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

NSABP B-55/BIG 6-13: A Randomised, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline *BRCA1/2* Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

What is the usual approach to my breast cancer?

You are being asked to take part in this research study because you have been found to carry a *BRCA1* or *BRCA2* mutation in your genes, and you have a type of breast cancer that is HER2-negative and is not sensitive to hormone treatment or HER2-negative and is sensitive to hormone treatment. You have already been treated with chemotherapy, surgery, and if needed, radiation therapy. People with breast cancer that is HER2-negative and is not sensitive to hormone treatment and who are not in a study usually do not have any further treatment unless the cancer comes back. People with breast cancer that is HER2-negative and is sensitive to hormone treatment and who are not in a study usually receive hormone treatment. 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

Why is this study being done?

The purpose of this study is to compare the addition of olaparib after the usual care of chemotherapy, surgery, and radiation for your type of cancer. If your cancer is sensitive to hormone treatment, you may receive hormone drugs as part of usual care. In this study, you will get either olaparib or placebo, a pill that looks like the study drug but contains no medication. The use of olaparib could reduce the risk of your cancer coming back but it could also cause side effects. To be better than placebo, the olaparib should decrease the chance of cancer coming back as compared to the placebo. As of March 20, 2015, approximately 3862 patients suffering from a variety of cancers have already taken olaparib at different doses, either on its own or with another chemotherapy drug. Olaparib has been approved by the Food and Drug Administration (FDA) for use in certain types of ovarian cancer. Its use in this study is considered experimental.

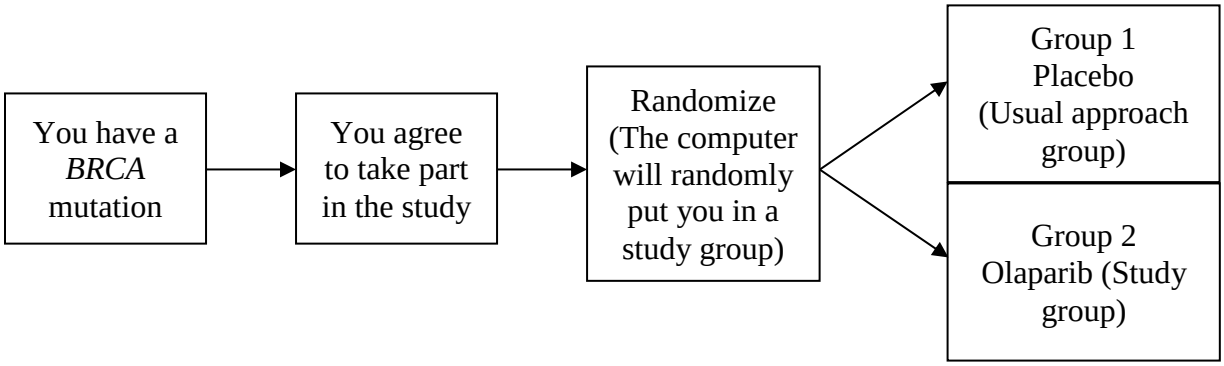
As of October 2013 about 248 patients with advanced breast cancer have been treated with olaparib. There will be about 1500 people worldwide taking part in this study.

What are the study groups?

This study has two study groups. Group 1 will receive a placebo in the form of a tablet that looks like the study drug but contains no medication, and Group 2 will receive the study drug olaparib in the form of a tablet. The study doctor will tell you how many tablets you should take each day. You should take the olaparib/placebo tablets by mouth at the same times each morning and evening of each day, approximately 12 hours apart with about 1 cup of water. The olaparib/placebo tablets should be swallowed whole and not chewed, crushed, dissolved, or divided. The olaparib/placebo tablets can be taken with a light meal/snack.

A computer will by chance assign you to treatment groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the other. Neither you, nor the study doctor will know which group you are assigned to unless needed for a medical emergency.

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 must not receive live virus and/or bacterial vaccines while receiving study treatment.
- It is important that you tell your study doctor about any other medications you are taking, or thinking of taking, before and during the study, including vitamins, nutritional supplements, or herbal preparations. You should avoid eating certain fruits (for example, grapefruit and products containing grapefruit juice) while you are taking olaparib/placebo because they may interfere with the action of olaparib. Your study doctor will tell you what medications you must avoid while on the study.

How long will I be in this study?

You will take the study drug or placebo for about 12 months. After you finish the study drug or placebo, your doctor will continue to watch you for side effects and follow your condition for 10 years. After the 10 years, your study doctor will continue to contact you to check on how you are doing. This contact will be done until 10 years after the last patient decides to participate on this study.

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 some extra procedures that you will need to have if you take part in this study. These are not part of the usual approach for your cancer.

