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

Study Title for Study Participants: Testing the addition of cabazitaxel to abiraterone for metastatic prostate cancer in patients that have had docetaxel

Official Study Title for Internet Search on https://ClinicalTrials.gov:
EA8153: Cabazitaxel with Abiraterone versus Abiraterone alone Randomized Trial for Extensive Disease following Docetaxel: the CHAARTED2 Trial

Version Date: June 5, 2018

What is the usual approach to my prostate cancer?

You are being asked to take part in this research study because you have prostate cancer that has spread, and is able to grow even though drugs or other treatments to lower the amount of male sex hormones are being used to manage the cancer. People who are not in a research study are usually treated with FDA approved hormone-based therapies, chemotherapy, immunotherapy, and radioactive drug or radiotherapy. For patients who receive the usual approach for this cancer, the average life expectancy is 3 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 your care. For example:

- you may choose to have the usual approach described above
- you may choose to take part in a different research study, if one is available
- or you may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

Why is This Study Being Done?

The purpose of this research study is to compare any good or bad effects of using the chemotherapy drug cabazitaxel (also known as Jevtana®) with the usual approach of the hormone based therapy abiraterone acetate (also known as Zytiga®) in combination with prednisone on patients with advanced prostate cancer that have already undergone treatment with hormone therapy and the chemotherapy drug docetaxel. In this research study, you will get either the standard of care combination of abiraterone acetate and prednisone, or you will get abiraterone acetate and prednisone in combination with the chemotherapy drug

cabazitaxel. To be better, the study drug should delay the development of resistance to abiraterone acetate and prednisone by 6 months or more compared to the usual approach. There will be about 210 people taking part in this research study.

What are the Study Groups?

This research study has two study groups. Group A will receive the study drug cabazitaxel in addition to the standard of care combination of abiraterone acetate and prednisone, and Group B will receive the standard of care combination of abiraterone acetate and prednisone.

Abiraterone acetate is to be taken on an empty stomach, and tablets must not be crushed or chewed. Prednisone is taken twice a day with food. Because abiraterone acetate must be taken on an empty stomach and prednisone must be taken with food, drug administration must be carefully spaced out.

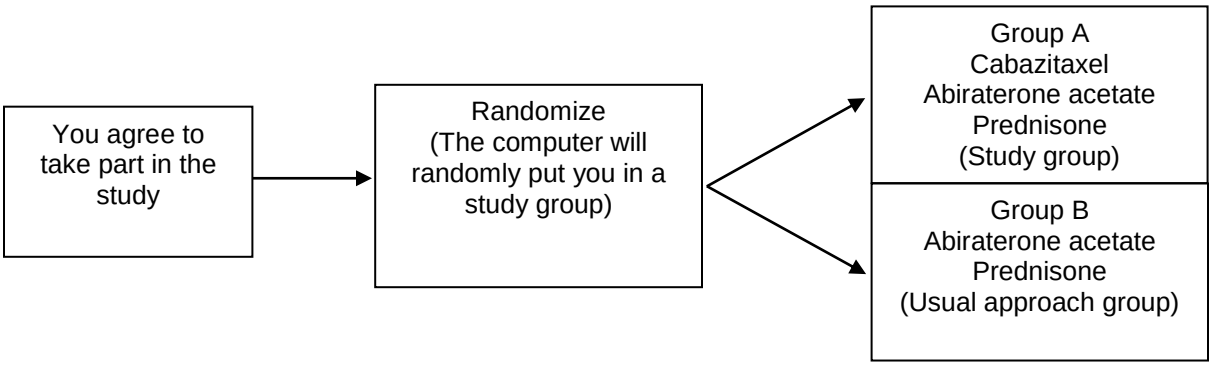
If you are assigned to Group A you will receive cabazitaxel intravenously (IV) once every 21 days.

You will be provided with a pill calendar to help you track your medication.

All patients will continue androgen deprivation, which is the standard of care.

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

Another way to find out what will happen to you during this research study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



How Long will I be in This Study?

