RTOG FOUNDATION

RTOG 3501

(ClinicalTrials.gov NCT #: 01711658)

TRYHARD: A PHASE II, RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED STUDY OF LAPATINIB (TYKERB®) FOR NON-HPV LOCALLY ADVANCED HEAD AND NECK CANCER WITH CONCURRENT CHEMORADIATION

Amendment 8: September 27, 2016

RTOG FOUNDATION STUDY 3501

TryHard: A Phase II, Randomized, Double Blind, Placebo-Controlled Study of Lapatinib (Tykerb®) for Non-HPV Locally Advanced Head and Neck Cancer with Concurrent Chemoradiation

Informed Consent (English Language)

<<PI_FIRST_NAME>> <<PI_LAST_NAME>>

<<PHONE_NUMBER>>

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have head and neck cancer.

Why is this study being done?

The combination of radiation and chemotherapy is the standard treatment for head and neck cancer. The purpose of this study is to compare the effects, good and/or bad, of chemoradiotherapy and lapatinib versus chemoradiotherapy and a non-active tablet (a placebo) on you and your head and neck cancer.

Lapatinib was approved in 2007 for use in treatment of breast cancer; however, its use for treatment of head and neck cancer is experimental. Lapatinib blocks the action of a protein that tells cancer cells to multiply.

The placebo is a tablet that looks the same as lapatinib and is taken like lapatinib, but it will have no effect on your cancer.

How many people will take part in the study? (9/27/16)

About 142 people will take part in this study.

What will happen if I take part in this research study? (8/13/15)

For patients with oropharyngeal cancer: Your tumor tissue will be tested for p16, a test that shows if the tumor is caused by the Human Papillomavirus (HPV). This tissue test is required for this study if your cancer is from the oropharynx. If your tumor is caused by HPV, you will not be eligible to take part in this study.

If your cancer was diagnosed by a fine needle aspiration biopsy of a lymph node in your neck, it may not be possible to test this sample for p16. If that is the case, a biopsy of your tumor may be necessary for p16 testing. The method used and the risks of a tumor biopsy will depend upon the size and location of your tumor. Please discuss the risks and benefits of tumor biopsy with your doctor.

Eligible participants will be "randomized". Randomization means a computer program will choose whether you receive lapatinib or placebo, and neither you nor your study doctor can choose or will know which you will receive. You will have an equal chance of receiving lapatinib or placebo.

If you participate in this study, you will receive intensity modulated radiation therapy (IMRT). IMRT is a form of radiation in which radiation beams are designed to avoid non-cancerous parts of your body, such as your salivary glands.

Your doctor also may decide to use a technique called image guided radiation therapy (IGRT). The purpose of IGRT is to give radiation treatment more accurately to your tumor while decreasing the radiation to normal tissues. Small adjustments in your radiation treatment are made each treatment day based on x-ray images taken right before each day's treatment to ensure that your radiation treatment is given as accurately as possible.

Week 1: You will take lapatinib or placebo, 6 tablets that you will swallow once a day on an empty stomach (either 1 hour before or 1 hour after meals) 7 days/week, for a week. These tablets also can be dissolved in liquid and put into a feeding tube. You will not receive radiation therapy or chemotherapy during this week. You will be asked to keep a record of each dose of lapatinib or placebo you take.

Weeks 2-7: You will receive radiation therapy 6 times a week during 5 of the 6 treatment weeks. You will receive the sixth radiation treatment either on Saturday or twice a day on Friday of each week. When given twice a day, there will be at least 6 hours between radiation treatments. Each treatment may take up to 20 to 25 minutes depending on the technique used.

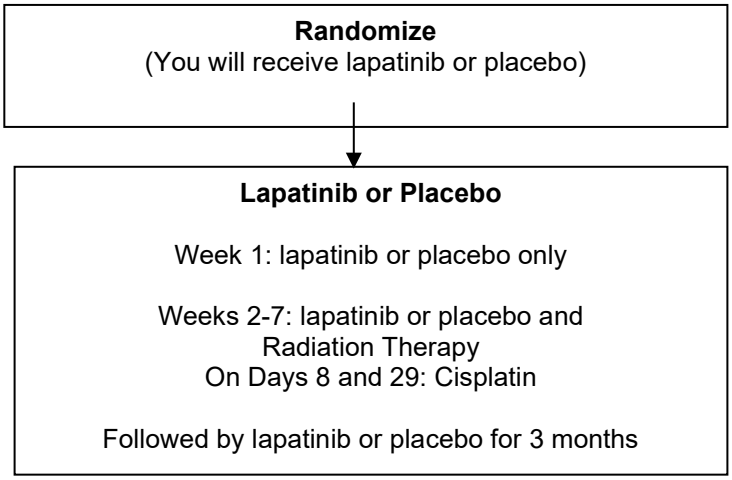
You also will receive a chemotherapy drug, cisplatin, through the vein, on days 8 and 29 (before or after radiation), for a total of 2 treatments. The chemotherapy will take about 4-6 hours, including administration of medications to prevent nausea and to replace body fluids. Your doctor may recommend that you stay in the hospital overnight to receive these medications.

