NRG ONCOLOGY
Radiation Therapy Oncology Group

RTOG 0920

(ClinicalTrials.gov NCT #:* 00956007*)

A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab Locally-Advanced Resected Head and Neck Cancer

Amendment 14: May 11, 2023

Informed Consent Template for Cancer Treatment Trials
(English Language)

RTOG 0920

A PHASE III STUDY OF POSTOPERATIVE RADIATION THERAPY (IMRT) +/- CETUXIMAB FOR LOCALLY-ADVANCED RESECTED HEAD AND NECK CANCER

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 that after surgery has an intermediate risk of recurring.

WHY IS THIS STUDY BEING DONE?

The standard treatment of surgery (which you have had) followed by radiation therapy can stop tumors from growing in the head and neck region in most patients. However, the cancer can recur or can spread to other parts of the body. Cetuximab is a drug that may delay or prevent tumor growth by blocking certain cellular chemical pathways that lead to tumor development. It was approved by the FDA in 2006 for the treatment of head and neck cancer.

The purpose of this study is to compare the effects, good and/or bad, of radiation therapy alone with radiation therapy and cetuximab on you and your cancer to find out which is better. In this study, you will get either radiation therapy alone OR radiation therapy and cetuximab.

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 important normal 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.

Use of IGRT may lead to improved accuracy of radiation treatment compared to regular radiation therapy and eventually, that will 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.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 700 people will take part in this study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY? (4/7/14)

For all patients: Your study doctor will need to send some of your tumor tissue (obtained when you had surgery) to be tested for EGFR expression. Epidermal growth factor receptor (EGFR) is a protein found on the surface of cells, which can start reactions that cause cancer cells to grow. Some studies have suggested that patients with high EGFR have a better response to treatment. This tissue submission for testing is required for this study to see if the results of this test can predict patients' response to the cetuximab.

For patients with oropharynx cancer: Your tumor tissue also will be tested for the Human Papillomavirus (HPV). This tissue test is required for this study. Some studies have suggested that HPV-related cancer is biologically and clinically different as compared to non-HPV-related cancer. Some studies have found that patients with HPV-related oropharynx cancer have a better response to treatment. This test will help researchers learn more about HPV-related cancer.

After you have completed treatment on this study, your study doctor can request your EGFR level and/or HPV status from NRG Oncology and discuss it with you.

Eligible participants will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

If you are in Group 1 (often called "Arm 1"), you will receive radiation therapy once a day, Monday through Friday, for about 6 weeks.

If you are in Group 2 (often called "Arm 2"), you will receive radiation therapy once a day, Monday through Friday, for about 6 weeks and cetuximab, (an initial dose 1 week prior to radiation and then once a week during radiation for a total of 7 doses). You also will receive cetuximab after you finish radiation therapy, once a week for 4 doses.

For Group 2 Patients
Before your first dose of cetuximab, you will be given some medicine through your vein to prevent an allergic reaction to cetuximab. Then you will be given the first dose of cetuximab through your vein for approximately two hours. You will not receive radiation therapy on the day you receive the first dose of cetuximab.

Your blood pressure and overall physical condition will be closely monitored while you receive cetuximab and for at least one hour afterwards. If you have a severe allergic reaction to the first dose of cetuximab or any later doses, the study doctor will treat you for the reaction, and you may not receive further cetuximab on this study. You and the study doctor can discuss other treatments that you can receive off study.

If you tolerate the first dose of cetuximab well, the following week you will begin receiving cetuximab once a week for 6 weeks and after you finish radiation therapy, you will receive cetuximab once a week for 4 weeks — a total of 11 doses of cetuximab.

For All Patients

Before you begin the study: (12/6/10)

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.