- ECG (electrocardiogram)
- If you had chemotherapy before surgery, at least one of the two samples listed are needed for you to join the study.
  - a sample of tissue from your previous biopsy before you received chemotherapy will be collected
  - a sample of tissue previously collected at the time of your surgery will be collected.
- If you had chemotherapy after surgery,
  - a sample of tissue from your previous biopsy before you received chemotherapy ***or***
  - a sample of tissue previously collected at the time of your surgery will be collected.
- All patients who join the B-55/6-14 study must have a known BRCA mutation status. Some patients allowed their BRCA mutation status testing to be done by signing the "Patients with unknown BRCE mutation status" consent form. If you already had a known *BRCA* mutation status and did not have to sign the "Patients with unknown BRCA mutation status" consent form, two blood samples (about 4 teaspoons) will be taken before you begin taking the study drug or placebo
- A blood sample (about 2 teaspoons) will be taken for the study:
  - before you begin taking the study drug or placebo
  - 30 days after you stop taking the study drug or placebo ***and***
  - if your cancer returns

The tissue and blood samples are required for you to participate in this study. Your samples provide important information about how cancer cells react to the particular drug being studied.

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.

If you already had a known BRCA mutation status and did not have to sign the "Patients with unknown BRCA mutation status" consent form to have your BRCA mutation status

testing, one of the blood samples collected before you begin the study drug will be sent for a *BRCA* test. It will be sent to Myriad, a central laboratory that is doing *BRCA* testing for B-55/6-13, to see whether the Myriad test result agrees with the result of the *BRCA* test that you already had done. Every person who is considering joining the B-55/6-13 study will have a blood sample tested at Myriad. Testing all of the samples at Myriad will also make sure that the *BRCA* testing was done in the same way for everyone. You may be asked to have another blood sample taken in the rare case that the Myriad result does not match the result of the BRCA test that you already had done to be sure the correct sample was tested.
CAUTION: Please be aware that the test that will be used in this study, to determine if you have a mutation in *BRCA1* or *BRCA2*, is an experimental test (Investigational Device) and is limited by Federal (or United States) law to experimental (investigational) use. Experimental means that the test is not approved by the U.S. Food and Drug Administration (FDA) and is still being tested in research studies. If the result confirms that your *BRCA1* or *BRCA2* gene is mutated, you may be provided with some additional cancer risk information (this information has not been reviewed or approved by the Food and Drug Administration [FDA] and does not form part of the research study).

There are three major risks associated with the experimental *BRCA* test

- Risk of a false-positive test result

  A false positive result is when the results of the test show that you have a *BRCA* mutation when in fact a mutation is not there. Measures have been put in place to make sure that test results are of high quality and are accurate. Patients included on the study based on an incorrect test result would be given study treatment but are less likely to respond to this treatment.

- Risk of a false-negative test result

  A false negative result is when the results of the test show that you do not have a *BRCA* mutation when in fact a mutation is there. Measures have been put in place to make sure that test results are of high quality and are accurate. Patients with a false negative result would not be included on the study and would not receive study treatment. Your family doctor or the study doctor can explain the other treatment options that may be available.

- Risk of a delayed test result

  If test results are delayed for any reason, it is possible that a patient may choose not to wait for results and may decide not to take part in the study but choose to be treated with another available treatment. If this is the case, the patient may be denied access to study treatment. Measures have been put in place to make sure that the risk of a delay to test results is low.

What are the risks for the extra procedures?

Blood draw risks:

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

What is involved with storing samples for B-55/6-13 use for 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 B-55/6-13 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 where tissue will be stored is being run by NRG Oncology and supported by the National Cancer Institute. The Biobank where some of the blood samples will be stored is being run by AstraZeneca and a biobank run by a partner of AstraZeneca.

Blood remaining after the *BRCA* testing will be stored at Myriad and used by Myriad (and any other companies with whom Myriad decides to work) for future research purposes of the B-55/6-13 study including exploratory testing and to help develop tests, which may be used in the future to assess the *BRCA* status of other patients. The second sample will be used by AstraZeneca (and any other companies with whom AstraZeneca decides to work),for the future research purposes of the B-55/6-13 study as well as to also to help develop tests, which may be used in the future to assess the *BRCA* status of other patients and to assess the status of other genes known or predicted to have a role in breast cancer.

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

Some of your health information and/or information about your specimens from this study will be kept in a central database for research.

Qualified researchers can submit a request to use the materials stored in the Biobanks for B-55/6-13 related studies. 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.

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
- Take a study drug that may not be better, and could possibly be worse, than the usual approach for your cancer

- Find out that the results of your experimental *BRCA* testing at Myriad do not agree with the results from your local laboratory

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

There is also a risk that you could have side effects from the study drug.

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.

Possible Side Effects of Olaparib/Placebo

COMMON, SOME MAY BE SERIOUS In 100 people receiving Olaparib/Placebo, more than 20 and up to 100 may have:
• Diarrhea, vomiting, nausea • Tiredness • Anemia which may require blood transfusions • Loss of appetite

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Olaparib/Placebo, from 4 to 20 may have:
• Bloating, constipation, heartburn • Pain • Swelling of arms, legs • Low white blood cell count which may lead to an infection • Fever • Dizziness, headache • Changes in taste • Cough, shortness of breath, sore throat • Irritation or sores in the lining of the mouth • Bruising, bleeding which rarely requires platelet transfusions • Rash

RARE, AND SERIOUS In 100 people receiving Olaparib/Placebo, 3 or fewer may have:
• Cancer of bone marrow (leukemia) caused by study treatment • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions • Inflammation of the lungs that may cause difficulty breathing and can be life-threatening Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Itchy rash on swollen, reddened skin (dermatitis)

Studies to determine the effect of olaparib on your ability to drive or use machinery have not been done. Patients have experienced weakness, tiredness, and dizziness while taking the study drug. If you have any of these symptoms, you should be careful when driving or using machinery.

