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

Study Title for Study Participants: Testing combination antibody treatment with trastuzumab and pertuzumab for advanced or metastatic colorectal cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
S1613, "A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/Metastatic Colorectal Cancer (mCRC) with HER-2 Amplification – Step 1

(S1613 HER-2 Amplification Specimen Submission Consent Form)

What is the usual approach to my colorectal cancer?

You are being asked to take part in this study because you have colorectal cancer which has grown or recurred. People who are not in a study are usually treated with drugs approved by the FDA. Sometimes, combinations of these are used and your doctor can explain which may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for several months or more.

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, but you may want to receive comfort care to relieve symptoms.

Why is this study being done?

The purpose of this screening step is to perform a genetic test on your colorectal cancer tumor sample to see if it has a HER-2 gene amplification. HER-2 is a human gene that makes a protein called HER-2. These proteins are receptors on cells that normally help control how a healthy cell grows, divides, and repairs itself. If the HER2 gene doesn't work correctly and makes too many copies of itself, this is known as HER-2 gene amplification. HER-2 testing is not common for this type of cancer, but it is common for other kinds of cancer including breast cancer. The performance of the test is not part of the research question in this study. If your tissue has HER-2 gene amplification, you will be eligible to participate in the study.

We expect that about 2381 patients will get this screening for this study and expect that about 130 patients will go on to the treatment part of the study.

The purpose of the treatment part of this study is to compare any good and bad effects of using a combination of antibodies, trastuzumab and pertuzumab, to using the usual chemotherapy, cetuximab and irinotecan. Treatment with antibodies could shrink your cancer, but it could also cause side effects. This study will allow the researchers to know whether this different approach is better, the same, or worse than the usual approach. The antibody drug combination of trastuzumab and pertuzumab is already FDA-approved for use in HER-2 positive breast cancer.

How long will I be in this study?

This part of the study is just about the HER-2 testing and submission of tissue for testing. You will be finished with this part of the study when your tissue is submitted for testing and the result is received. Then, if you are eligible to continue on the study, you will be asked to sign another consent form for the study treatment.

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

You will not have any extra tests or procedures for this part of the study. You have already had a surgery or biopsy to remove some of your cancer tissue. This tissue will be collected and sent to a laboratory at Moffitt Cancer Center for HER-2 testing. The names of the HER-2 tests that will be used are VENTANA HER-2/neu (4B5) IUO ASSAY and INFORM HER2 DUAL ISH DNA PROBE COCKTAIL IUO ASSAY. Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. You and your study doctor will receive the results from the test before you decide whether to join the treatment part of the study. The result of the test will be included in your health record.

Neither you nor your health care plan/insurance carrier will be billed for the collection and testing of the tissue that will be used for this study.

Why is this test being done?

We are using the HER-2 test to determine whether patients are eligible to continue to the treatment part of this clinical trial. We are asking that you give permission for your colorectal cancer tissue to be tested.

If your HER-2 results are not amplified, then you will not be eligible to participate in the treatment part of the study. In this case, we are asking that you discuss other treatment options with your study doctor.

If your HER-2 results are amplified, then you will be eligible to participate in the treatment part of this study. We ask that you discuss participation in this study with your study doctor and consider joining the treatment part of the study.

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

There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back 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. In some cases, this information could be used to make it harder for you to get or keep a job. There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

The HER2 tests used in this study are investigational (not standard). Their ability to find patients who might respond to the selected treatments has not been proven. Because the tests are new for colorectal cancer, there is a chance of false results. False positive results may lead to treatment that is not medically necessary and also may result in side effects. False negative results may occur, leading to being excluded from this study and not receiving the study treatment. If you do not take part in this study, you will receive the standard treatment for your illness.

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

Taking part in this part of the study will not have any impact on your health because no treatment is given. We do know that the information from this part of the study will help doctors learn more about the use of HER-2 testing. This information could help future cancer patients.

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 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 study will pay for the cost of the HER-2 testing which will be completed at a central laboratory using your tissue sample from a previous biopsy or surgery. You and/or your health plan/insurance company will need to pay for all of the other costs of your cancer while in this study, including the cost 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.

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 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.

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, SWOG, 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.
- Alliance
- ECOG-ACRIN
- NRG

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.

FUTURE CONTACT:

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

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_____

Specimen Consent Supplemental Sheets

How are Specimens Used for Research?

Where do specimens come from?

A specimen may be from a blood sample or from bone marrow, skin, toenails or other body materials. People who are trained to handle specimens and protect donors' rights make sure that the highest standards of quality control are followed by SWOG. Your doctor does not work for SWOG, but has agreed to help collect specimens from many patients. Many doctors across the country are helping in the same way.

Why do people do research with specimens?

Research with specimens can help to find out more about what causes cancer, how to prevent it, how to treat it, and how to cure it. Research using specimens can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

What type of research will be done with my specimen?

Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen may look for genetic causes and signs of disease.

How do researchers get the specimen?

Researchers from universities, hospitals, and other health organizations conduct research using specimens. They contact SWOG and request samples for their studies. SWOG reviews the way that these studies will be done, and decides if any of the samples can be used. SWOG gets the specimen and information about you from your hospital, and sends the specimen samples and some information about you to the researcher. SWOG will not send your name, address, phone number, social security number or any other identifying information to the researcher.

Will I find out the results of the research using my specimen?

You will not receive the results of research done with your specimen. This is because research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future.

Why do you need information from my health records?

In order to do research with your specimen, researchers may need to know some things about you. (For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked?) This helps researchers answer questions about diseases. The information that will be given to the researcher may include your age, sex, race, diagnosis, treatments and family history. This information is collected by your hospital from your health record and sent to SWOG. If more information is needed, SWOG will send it to the researcher.

Will my name be attached to the records that are given to the researcher?

No. Your name, address, phone number and anything else that could identify you will be removed before they go to the researcher. The researcher will not know who you are.

How could the records be used in ways that might be harmful to me?

If your confidential genetic information is discovered, you may suffer from genetic discrimination. Genetic discrimination occurs if people are treated unfairly because of differences in their genes that increase their chances of getting a certain disease. In the past, this could have resulted in the loss of health insurance or employment. Because of this, The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, was passed by Congress to protect Americans from such discrimination. The new law prevents discrimination from health insurers and employers. This act was signed into federal law on May 21, 2008, and went into effect May 2009. This law does not cover life insurance, disability insurance and long-term care insurance.

While this study has safeguards in place to protect your confidential genetic information and to make it extremely unlikely that your identity would be connected with any special studies that are performed on your tissue, it is possible that this information could be discovered by someone who is unauthorized to have access to it.

How am I protected?

SWOG is in charge of making sure that information about you is kept private. SWOG will take careful steps to prevent misuse of records. Your name, address, phone number and any other identifying information will be taken off anything associated with your specimen before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person which will help to protect your privacy.

What if I have more questions?

If you have any questions, please talk to your doctor or nurse, or call our research review board at (Insert IRB's Phone Number).