If you are in Group A you will receive treatment with abiraterone acetate once daily, prednisone twice daily, and cabazitaxel once every 21 days for up to 6 times on this study. The 21-day period from one treatment with cabazitaxel to the next is called a cycle. As such you will receive up to 6 cycles of treatment with cabazitaxel for a total of 126 days. After you finish treatment with cabazitaxel, you will continue treatment with abiraterone acetate and prednisone. You will be asked to take abiraterone acetate and prednisone until your

cancer gets worse or until you or your doctor decides that it is in your best interest to stop the study. After you are finished taking the study drugs, your doctor will ask you to visit the office for follow-up exams. The doctor would like to see how you are doing every 3 months if you are less than 2 years from study entry, every 6 months if you are 2-3 years from study entry and then annually for up to year 5. Keeping in touch with you and checking on your condition helps the study staff look at the long-term effects of the study.

If you are in Group B you will receive treatment with abiraterone acetate once daily, and prednisone twice daily. You will be asked to take abiraterone acetate and prednisone until your cancer gets worse or until you or your doctor decides that it is in your best interest to stop the study. After you are finished taking the study drugs, your doctor will ask you to visit the office for at least one follow-up exam. If you are no longer seeing your study doctor, a staff member will call you on the telephone. The doctor would like to see how you are doing every 3 months if you are less than 2 years from study entry, every 6 months if you are 2-3 years from study entry and then annually for up to year 5. Keeping in touch with you and checking on your condition helps the study staff look at the long-term effects of the study.

If your condition gets worse while on this study, or you decide you do not want to be on the study any more, your doctor will take you off study treatment.

What extra tests and procedures will I have if I take part in this study?

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

Before you begin the study:

After you agree to take part and sign this consent form, you will have tests and procedures to find out if you can take part in this study. Most of these screening tests and procedures are part of regular cancer care and may be done even if you do not join this study. You will have up to 28 days before you begin taking the study drug to complete them.

The screening activities include the following:

- A complete medical history, including a review of your prostate cancer diagnosis and any treatments you had before.
- A review of medications you are taking today or took in the 4 weeks before you begin taking the study drug. These include over-the-counter medications (nonprescription), herbal remedies, and vitamins.
- A physical examination and a check of your current health.
- Vital signs (blood pressure, heart rate, and temperature), height, and weight.
- An electrocardiogram (ECG), which is an electrical tracing of your heart activity.
- A bone scan
- A computed tomography (CT) scan of your chest, abdomen, and pelvis.

- Laboratory blood tests to check your overall health, including PSA and testosterone (about 2 teaspoons or 10 mL of blood).

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

If you choose to take part in this research study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- The study drug(s)/study approach may not be better, and could possibly be worse, than the usual approach for your cancer.
- There can also be a risk in finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study.

The chemotherapy drugs used in this research study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health. These risks are described in more detail below.

There is also a risk that you could have other side effects from the study drug(s)/study approach.

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 A and B

Possible Side Effects of Abiraterone (Table Version Date: May 20, 2015)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Abiraterone, more than 20 and up to 100 may have:
• Swelling of the body • Flushing • Diarrhea • Anemia which may require blood transfusion • Tiredness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Abiraterone, from 4 to 20 may have:
• High blood pressure which may cause headaches, dizziness, blurred vision • Abnormal heartbeat • Heart attack, which may cause chest pain, or fatal heart attack • Bruising • Vomiting • Urine infection, which may cause painful and frequent urination • Cough • Shortness of breath

RARE, AND SERIOUS In 100 people receiving Abiraterone, 3 or fewer may have:
• Heart failure which may cause swelling of ankles • Pain in chest

Study Group A

Possible Side Effects of Cabazitaxel (Table Version Date: May 20, 2015)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cabazitaxel, more than 20 and up to 100 may have:
• Vomiting, nausea, diarrhea, or constipation • Bruising, bleeding • Infection, especially when white blood cell count is low • Anemia which may require blood transfusion

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cabazitaxel, more than 20 and up to 100 may have:
• Tiredness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cabazitaxel, from 4 to 20 may have:
• Hair loss • Loss of appetite • Swelling of the stomach and bowels, which may cause pain, require surgery • Internal bleeding in the belly or gut, which may cause belly pain, black tarry stool, blood in vomit • A tear or a hole in the stomach which may require surgery • Pain in back • Muscle weakness • Blood in urine • Fever • Cough, shortness of breath

