NRG ONCOLOGY
Radiation Therapy Oncology Group

RTOG 1016

(ClinicalTrials.gov NCT #:* 01302834*)

Phase III Trial of Radiotherapy Plus Cetuximab versus Chemoradiotherapy in HPV-Associated Oropharynx Cancer

Amendment 8: February 23, 2016

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Informed Consent Template for Cancer Treatment Trials (English Language)

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 may be positive for the Human Papillomavirus (HPV).

Why is this study being done?

The purpose of this study is to compare the effects, good and/or bad, of two standard treatments for head and neck cancer: radiation therapy and cisplatin or radiation therapy and cetuximab. The two treatments may be comparable in treating your cancer, but radiation and cetuximab may result in less severe side effects.

Cisplatin is a classic chemotherapy drug. Cetuximab is a drug that blocks the epidermal growth factor receptor, a protein that affects cancer growth and many other functions. Radiation and cetuximab may result in less severe side effects. However, it is unknown whether it is equally effective as radiation and cisplatin for your type of cancer.

This study is being done in patients whose head and neck cancer was caused by Human Papillomavirus Virus (HPV). Some studies have found that patients with HPV positive oropharynx cancer have a better response to treatment and live longer. Thus, this study aims to see if treatment with radiation plus cetuximab has less side effects and is as effective as radiation plus cisplatin.

How many people will take part in the study? (10/17/13)

About 834 people will take part in this study.

What will happen if I take part in this research study? (6/25/13)

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.

For all patients:
Your tumor tissue will be tested for p16, a test that shows that the tumor is caused by the Human Papillomavirus (HPV). This tissue test is required for this study. If the test is negative, you will not be able to participate 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.

For all patients:
Some studies have suggested that a history of tobacco smoking may affect survival of patients with HPV-positive cancer. Because of this, you will be asked to answer confidential survey questions about your tobacco smoking history on a computer. The brief survey of smoking history is required for this study. The data will be used to make sure that there are equal numbers of smokers and non-smokers in both groups of the study. The data will not be available to your doctor and will not be part of your medical record. Depending on your smoking history, it will take from 1 to 5 minutes to complete. You also can choose to complete the entire head and neck risk factor survey (described later in this consent form).

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, you will receive radiation therapy once a day for 4 days of the week and twice a day on the fifth day, for about 6 weeks. When given twice a day on the fifth day, there will be at least 6 hours between radiation treatments. Each treatment may take up to 15-30 minutes depending on the technique used. You will also receive a chemotherapy drug, cisplatin, through the vein, on days 1 and 22 (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.

If you are in Group 2, you will receive radiation therapy once a day for 4 days of the week and twice a day on the fifth day, for about 6 weeks. When given twice a day on the fifth day, there will be at least 6 hours between radiation treatments. Each treatment may take up to 15-30 minutes depending on the technique used. You will also receive cetuximab, (an initial dose 1 week prior to radiation, once a week during radiation, and 1 dose after radiation for a total of 8 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 (may include hives, low blood pressure, wheezing, swelling of the throat, and difficulty breathing) 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 before radiation therapy for 6 weeks and after you finish radiation therapy, you will receive one additional cetuximab dose— a total of 8 doses of cetuximab.

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
- 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.
- You will have the following:
    a. A CT (Computed Tomography) scan of your neck (with contrast) and a chest CT scan (with or without contrast) **or**
    b. An MRI (Magnetic Resonance Imaging) of your neck (with contrast) and a chest CT scan (with or without contrast) **or**
    c. A CT scan of your neck (with contrast) and a PET/CT (Positron Emission Tomography) scan of your neck and chest (with or without contrast) **or**
    d. An MRI of the neck (with contrast) and a PET/CT scan of your neck and chest (with or without contrast).
        – A CT scan is a study using x-rays to look at one part of your body. It may be done with or without contrast.
        – Contrast means that dye is injected into your vein to increase the differences between normal and abnormal tissue.
        – An MRI is imaging using a strong magnetic field 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.
- Evaluation of your ability to carry out daily activities
- Blood tests (about 3 teaspoons of blood will be taken from your vein)
- For women able to have children, a pregnancy test
- A dental evaluation
- An evaluation of your ability to chew and swallow
- A hearing test
- You will be asked about your diet, eating, and speech.