You will take lapatinib or placebo, 6 tablets that you will swallow once a day on an empty stomach (either 1 hour before or 1 hour after meals) 7 days/week, during radiation therapy.

After radiation, you will continue to take lapatinib or placebo, 6 tablets, once a day, 7 days/week for 3 months. You will be asked to keep a record of each dose of lapatinib or placebo you take orally.

Study Plan (1/16/14)

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



Before you begin the study:

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Physical examination by several doctors and recording of your weight
- Examination of the back of your throat and voice box (larynx) with a mirror and/or a flexible lighted tube inserted through your mouth by an ear, nose and throat specialist or by a head and neck surgeon; this examination may be done in an office or may need to be done in the hospital under general anesthesia. The specialist or surgeon will talk with you about this procedure.
- Evaluation of your ability to carry out daily activities
- A CT (Computed Tomography) scan or PET/CT scan of your chest— A CT scan is a study using x-rays to look at one part of your body. A PET (Positron Emission Tomography) scan is a computerized image that looks at the activity of tumor cells in your entire body and that requires injection of a special marker into your vein, such as sugar (glucose) combined with a low-dose radioactive substance (a tracer). A camera records the tracer's signal as it travels through your body.
- A CT scan or an MRI (Magnetic Resonance Imaging) or a PET/CT scan with contrast (contrast means that dye is injected into your vein to increase the differences between normal and abnormal tissue) of the site of your tumor and nodes in your neck — An MRI is imaging using a strong magnetic field to look at one part of your body
- An EKG, a test of your heart function
- An echocardiogram or MUGA scan — These tests use ultrasound waves (ECHO) or a radioactive isotope (MUGA) to make images of the heart chambers, valves and surrounding structures.
- Blood tests (about 2-3 teaspoons of blood will be taken from your vein)
- For women able to have children, a pregnancy test

<u>If your study doctor recommends</u>:

- A dental evaluation
- A hearing test
- An evaluation of your ability to chew and swallow
- Placement of a feeding tube to provide food and liquids
- You will be asked about your diet and eating habits.
- A whole body PET /CT scan

During the study: (10/3/13)

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

Weekly during treatment:

- A physical examination
- Evaluation of your ability to carry out daily activities
- Blood tests (about 2-3 teaspoons of blood will be taken from your vein)
- Your weight will be recorded
- Evaluation of any side effects from treatment you may be having

You will need these tests and procedures in follow-up visits: (8/13/15)
These tests and procedures are being done to see how you and your cancer was affected by the treatment you received. These tests and procedures are part of regular cancer care.

At 4 weeks from the end of radiation treatment:

- Physical examination by several doctors
- Blood tests (about 2-3 teaspoons of blood will be taken from your vein)
- An echocardiogram or MUGA scan to test your heart function
- Evaluation of any side effects from treatment you may be having
- If your doctor recommends: Examination of the back of your throat and voice box (larynx) with a mirror and/or a flexible lighted tube inserted through your mouth by an ear, nose and throat specialist or by a head and neck surgeon

At 3 months from the end of treatment:

- Physical examination by several doctors
- If your doctor recommends: Examination of the back of your throat and voice box (larynx) with a mirror and/or a flexible lighted tube inserted through your mouth by an ear, nose and throat specialist or by a head and neck surgeon
- Your weight will be recorded
- Evaluation of your ability to carry out daily activities
- Blood tests (about 2-3 teaspoons of blood will be taken from your vein)
- A CT scan or an MRI of your tumor and nodes in your neck with contrast (or a PET/CT scan if your doctor recommends)
- Evaluation of any side effects from treatment you may be having

If your cancer is present 3 months from the end of treatment, surgery may be necessary.

At 9 months from the end of treatment: You will have the same tests and procedures as at 3 months from the end of treatment (above), except the CT scan or MRI.

At 6 and 12 months from the end of treatment: You will have the same tests and procedures as at 3 months from the end of treatment (above), with the addition of a CT scan of your chest.