RARE, AND SERIOUS In 100 people receiving Cabazitaxel, 3 or fewer may have:
• Kidney damage and failure which may require dialysis

Study Group A and B

Possible Side Effects of Prednisone (Table Version Date: June 24, 2013)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Prednisone, more than 20 and up to 100 may have:
• In children and adolescents: decreased height • Loss of bone tissue • Mood swings • Skin changes, acne • Swelling of the body, tiredness, bruising • High blood pressure which may cause headaches, dizziness, blurred vision • Pain in belly • Increased appetite and weight gain • Weight gain in the belly, face, back and shoulders

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Prednisone, from 4 to 20 may have:
• Cloudiness of the eye, visual disturbances • Glaucoma • Infection • Non-healing wound • Diabetes • Damage to the bone which may cause joint pain and loss of motion • Kidney stones • Heartburn

RARE, AND SERIOUS In 100 people receiving Prednisone, 3 or fewer may have:
• Bleeding from sores in the stomach • Broken bones

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 father a baby while on this research study because the drugs in this study can affect a fetus.

If your partner becomes pregnant while you are on the study or within 28 days after your last dose of study drug, you must notify the investigator. Your pregnant partner is advised to call their healthcare provider immediately.

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

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

It is not possible to know at this time if the study drug(s)/study approach is better than the

usual care for this cancer so this research study may or may not help you. But, this research study will help researchers learn things that will help people in the future. In addition, commercial products may be developed from the data collected from and about you for this research study. However, it is not expected that you will be able to share in the profits from commercialization of products developed from your data.

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.

What are my rights in this study?

Taking part in this research 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 Central Institutional Review Board at 888-657-3711.

What are the costs of taking part in this study?

The cabazitaxel will be supplied at no charge while you take part in this research study. The cost of getting the cabazitaxel ready and giving it to you is not paid by the study sponsor, so you, your health plan, or your insurance company will have to pay for this. It is possible that the cabazitaxel may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

From the study treatments, abiraterone acetate, and prednisone, will be covered by you, your health plan, or your insurance company.

You, your health plan, or your insurance company will need to pay for all of the other costs of treating your cancer while in this research study, including the cost of study drug preparation and administration, tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are being done at no charge. Before you decide to be in

the research study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this research 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 research 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 research 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 research 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 specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

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

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor and any drug company supporting the study
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ (*insert name of study doctor[s*]) at _____ *(insert telephone number).*

Additional Studies Section:

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

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

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say 'no' to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

Optional Imaging Research Study

Researchers are trying to learn more about cancer and other health problems. Much of this research is done using imaging technology. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

At this time, we are requesting that you consent to undergo two additional scans for research on correlative analysis of tumor burden and how you respond to treatment.

Additionally, we are requesting that you allow the storage of these images to be used for this research. This storage will be done securely through an image exchange software application.

What is involved if you agree to take part in this study?

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

1. You will undergo a type of positron emission tomography (PET) scan that uses a radionuclide (radioactive material) called sodium fluoride, to see cancer in the bones

better than standard bone scans. While you are getting the PET scan, a computed tomography (CT) scan will be done at the same time. This imaging method is called a sodium fluoride PET/CT scan. Although sodium fluoride PET/CT scans are approved by the FDA to monitor your type of cancer, they are not used as a standard of care as often as other types of imaging. The PET/CT scans in this study are just for research purposes and will not be used to make clinical decisions. You will not be informed of the results or any incidental findings from these scans. You will not be charged for these scans. You will have a sodium fluoride PET/CT scan once before starting therapy on the study and once during your study therapy.

2. Your images and some related health information will be sent to a researcher for use in the study described above and stored by a secure image exchange software application.
3. Results from the research may be placed in centralized storage systems called databases. It is possible that some of your genetic information and your health information may be placed in these databases. It is also possible that some of these databases may be public.

What are the possible risks in taking part in this imaging research study?