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

- Whole body PET/CT
- An EKG, a test of your heart function
- An evaluation of your diet to see if a feeding tube is needed

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>Weekly during treatment:</u>

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

<u>During treatment, if your study doctor recommends:</u>

- A whole body PET/CT

- A CT scan, MRI, or PET/CT of your neck
- A biopsy to check for recurrence of the cancer
- Evaluation of any side effects from treatment more often than weekly, if needed

You will need these tests and procedures in follow-up visits: (10/17/13)
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 1 month after you finish treatment:
- A physical examination
- Examination of the back of your throat and voice box (larynx) with a mirror and/or a flexible lighted tube inserted through your mouth
- Evaluation of your ability to carry out daily activities
- Blood tests (about 1 teaspoon of blood will be taken from your vein)
- Evaluation of any side effects from treatment you may be having

Every 3 months after you finish treatment for 2 years, every 6 months for 3 years, then once a year:
- A physical examination
- Examination of the back of your throat and voice box (larynx) with a mirror and/or a flexible lighted tube inserted through your mouth
- An evaluation of your diet to see if a feeding tube is needed
- Evaluation of your ability to carry out daily activities
- Evaluation of any side effects from treatment you may be having

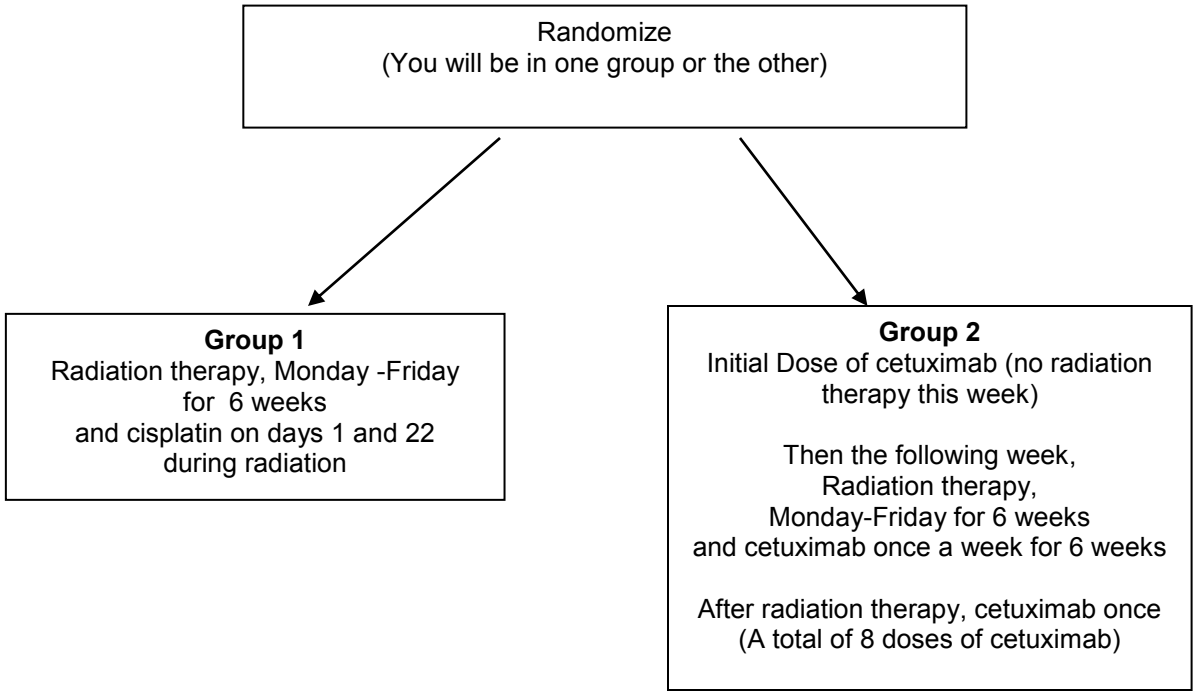
At 1, 2, 5, and 10 years: A dental evaluation

After you finish treatment, Once a year for 5 years: A chest CT scan or chest PET/CT scan

If your study doctor recommends:
- 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
- A CT scan, MRI, or PET/CT of your neck with contrast
- A whole body PET/CT with contrast
- After 5 years, a chest CT scan or chest PET/CT scan once a year

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 and cisplatin on days 1 and 22 during radiation.

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 once after radiation therapy, for a total of 8 weeks of treatment.

All patients will be asked to visit the office for follow up at 1 and 3 months from the end of treatment, then every 3 months through year 2, every 6 months for 3 years, 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 cisplatin 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? (6/25/13)

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 cisplatin or 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 therapy, more than 20 and up to 100 may have:
• Sores in the mouth and/or throat which can be painful and make it very difficult to chew and or swallow foods • Mouth dryness or changes in taste and/or smell that may be permanent • Thick saliva • Hoarseness • Tanning or redness and/or irritation of the skin in the head and neck area being treated with radiation • Ear pain and/or pressure • Fatigue • Weight loss • Permanent hair loss in the area treated with radiation (face, chin, neck) • Loss of teeth, or cavities in the teeth, if strict dental care is not followed and/or hypersensitivity of teeth

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, from 4 to 20 may have:
• Decrease in function of the thyroid gland that may require you to take thyroid replacement medicine to prevent you from feeling tired or sleepy • Serious damage to the spinal cord, nerves in the neck, jawbone, voice box, skin, or other parts of the head and neck that may require a major operation to correct and, rarely, can even be life threatening • Temporary pain or scarring around nerves in the shoulder that could cause numbness and/or weakness • Breathing problems • Difficulty with swallowing and eating for which you might need a long term or permanent feeding tube; possibility of inhaling food and/or liquids into the lungs – which could also result in pneumonia. This side effect is more likely for patients receiving radiation and cisplatin (Group 1). • Serious ear infections and/or hearing loss • Damage to the spinal cord leading to permanent weakness and/or symptoms like a "stroke" • Loss of hearing