You must not receive live virus and/or bacterial vaccines while receiving study treatment.

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: Women should not get pregnant or breastfeed a baby while receiving study drug or placebo and for at least 1 month after stopping study drug or placebo. Men should not father a baby or donate sperm while taking study drug or placebo and for at least 3 months after stopping study drug or placebo. The drug 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 of storing samples?

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 and 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 study drug is better than the usual approach 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
- Based on the results of your *BRCA* testing at Myriad

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 B-55/6-13 study.) Samples or related information that have already been given to or used by researchers will not be returned.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the NCI Community Oncology Research Program – Kansas City Institutional Review Board at 913-948-5588.

What are the costs of taking part in this study?

The study drug will be supplied at no charge while you take part in this study. It is possible that the study drug may not continue to be supplied free while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options. The cost of the ECG done to see if you can take part in the study will be provided at no charge.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the costs of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

There are no costs to you or your insurance for the collection and submission of the blood and tissue samples or the biobanking. 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.

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 (The NSABP has joined with two other clinical trials groups to form NRG Oncology as required by the National Cancer Institute.)
- Alliance for Clinical Trials in Oncology
- ECOG-ACRIN Cancer Research Group
- SWOG
- AstraZeneca, the drug company supporting this study
- Breast International Group
- Frontier Science
- Myriad, the company testing blood samples for *BRCA* mutations
- 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 clinical 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) If your *BRCA* mutation status was not done as a part of pre-entry testing for B-55/6-13, the sample sent to Myriad, will contain your date of birth but no other information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) 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.
3) 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.

4) Researchers to whom the 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.
5) Information that identified you will not be given to anyone, unless required by law.
6) 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. Your doctor will only be given the results of your *BRCA* testing.

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).*

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 these studies. The researchers leading these optional studies hope the results will help other people with cancer in the future.

The results will not be added to your medical records, nor will you or your study doctor 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 these studies. If you sign up for but cannot complete these optional studies for any reason, you can still take part in the main study.

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

Optional Quality of Life Study

You may be asked to take part in this study. If you choose to rake part in this study, you will be asked to fill out a form with questions about your physical and emotional well-being. Researchers will use this information to learn more about how cancer and cancer treatment affects people.

You will be asked to fill out this form at 5 times during your visits:

- before you join the study
- two times while you are receiving study drug
- two times after you finish study drug

Each form will take about 20-30 minutes to complete. The forms will ask about things like how you are feeling physically and emotionally during the time you are on study drugs and symptoms related to nausea, diarrhea, and fatigue. You may feel uncomfortable answering some of the questions, and you can skip any you do not want to answer.

Please circle your answer:

I choose to take part in the Quality of Life study and will fill out these forms.

YES NO

Optional Sample Collections for Biobanking for Possible Future Studies Related to B-55/6-13

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 and differences in genes affect cancer and how your body responds to treatment. If you take part in this optional study, a blood sample (2 teaspoons) will be collected before you begin

the study drug or placebo. Also, if your cancer comes back and you agree to this optional biopsy a sample of tissue will be collected from the optional biopsy.

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 B-55/6-13 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 samples is being run by AstraZeneca, the drug company supporting the study. The Biobank for the optional tumor tissue from the additional biopsy is being run by the 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) About 2 teaspoons of blood will be collected from a vein in your arm. Also, a sample of tissue will be collected from a biopsy if your cancer comes back.
2) Your samples and some related information may be stored in the Biobanks, 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.
3) Qualified researchers can submit a request to use the materials stored in the Biobanks. 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.
4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5) 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 study?

1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, which can be treated with regular pain medications, and bruising. Rarely, an infection can occur. You may sign a separate consent form before the biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place.

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.

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 NSABP staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom the NSABP 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 optional 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.

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)*.

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

Optional Sample Collections for Future Research Studies Related to B-55/6-13:

I agree to have a blood sample collected and to allow my blood sample and related information to be kept in a Biobank for use in future research related to the B-55/6-13 study.

YES NO

I agree to have an optional tumor biopsy if my cancer returns and to allow my tumor tissue sample from the optional biopsy and related information to be kept in a Biobank for use in future research related to the B-55/6-13 study.

YES NO

This is the end of the section about optional studies.

SAMPLES FOR OTHER FUTURE STUDIES

The researchers also would like your permission to use all your samples collected for the study for future health research not related to the purposes of the B-55/6-13 study.

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

YES NO

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

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'.

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_____