

NRG-BR003
Amendment 1
Version Date: 12/18/2017

NCI Community Oncology Research Program – Kansas City (NCORP-KC)

NRG-BR003 Informed Consent Form

Study Title for Study Participants

Testing the addition of carboplatin to usual chemotherapy in high-risk triple-negative breast cancer

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>:

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

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.

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What are the study groups?

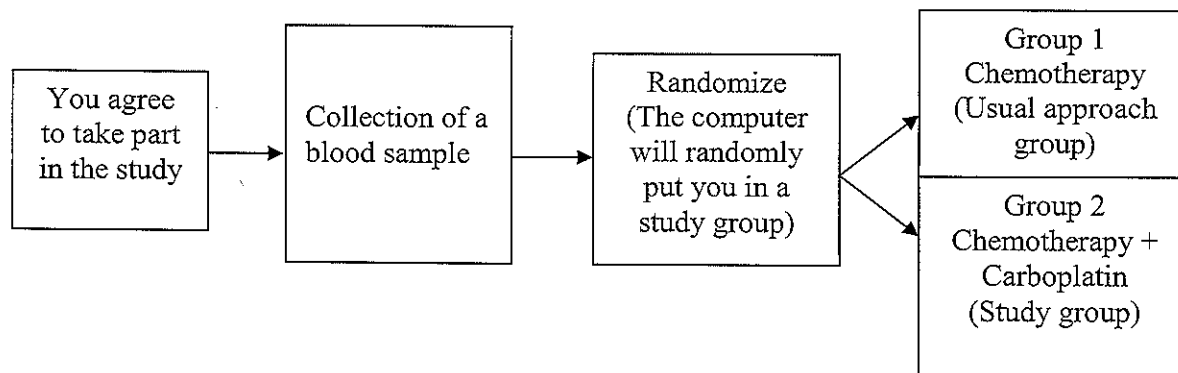
This study has two study groups.

- 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 you receive your chemotherapy drugs will have its own 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

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- 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 are not a 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.

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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
In 100 people receiving doxorubicin , more than 20 and up to 100 may have:
<ul style="list-style-type: none"> • Hair loss • Vomiting • Red colored urine, saliva, or sweat

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OCCASIONAL, SOME MAY BE SERIOUS

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
- Abnormal heartbeat
- Damage to the lungs which may cause shortness of breath when combined with radiation
- Infection, especially when white blood cell count is low
- Bruising, bleeding
- Swelling and redness at the site of the medication injection or area of previous radiation
- Belly pain
- Sores in the mouth or throat
- Nausea, diarrhea
- Hepatitis or damage to the liver which may cause yellowing of eyes and skin, swelling
- Kidney damage which may require dialysis
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Damage to the skin which may cause pain
- Cancer of the bone marrow (leukemia) caused by chemotherapy
- Darkening of the nail beds or skin on hands and feet
- Loss of nails

RARE, AND SERIOUS

In 100 people receiving **doxorubicin**, 3 or fewer may have:

- Severe blood infection

Possible Side Effects of Cyclophosphamide

COMMON, SOME MAY BE SERIOUS

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

- Hair loss, skin changes, rash, change in nails
- Nausea, vomiting, diarrhea, loss of appetite, pain in belly
- Sores in mouth
- Infection, especially when white blood cell count is low
- Absence of menstrual period which may decrease the ability to have children
- Blood in urine

OCCASIONAL, SOME MAY BE SERIOUS

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

- Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions

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OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving **cyclophosphamide**, 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
- Loss or absence of sperm which may lead to an inability to father children
- Stuffy nose
- Scarring of the lungs which may cause shortness of breath
- Fluid around the heart

RARE, AND SERIOUS

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
- Damage to the heart or heart failure which may cause shortness of breath, swelling of ankles, cough or tiredness
- A new cancer including cancer of bone marrow (leukemia) caused by chemotherapy
- Swelling of the body including the brain which may cause dizziness, confusion

Possible Side Effects of Paclitaxel

COMMON, SOME MAY BE SERIOUS

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

- Anemia which may cause tiredness, or may require blood transfusions
- Infection, especially when white blood cell count is low
- Diarrhea, nausea, vomiting
- Sores in mouth which may cause difficulty swallowing
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Bruising, bleeding
- Pain
- Muscle weakness
- Numbness, tingling or pain of the arms and legs
- Hair loss

OCCASIONAL, SOME MAY BE SERIOUS

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

- Abnormal heartbeat
- Damage to the lungs which may cause shortness of breath
- Blood clot which may cause swelling, pain, shortness of breath

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RARE, AND SERIOUS
In 100 people receiving paclitaxel , 3 or fewer may have:
<ul style="list-style-type: none"> • Heart attack or heart failure which may cause shortness of breath, swelling of ankles, and tiredness • 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
In 100 people receiving carboplatin , more than 20 and up to 100 may have:
<ul style="list-style-type: none"> • 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

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving carboplatin , from 4 to 20 may have:
<ul style="list-style-type: none"> • Diarrhea, Constipation • Numbness and tingling in fingers and toes • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Changes in taste • Changes in vision

RARE, AND SERIOUS
In 100 people receiving carboplatin , 3 or fewer may have:
<ul style="list-style-type: none"> • 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:

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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, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* 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.

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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 NCI Community Oncology Research Program – Kansas City Institutional Review Board at 913-948-5588.

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.

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 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

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- 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.

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 _____ (*insert name of study doctor[s]*) at _____ (*insert telephone number*).

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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.

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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, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* 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.

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What if I have more questions?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

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.

Release

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

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

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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 _____

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