- Assessment of tumor tissue removed during your surgery to see if you have the risk factors required in this study
- Physical examination by several doctors
- Evaluation of your ability to carry out daily activities

- A chest x-ray or chest CT (Computed Tomography) scan or chest CT/PET (Positron Emission Tomography) scan
  – A CT scan is a study using x-rays to look at one part of your body.
  – A PET 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.
- Blood tests (about 2 teaspoons of blood will be taken from your vein)
- For women able to have children, a pregnancy test
- A dental evaluation before receiving radiation
- An evaluation of your ability to chew and swallow
- If your study 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; 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.
  - A CT scan with contrast (contrast means that dye is injected into your vein to increase the differences between normal and abnormal tissue), or a CT/PET scan and/or an MRI of your head and neck (Magnetic Resonance Imaging or MRI is imaging that uses a strong magnetic field to look at one part of your body.)
  - An evaluation of your diet to see if a feeding tube is needed
  - An EKG, a test of your heart function

(6/4/10) During the study:

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.

<u>At week 1 during radiation or radiation plus cetuximab</u>

- A blood test (about 1 teaspoon of blood will be taken from your vein)

<u>Weekly during radiation or radiation plus cetuximab</u>:

- A physical examination by several doctors
- Evaluation of your ability to carry out daily activities
- Evaluation of any side effects from treatment you may be having

<u>Every 3 weeks during radiation or radiation plus cetuximab, and during cetuximab after radiation is completed</u>:

- Blood tests (about 1 teaspoon of blood will be taken from your vein)

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

- CT scan with contrast, or CT/PET scan, and/or MRI of your head and neck
- A chest x-ray or chest CT scan or chest CT/PET scan
- A biopsy to check for recurrence of the cancer

(11/15/11) You will need these tests and procedures in follow-up visits:

They 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.

<u>For Patients Receiving Cetuximab:</u> After you finish taking cetuximab, you will have blood tests every 3 weeks for a total of 9 weeks (about 1 teaspoon of blood will be taken from your vein).

<u>For All Patients: At 1 month after you finish radiation therapy (with or without cetuximab):</u>

- A physical examination

- Evaluation of your ability to carry out daily activities
- Blood tests (about 1 teaspoon of blood will be taken from your vein)
- An evaluation of your ability to chew and swallow
- Evaluation of any side effects from treatment you may be having
- If your study 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

For All Patients: Every 3 months from the end of radiation therapy for 2 years, every 6 months for 3 years, then once a year:

- A physical examination
- Evaluation of your ability to carry out daily activities
- An evaluation of your ability to chew and swallow
- Evaluation of any side effects from treatment you may be having
- If your study 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
  - A CT scan with contrast, or CT/PET scan, and/or MRI of your head and neck

For All Patients: Once a year for 5 years:

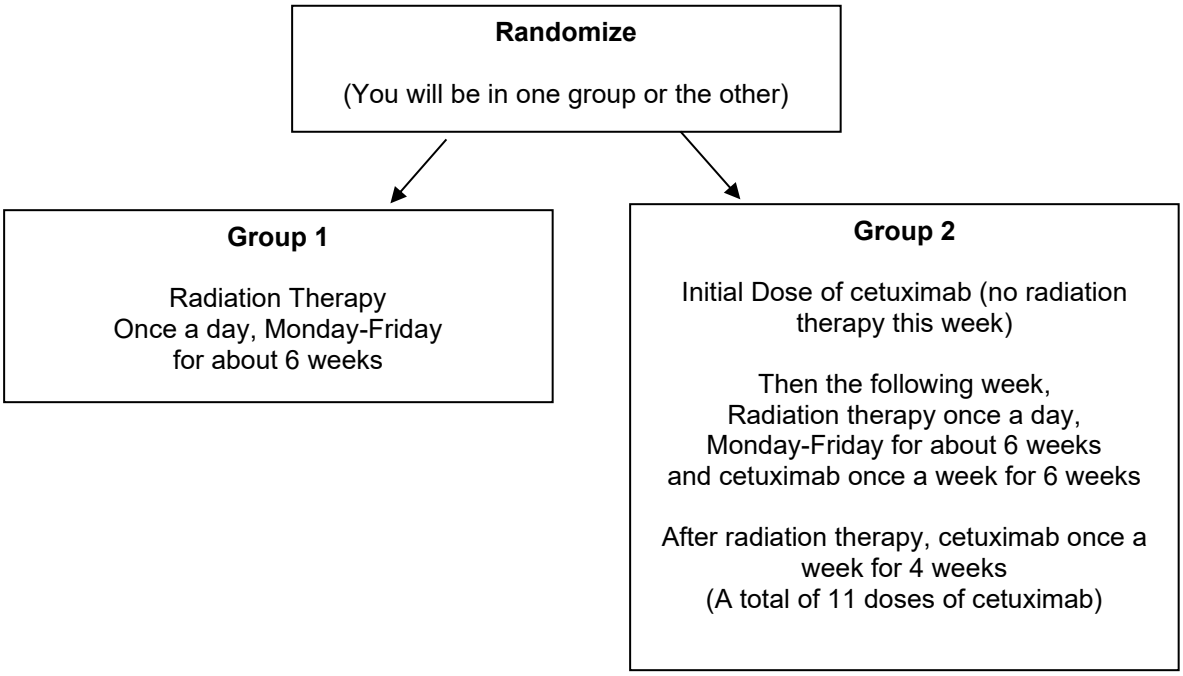
- A chest x-ray or chest CT scan or chest CT/PET scan