Once a year until year 5: A CT scan of your chest and a CT scan or MRI with contrast of your head and nodes in your neck

Every 3 months for year 2, every 6 months for years 3-5, then yearly

- Physical examination by several doctors
- If your doctor recommends: Examination of the back of your throat and voice box (larynx) with a mirror and/or a flexible lighted tube inserted through your mouth by an ear, nose and throat specialist or by a head and neck surgeon
- Your weight will be recorded
- Evaluation of your ability to carry out daily activities
- Evaluation of any side effects from treatment you may be having

How long will I be in the study? (1/16/14)

You will receive lapatinib or placebo, radiation therapy, and cisplatin for 7 weeks. After treatment, you will take lapatinib or placebo for 3 months.

After you are finished 7 weeks of treatment, the study doctor will ask you to visit the office for follow-up exams at the following time points from the end of treatment: 4 weeks, every 3 months for years 1 and 2, every 6 months for years 3, 4, and 5, and then yearly for your lifetime.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the treatment can be evaluated by him/her. Another reason to tell your study doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study? (8/13/15)

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop treatment. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to the head and neck radiotherapy include those which are:

COMMON, SOME MAY BE SERIOUS In 100 people receiving head and neck radiation, more than 20 and up to 100 may have:
• Sores in the mouth and throat which may be painful especially with swallowing • Dry mouth, changes in taste, reduced sense of smell—may be permanent • Thick saliva • Hoarseness • Skin changes that may be permanent, swelling and redness of the skin in the area of radiation • Pain or pressure in the ear • Tiredness • Weight loss • Permanent hair loss in the area of radiation (face, chin, neck) • Cavities, tooth decay; loss of teeth; tooth sensitivity

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving head and neck radiation, from 4 to 20 may have:
• Decrease in function of the thyroid gland that may require you to take thyroid replacement medicine • Damage to the nerves of the shoulder and arm which may cause decreased movement and feeling • Ear infection • Hearing loss • Difficulty swallowing which may require a long term or permanent feeding tube

RARE, AND SERIOUS In 100 people receiving head and neck radiation, 3 or fewer may have:
• Breathing and swallowing problems that may require a surgical procedure to create an opening through the neck into the windpipe • Damage to the nerves in the head and neck that control sensation, expression, or other motor functions • Damage to the jawbone which may cause jaw pain and loosening of teeth • Damage to the voice box or nerves to the voice box which may cause hoarseness, shortness of breath, inability to speak

RARE, AND SERIOUS In 100 people receiving head and neck radiation, 3 or fewer may have:
• Damage to the skin, soft tissues, or other parts of the head and neck that may require a major operation to correct and, rarely, can be life threatening • Damage to the spinal cord which may cause permanent weakness

Use of image guided radiation therapy (IGRT) to give radiation treatment more accurately to your tumor while decreasing the radiation to normal tissues may lead to improved accuracy of radiation treatment compared to regular radiation therapy and eventually, may be more useful against cancer. At this time, however, there is no proof that using this technique is more useful against cancer than regular radiation treatment without this technique. The dose from these x-ray images is much smaller than the dose used to treat your cancer. However, this dose will cover a somewhat larger region and can spill over to healthy tissues and organs that are not affected by your disease. There is a small risk that the dose from these x-ray images can be harmful, and every effort will be made to minimize this dose to healthy tissues. In this effort, it is important that we have your full cooperation in maintaining your position during treatment. In order to help you stay in position, your doctor will use a special device, sometimes called an immobilization mask. The mask is plastic mesh formed to the head and shoulder area to help stabilize your position during treatment

Risks and side effects related to Lapatinib: (3/22/16)

Like all medicines, lapatinib can cause side effects, although not everybody gets them. As of December 2010, lapatinib has been given to over 19,600 patients in clinical trials and its benefits have been proved in some circumstances, but further studies are underway to prove its benefits in other circumstances. Not all the side effects of lapatinib are known. You should notify any other healthcare providers you are seeing that you are participating in this study, especially if you are about to undergo surgery, dental treatment, or any other drug treatment. You should not donate blood while participating in this study.

Some patients have died while receiving lapatinib. All of these patients suffered from cancer and its complications. It is not known whether lapatinib may have contributed to some of the deaths in these patients with cancer and other medical conditions.