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. 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

Possible side effects related to cisplatin (for Group 1 patients) [Table Version Date: December 12, 2012]

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 decrease, including ringing in ears • Change in taste

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, 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 • Difficulty with balance • Numbness in the fingers and toes • Low blood pressure • Low magnesium in the blood, which may cause heart beat irregularities that are possible life threatening

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

Possible Side Effects of Cetuximab (For Group 2 patients) [Table Version Date: January 23, 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

Diphenhydramine (or other antihistamine) pre-medication used prior to cetuximab may impair your ability to drive home, and you may need to seek alternative transportation home. It may also impair your ability to safely use power equipment for several hours.

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
You should not become pregnant or father a baby while on this study because the radiation treatment and/or cisplatin 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 cetuximab will be as effective in keeping your head and neck cancer from growing as radiation therapy and cisplatin with less severe side effects, there is no proof of this yet. The effects of a combination of radiation and cetuximab may be no different or worse than radiation and cisplatin. 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 that is HPV positive. This information could help future cancer patients.

What other choices do I have if I do not take part in this study? (10/17/13)

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
- You may choose not to be treated for cancer, but you may want to receive comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

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? (6/3/14)

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
- 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
- Qualified representatives of the pharmaceutical collaborator

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. NRG Oncology will make no voluntary disclosures related to your participation in this research study.

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? (6/25/13)

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.

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 each of the following studies. Below, please mark your choice for each study.

Quality of Life Study (6/25/13)

The quality of life research was planned for 400 patients, and as of 2/28/13, these patients were enrolled. No more patients are needed for this research, but you can still take part in main study and the use of your tissue and blood. You also can choose to complete the Work Status Questionnaire and the computer survey before beginning treatment.

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 6 questionnaires at 5 time points: before treatment, at the end of treatment, and at 3, 6, and 12 months after you finish treatment. It takes about 15-20 minutes to fill out these questionnaires.

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 6 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.

Work Status Questionnaire

We would like to ask some questions about your work status.

Please circle your answer.

I agree to fill out the questionnaire after I am enrolled on the study. I agree to fill out the questionnaire on the computer.

YES **NO**

Computer Survey about Risk Factors for Head and Neck Cancer (6/25/13)

Researchers have very recently learned that Human Papillomavirus (HPV) can cause head and neck cancer. Some studies have suggested that other behaviors that increase risk of head and neck cancer might affect how patients with HPV-positive oropharynx cancers respond to treatment. An example is tobacco smoking. Other risk factors for head and neck cancer include alcohol drinking, marijuana smoking, family history of cancer, sexual behavior, diet, and dental health. Researchers also want to better understand factors that might increase a person's risk for getting HPV-positive oropharynx cancer. To do this, researchers will compare the behavior of people with HPV-positive oropharynx cancer with people of the same age and gender who do not have cancer.

You are required to answer confidential survey questions about your tobacco smoking history for this study. We are asking for your consent to administer the complete confidential survey on a computer that will ask you about your history of alcohol drinking, marijuana smoking, family history of cancer, sexual behavior, diet, and dental health. You would take the survey once before starting treatment. It will take you approximately 20 minutes to complete.

The survey is given on a small touch screen computer. You may be familiar with this type of computer. Similar computers are used in bank machines, airport check in lines, and at gas stations.

Your answers to the survey will not be available to your doctor or medical staff, will not be part of your medical record, and will not be linked to anything that might identify you (for instance, your name, date of birth, etc). The information will be available only to the researchers. The information will help doctors understand what factors affect response to treatment.

Please circle your answer.

I choose to take part in the Risk Factor Survey before treatment. I agree to fill out the survey on the computer.

YES **NO**

Consent Form for Use of Tissue and Blood for Research (12/14/11)

About Using Tissue and Blood for Research

Your doctor performed a biopsy to make a diagnosis of oropharynx cancer. That tissue will be used to determine the p16 status of your tumor.

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 3-4 teaspoons of your blood at 3 time points: blood for research will be collected before you begin treatment and at 3 and 6 months from the end of treatment. Blood for research is collected at the same time your blood is collected for other tests required in the main part of this study.

If you agree, this tissue and blood will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How is Tissue Used for Research" to learn more about tissue research. This information sheet is available to all at the following web site: http://cdp.cancer.gov/humanSpecimens/ethical_collection/patient.htm.

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 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. Just contact us and let us know that you do not want us to use your tissue. 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 the institution/doctor 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 blood is used for genetic research (about diseases that are passed on in families). Even if your tissue and 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 and other diseases 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 (6/25/13)

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 (6/3/14)

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

Where can I get more information? (12/14/11)

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://www.cancer.gov/cancertopics/**

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 _____