For All Patients: If recommended by your study doctor:

- A biopsy to check for recurrence of the cancer
- Blood tests (about 1 teaspoon of blood will be taken from your vein)
- Evaluation of any side effects from treatment you may be having

STUDY PLAN

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.



HOW LONG WILL I BE IN THE STUDY?

Group 1 patients will receive radiation therapy for about 6 weeks.

Group 2 patients will receive a dose of cetuximab a week before radiation therapy, and if they tolerate cetuximab well, will receive cetuximab once a week during the 6 weeks of radiation therapy and after radiation therapy, once a week for 4 weeks — a total of 11 weeks of treatment.

All patients will be asked to visit the office for a follow-up exam one month after finishing radiation therapy with or without cetuximab, then will be seen every 3 months from the end of radiation therapy for 2 years, every 6 months for 3 years, and then once a year for their lifetimes.

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 radiation and/or cetuximab 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? (1/25/16)

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 radiation therapy or stop taking the cetuximab. 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.

Possible Side Effects of Radiation to the Head and Neck

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation to the head and neck, 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 radiation to the head and neck, 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 radiation to the head and neck, 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 • 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

Possible Side Effects of Cetuximab (Table Version Date: May 28, 2013)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cetuximab, more than 20 and up to 100 may have:
• Change in nails • Swelling and redness of the area of radiation • Rash, itching, dry skin, acne • Dehydration, weight loss, loss of appetite • Sores in mouth which may cause difficulty swallowing • Constipation, diarrhea, vomiting, nausea • Difficulty sleeping • Headache, tiredness • Pain • Fever • Infection, especially when white blood cell count is low • Cough, shortness of breath

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cetuximab, from 4 to 20 may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Confusion, depression, worry • Fainting • Severe blood infection • Blood clot which may cause swelling, pain, shortness of breath

RARE, AND SERIOUS In 100 people receiving Cetuximab, 3 or fewer may have:
• Scarring of the lungs • Kidney damage which may require dialysis • Heart stops beating

Risks Associated with Cetuximab and Radiation Therapy
The combination of cetuximab with radiation therapy could increase the likelihood and/or severity of the side effects of radiation therapy. The combination also could increase the risk of heart damage, including heart attack, abnormal heart rhythms, and/or heart failure, which could lead to death.

Reproductive risks (12/6/10)
You should not become pregnant or father a baby while on this study because the radiation treatment and/or cetuximab in this study can affect an unborn baby. Women who are able to have children will have a pregnancy test before beginning treatment. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. The treatment in the study may make you unable to have children in the future. Women of childbearing age can ask their doctor for information about pre-treatment or post-treatment reproductive or fertility options prior to agreeing to participate in the study.