The following side effects have been seen in cancer patients and healthy volunteers who have taken lapatinib:

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

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving lapatinib, from 4 to 20 may have:
• Anemia which may require blood transfusion • Bloating, heartburn, passing gas, nausea, vomiting • Pain • Sores in mouth which may cause difficulty swallowing • Tiredness • Flu-like symptoms including fever, chills, body aches, muscle pain • Infection • Loss of appetite, dehydration • Changes in taste • Headache • Cough, sore throat • Nose bleed • Hair loss, itching, acne • Dry skin • Change in or loss of some or all of the finger or toenails • Flushing, hot flashes

RARE, AND SERIOUS In 100 people receiving lapatinib, 3 or fewer may have:
• Heart failure which may cause shortness of breath, swelling of ankles, and tiredness • Liver damage which may cause yellowing of eyes and skin, swelling • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Change in heart function • Change in the heart rhythm • Swelling of the lungs which may cause shortness of breath • Redness, pain or peeling of palms and soles • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body

Risks and side effects related to cisplatin (8/13/15)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, more than 20 and up to 100 may have:
• Nausea, vomiting, • Infection, especially when white blood cell count is low • Anemia which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Kidney damage which may cause swelling, may require dialysis • Hearing loss including ringing in ears

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, from 4 to 20 may have:
• Hair loss • Change in taste • Diarrhea • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Confusion • Difficulty with balance • Numbness and tingling of the arms and legs • Blurred vision or changes in ability to see colors (especially blue or yellow)

RARE, AND SERIOUS In 100 people receiving Cisplatin, 3 or fewer may have:
• Cancer of bone marrow caused by chemotherapy later in life • Seizure

Reproductive risks:

The manufacturer of lapatinib has identified a chemical present in lapatinib in very small quantities that can cause changes to genes (DNA). However, many cancer drugs have the potential to damage genes including drugs that are being given with lapatinib in this trial and/or those you may have previously received in your cancer treatments or might receive as alternate treatment. The benefits of these drugs are believed to be greater than their risks in patients with cancer. While the risk of harm to you from this chemical in lapatinib is thought to be low, the risk to an unborn baby, while unknown, may be higher.

You should not become pregnant or father a baby while on this study because the drugs as well as the radiation therapy in this study can affect an unborn baby. If you are a woman of child-bearing potential and choose to participate in this study, part of the blood sample taken in the screening process will be used for a pregnancy test. Women should not breastfeed a baby while on this study. You will also be asked to use one of the allowed contraceptive methods (a way to prevent you from becoming pregnant) from 2 weeks before your first study treatment until 60 days after your final study treatment. Ask your study doctor about the choices available and which might be best for you.

Even when you use one of the allowed contraceptive methods, there may be a small risk that a woman of child-bearing potential could become pregnant. If you become pregnant, you must tell your study doctor immediately so that he/she may discuss with you the possibility of stopping treatment. Your doctor will need to report this information and the outcome of your pregnancy to the manufacturer of lapatinib. The chemotherapy used in the study may make you unable to have children in the future.

Risks and side effects related to Radiological Tests

Some of the tests that will be performed (MUGA scans, X-rays, CT scans, and/or bone scans) will expose you to controlled amounts of radiation. The MUGA scan and CT scans will involve dyes being injected into one of your veins. There is a risk of allergic reaction to the dye. This reaction may be mild (such as a skin rash or hives) to severe (such as breathing difficulties and shock). There also is a risk that the injection of dyes or collection of blood samples may cause pain, swelling, bruising, irritation or redness at the site, infection at the site of the needle puncture, or feeling faint. Your study doctor will take steps to prevent this from happening, and may recommend medications that may help with these particular side effects.

It is very important that you report any side effects to your study doctor as soon as possible; you should not wait until your next scheduled visit.

Risks and side effects related to a biopsy

A biopsy is a procedure to remove a small piece of tumor tissue. A numbing medicine (also called local anesthetic) is given under the skin and a needle inserted to remove tumor tissue or cells. You may feel some pain or irritation where the biopsy needle is put in. There is a chance for bruising or bleeding and a slight risk for infection where the needle goes into the skin. Your doctor will explain the risks of the biopsy procedure to you and answer any questions you may have.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While researchers hope that adding lapatinib to radiation therapy and chemotherapy will be more effective in keeping your head and neck cancer from growing as the standard treatment of radiation therapy and chemotherapy, there is no proof of this yet. We do know that the information from this study will help doctors learn more about these therapies as a treatment for head and neck cancer. This information could help future cancer patients.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

Talk to your study doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private? (3/22/16)

Data are housed at RTOG Headquarters in a password-protected database. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- RTOG® Foundation, Inc. (RTOG)
- Novartis, supplier of the lapatinib and the placebo
- Biologics, Inc., distributor of lapatinib and the placebo
- The Institutional Review Boards (IRB) associated with this study. The IRBs are groups of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration (FDA) and other government agencies, such as the Office of Human Research Protections (OHRP), involved in keeping clinical research safe for patients and/or government agencies in other countries where the study drug may be considered for approval.