1. The sodium fluoride PET/CT scans will expose you to a small amount of radiation, approximately equal to three bone scans. The amount of radiation you will receive from this study is within the limits of the federal government's rules and regulations and is thought to be safe. The Food and Drug Administration (FDA) has found no side effects related to NaF injection. Risks generally associated with having a blood test taken from your arm or insertion of a catheter (i.e. for tracer administration) include pain, bruising, lightheadedness, and on rare occasions, infection.
2. 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.
3. There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, 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.

When my images are used for research, 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 images are sent to the researchers, no information identifying you (such as your name) will be sent. Specimens will be identified by a unique code only.
2. Information that identifies you will not be given to anyone, unless required by law.
3. If research results are published, your name and other personal information will not be used.

What are the Possible Benefits of taking part in this imaging research study?

You will not benefit from taking part. The researchers, using the images from you and

others, might make discoveries that could help people in the future.

Are there any costs or payments associated with taking part in this imaging research study?

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 about taking part in this imaging research study?

If you decide you no longer want your specimens 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 specimens that remain in the bank will no longer be used and related health information will no longer be collected. Specimens 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 images for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

Please circle your answer to show whether or not you would like to take part in each option:

IMAGING RESEARCH STUDY:

Will you undergo NaF PET/CT scans for this research study?

- **I choose to take part in the imaging study and will have the experimental NaF PET/CT scans.**

YES **NO**

Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

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

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

At this time, we are requesting that you allow the collection and submission of blood to be tested for the presence of cancer cells in your blood. Additional tests will be done if cancer cells are detected in your blood in order to better understand how cancer continues to grow despite therapy.

Additionally, we are requesting that you allow the storage of your blood for future research projects. The research that may be done is unknown at this time. Storing specimens for future studies is called "Biobanking." The Biobank is being run by ECOG-ACRIN and supported by the National Cancer Institute.

What is involved if you provide your samples for research?

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

1. About eight (8) tablespoons of blood will be collected from a vein in your arm before the start of therapy, on week twelve (12) after starting therapy, and once the treatment is no longer effective for your disease. The blood specimens will usually be collected at the same time as the blood collected for your clinical tests to monitor your health. In most cases an additional needle stick will not be required to collect the blood.
2. Your specimens and some related health information will be sent to a researcher for use in the study described above and stored in the Biobank, along with specimens and information from people who took part in this or other research studies. The specimens will be kept until they are used up. Information from your medical record will be updated from time to time.
3. Only qualified researchers can submit a request to use the materials stored in the Biobanks. A committee of experts at ECOG-ACRIN, and/or the National Cancer Institute, will review each request to use the specimens for research. All research projects using these specimens will also be reviewed by an ethics or institutional review board to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you. 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 specimens.
4. Results from the research may be placed in centralized storage systems called databases. It is possible that some of your genetic information and your health information may be placed in these databases. It is also possible that some of these databases may be public.

What are the possible risks in providing your samples for research?

1. The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
2. 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.
3. 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.
4. 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.

When my samples are used for research, 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 specimens are sent to the researchers, no information identifying you (such as your name) will be sent. Specimens 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 specimens and health information. Any Biobank and ECOG-ACRIN staff with access to the list must sign an agreement to keep your identity confidential.
3. Researchers to whom ECOG-ACRIN sends your specimens 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 of allowing my samples to be used for research?

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

Are there any costs or payments associated with providing my samples for research?

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 about allowing my blood collections to be used for research?

If you decide you no longer want your specimens 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 specimens that remain in the bank will no longer be used and related health information will no longer be collected. Specimens 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 specimenss for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

Please circle your answer to show whether or not you would like to take part in each option:

SAMPLES FOR THE LABORATORY STUDIES:

May we have samples of your blood for laboratory research studies?

- **I agree to have my samples collected and I agree that my samples and related information may be used for the laboratory studies described above.**

YES **NO**

SAMPLES FOR FUTURE RESEARCH STUDIES:

May we have samples of your blood for research?

- **I agree to provide additional blood for research.**

YES **NO**

May we keep any blood leftover after the laboratory research studies for future research?

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

YES **NO**

This is the end of the section about optional studies.

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.

My signature agreeing to take part in the main study

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

Participant _____

Participant's signature_____

Date of signature_____

Person obtaining consent_____

Signature of person obtaining consent_____

Date of signature_____