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 doctors hope radiation therapy with or without cetuximab may keep your head and neck cancer from growing, there is no proof of this yet. The effects of a combination of radiation and cetuximab may be no different or worse than radiation alone. We do know that the information from this study will help doctors learn more about these therapies as a treatment for 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? (26-JAN-2018)

Data are housed at NRG Oncology 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:

- NRG Oncology
- Other organizations in the National Clinical Trials Network (NCTN): Alliance for Clinical Trials in Oncology (ALLIANCE), ECOG-ACRIN Cancer Research Group (ECOG-ACRIN), and SWOG
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- The Cancer Trials Support Unit (CTSU), a service sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
- The Central Institutional Review Board (CIRB)
- Qualified representatives of Eli Lilly and Company or its local affiliate.
- VisionTree Software, Inc.

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.

[Note to Informed Consent Authors: the above paragraph complies with the new FDA regulation found at 21 CFR 50.25(c) and must be included verbatim in all informed consent documents. The text in this paragraph cannot be revised.]

[Note to Local Investigators: The NCI has recommended that HIPAA regulations be addressed by the local institution. The regulations may or may not be included in the informed consent form depending on local institutional policy.]

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY? (26-JAN-2018)

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.

Eli Lilly and Company or its local affiliate is supplying cetuximab at no cost to you. However, you or your health plan may need to pay for costs of the supplies for drug administration and personnel who give you the cetuximab.

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

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

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.]*

***You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only).** *[*Only applies to sites using the CIRB.]*

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 the following study. Below, please mark your choice.

QUALITY OF LIFE STUDY (26-JAN-2018)

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 your diet and your ability to chew, swallow, speak clearly, and looks at any changes to your skin.

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 4 questionnaires at the following times: Before you begin treatment and at 3, 12, and 24 months from the end of your radiation therapy. It takes about 5-10 minutes to fill out each questionnaire.

In the past, patients often have filled out these quality of life questionnaires on paper. NRG Oncology is working with a company, VisionTree Software, Inc., that has a web site where patients can fill out these questionnaires anywhere there is a computer with Internet access. This option is being offered as some patients may find it more convenient to fill out the forms electronically from any location, including home. When you log on to the web site, it will take you through the process of completing the questionnaires step by step. You will need an e-mail address that you agree to use for this purpose. The e-mail address is needed to identify you on the VisionTree web site and for e-mail reminders that will be sent to you when the questionnaires are due. Your e-mail address will only be used for the purpose of this study, not for mail or marketing purposes. If you are interested in filling out quality of life questionnaires electronically but do not have an e-mail address, you may obtain one (quickly and for no charge at web sites such as Yahoo!, Hotmail, or AOL). You will only be sent e-mail reminders at the time that the questionnaires are due (a maximum of 3 e-mail reminders per time point). Your access to the VisionTree web site is password protected and secure. You can use your e-mail address to retrieve your password if you forget it or lose your login card. You will receive a login card either by regular mail or e-mail, and it will include the information you need to log in to the VisonTree web site the first time. You can choose to complete the questionnaires online or on paper. The choice is up to you.

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 4 questionnaires. 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 answers.

I choose to take part in the Quality of Life Study. I agree to fill out the 4 Quality of Life Questionnaires.

YES NO

I choose to use the VisionTree Software. I agree to fill out the Quality of Life Questionnaires electronically using the VisonTree web site.

YES NO

ABOUT USING TISSUE AND BLOOD FOR RESEARCH (5/18/15)

You have had surgery to remove your cancer. Your doctor has removed 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 teaspoons of your blood. Blood for research will be collected once, 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/or 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 your 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. We will use your tissue and blood until you contact us and let us know that you do not want us to use your tissue and/or blood. Then any tissue or 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 (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 are used for genetic research (about diseases that are passed on in families). Even if your tissue and blood are 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 products 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

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 tissue may be kept for use in research to learn about, prevent, or treat cancer.

Yes No

2. My blood may be kept for use in research to learn about, prevent, or treat cancer.

Yes No

3. My tissue 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).

Yes No

4. My blood 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).

Yes No

5. Someone may contact me in the future to ask me to take part in more research.

Yes No

WHERE CAN I GET MORE INFORMATION? (2/13/12)

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/

- **For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/**
- **For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/**

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 _____