What are the costs of taking part in this study? (2/2/16)

Novartis will provide lapatinib and placebo free of charge to patients enrolled on this study.

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, _____ *[investigator's name(s)],* if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call him/her at _____ *[telephone number].*

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

A Data Monitoring Committee (DMC) will be regularly meeting to monitor safety and other data related to this study. The Committee members may receive confidential patient information, but they will not receive your name or other information that would allow them to identify you by name.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor _____ *[name(s)]* **at _____** *[telephone number].*

For questions about your rights while taking part in this study, call the _____ *[name of center]* **Institutional Review Board (a group of people who review the research to protect your rights) at** _____ *(telephone number). [Note to Local Investigator: Contact information for patient representatives or other individuals in a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can be listed here.]*

Please note: This section of the informed consent form is about additional research that is being done with people who are taking part in the main study. You may take part in this additional research if you want to. You can still be a part of the main study even if you say 'no' to taking part in this additional research.

You can say "yes" or "no" to each of] the following studies. Below, please mark your choice for each study.

Quality of Life Study

We want to know your view of how your life has been affected by cancer and its treatment. This "Quality of life" study looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities.

This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer.

You will be asked to complete 2 questionnaires and to answer some questions about your eating, diet, and speech at the following time points: on your first visit and at 3, 12, and 24 months after treatment. It takes about 5-10 minutes to fill out each questionnaire and about 5 minutes to answer the questions.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

If you decide to take part in this study, the only thing you will be asked to do is fill out the 2 questionnaires and answer the questions. You may change your mind about completing the questionnaires at any time.

Just like in the main study, we will do our best to make sure that your personal information will be kept private.

Please circle your answer.

I choose to take part in the Quality of Life Study. I agree to fill out the Quality of Life Questionnaires.

YES NO

Consent Form for Use of Tissue and Blood for Research

About Using Tissue and Blood for Research

You are going to have a biopsy (or surgery) to see if you have cancer. Your doctor will remove some body tissue to do some tests. The results of these tests will be given to you by your doctor and will be used to plan your care.

We would like to keep some of the tissue that is left over for future research. In addition to the tumor tissue, we would like to collect 2-3 teaspoons of your blood. Blood for research will be collected 3 times: before treatment, at the end of radiation therapy, and at 6 months after the end of treatment. Blood for research will be collected at the same time your blood is collected for other tests required in the main part of this study.

If you agree, the tissue and blood will be kept and may be used in research to learn more about cancer and other diseases.

Your tissue and blood may be helpful for research whether you do or do not have cancer. The research that may be done with your tissue and blood is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your tissue and blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us keep the left over tissue and blood for future research is up to you. No matter what you decide to do, it will not affect your care or your participation in the main part of the study.

If you decide now that your tissue and blood can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue and blood. Then any tissue and blood that remains will no longer be used for research and will be returned to the institution that submitted it.

In the future, people who do research may need to know more about your health. While the doctor/institution may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes tissue and/or blood is used for genetic research (about diseases that are passed on in families). Even if your tissue and/or blood is used for this kind of research, the results will not be put in your health records.
Your tissue and blood will be used only for research and will not be sold. The research done with your tissue and blood may help to develop new treatments for cancer in the future.

Benefits

The benefits of research using tissue and blood include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

Risks (10/3/13)

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

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. The samples are given a code to protect your privacy before they are used. Any related information given to researchers will also be coded. Researchers will receive the code instead of any information that might directly identify you.

There can 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 research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded. Research results will not be returned to you or your doctor.

Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, life insurance companies may charge a higher rate based on this information.

Some states have laws to protect against genetic discrimination [list appropriate state information if your state has such laws]. A federal law called the Genetic Information Non-Discrimination Act, or GINA is in effect. This law does not allow discrimination by insurers or employers. The law does not include other types of misuse by life insurance, disability, or long term care insurance. To learn more about the GINA Law, please ask [Note to local investigator: List contact information here for patient representatives or other individuals who take calls regarding clinical trials but who are not on the site IRB or research team.]

Making Your Choice
Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at _____ [IRB's phone number].

No matter what you decide to do, it will not affect your care.

1. My specimens may be kept for use in research to learn about, prevent, or treat cancer, as follows:
   - Tissue ☐Yes ☐ No
   - Blood ☐Yes ☐ No

2. My specimens may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease), as follows:
   - Tissue ☐Yes ☐ No
   - Blood ☐Yes ☐ No

3. Someone may contact me in the future to ask me to take part in more research.
   ☐Yes ☐ No

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

Signature

I have been given a copy of all _____ *[insert total of number of pages]* **pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.**

Participant _____
Date _____