are required and considered standard care.

Carboplatin, liposomal doxorubicin, paclitaxel, and epirubicin are all commercially available drugs. You or your insurance company will be billed for the cost of these medications.

If you have any questions about insurance coverage, including any out of pocket expenses you might incur, or which laboratory or facilities you are allowed to have tests at, a financial counselor will be made available to you upon request.

Optional and/or research related items such as tumor tissue collection and blood samples will be paid for by the [redacted]

Will you be paid to take part in this study?
You will not be paid for your participation in this research study.

How will information about you be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

Your personal health information, identifiers and research data are stored and kept in a secure area in the [redacted]. Computer screens containing personal health identifiers are inaccessible to public view. Only the study doctor and research team will have direct access.

A description of this clinical trial will be available on 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 website at any time.

What will happen if you are injured during this study?
If you take part in this study, you will be exposed to certain risks of physical personal injury in addition to those associated with standard forms of treatment.

In addition, it is possible that during the course of this study, new adverse effects of doxorubicin or epirubicin formulations, paclitaxel, or carboplatin that result in personal injury may be discovered. Please refer to section 'What are the risks and/or discomforts you might experience if you take part in this study?'.

The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the

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University.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?
Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing to [redacted] d (address provided on page 1).

Any data that has already been sent to the [redacted] of [redacted] cannot be withdrawn because there may not be any identifiers to link the data with you. We are required by the Food and Drug Administration however, to continue to report anything that relates to the safety of these drugs.

At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can you call if you have any questions?
If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

[redacted]

If you have any questions about your rights as a research subject, you can call:

[redacted]

What are your rights if you decide to take part in this research study?
You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

Protected Health information

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Protected Health Information (PHI) under HIPAA means any information that identifies an individual and relates to at least one of the following:

- The individual's past, present or future physical or mental health
- The provision of health care to the individual
- The past, present or future payment for health care

The next few paragraphs tell you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization (permission) and informed consent form as required or allowed by law. Because we are committed to protecting your health information, some of the paragraphs that follow repeat what we described to you earlier in this consent form about what information we will collect about you, how we will use it, when or if it will be shared with others, and the measures we will take to protect your privacy and the confidentiality of your personal information.

Please read this authorization section and the consent form carefully. Ask questions if anything is not understandable to you.

Authorization to use your health information for research purposes
Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

Do you have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study and receive any research related products. However, signing the form is not a condition for receiving any medical care outside the study.

If you sign, can you revoke your authorization or withdraw your information later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows the researchers to continue using and disclosing your information. Therefore, you should be aware that the researchers may continue to use and disclose the health information that was provided before you withdrew your authorization if necessary to maintain integrity of the research or if the data had already been stripped of all identifiers.

If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you may do so in writing by contacting [redacted] in writing.

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What personal information will be used or disclosed?
Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, information in your medical record such as certain information indicating or relating to a particular medical condition, blood and other tissue samples and related records, physical examinations, x-rays, MRI's, etc. Your personal identity, that is your name, address, and other identifiers, will be kept confidential. You will have a code number and your actual name will not be used. Only your study doctor will be able to link the code number to your name.
Your data may be used in scientific publications. If the findings from the study are published, you will not be identified by name. Your identity will be kept confidential. The exception to this rule will be when there is a court order or when a law exists requiring the study doctor to report communicable diseases. In this case, you will be informed of the intent to disclose this information to the state agency. Such a law exists in New Jersey for diseases such as cancer, infectious diseases such as hepatitis, HIV, viruses and many others.

In applications for marketing authorization your data may be submitted to domestic and foreign drug regulatory agencies.

Your data may also be sent to domestic and foreign drug regulatory agencies if you should suffer a bad reaction to the study drug.

Who may use or disclose the information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- [redacted]

Who may receive/use the information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- U.S. Food and Drug Administration (FDA)
- The Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (DHHS)

Your information may be re-disclosed (shared) by the recipients described above, if they are not required by law to protect the privacy of the information.

When will your authorization expire?
There is no set date at which your authorization will expire. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be

complete.

Will access to your medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you and was included in your official medical record.

Where can you get more information?
You may call the National Cancer Institute's Cancer Information Service at:
Voice: 1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/
For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

If you do not have access to a personal computer, you may access these websites and other information at a computer in the Resource and Learning Center on the second floor of the Cancer Institute of New Jersey at no cost to you.

AGREEMENT TO PARTICIPATE
I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

I agree to take part in this study.

Subject Name:_____

Subject Signature:_____ Date:_____

Signature of Reader/Translator If the Patient Does Not Read English Well:
The person who has signed above, _____, does not read English well. You read English well and are fluent in _____ (*name of the language)*, a language that the patient understands well. You understand the content of this consent form and you have translated for the patient the entire content of this form. To the best of your knowledge, the patient understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and these questions have been answered.

Reader/Translator Name:_____

Reader/Translator Signature:_____ Date:_____

Witness Name:_____

[redacted]
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Witness Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:
To the best of your ability, you have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____

Thank you for considering participation in this research.

You have read this entire form, or it has been read to you, and you believe that you understand what has been discussed.

All of your questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____

[redacted]
Expiration Date: 7/30/2016