

MARQUETTE GENERAL HEALTH SYSTEM
Regional Medical Center

CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY

TITLE: RTOG 0522 - A Randomized Phase III Trial of Concurrent Accelerated Radiation and Cisplatin Versus Concurrent Accelerated Radiation, Cisplatin, and Cetuximab (C225) [Followed by Surgery for Selected Patients] for Stage III and IV Head and Neck Carcinomas

INVESTIGATORS: Nelson Adamson, MD
DCHS Radiation Oncology
1711 S. Stephenson Ave.
Iron Mountain, MI 49801

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 advanced head and neck cancer.

Why is this study being done?

The purpose of this study is to compare the effects, good and/or bad, of radiation therapy and chemotherapy (cisplatin) with radiation therapy, chemotherapy, and cetuximab (C225) on you and your advanced head and neck cancer to find out which is better. In this study, you will get either radiation and cisplatin or radiation, cisplatin, and C225.

C225 was approved in 2004 as a treatment for patients with colorectal cancer, and when this study began, C225 was an experimental treatment for patients with head and neck cancer. In 2006, the FDA approved C225 for the treatment of head and neck cancer. C225 may delay or prevent tumor growth by blocking certain cellular chemical pathways that lead to tumor development.

In addition, some patients in this study will have a combination of a PET (Positron Emission Tomography) and CT (Computed Tomography) scan (explained below). For those patients, this study will see if PET/CT is a good way to find out the effect of treatment on their cancer.

How many people will take part in the study?

About 720 people will take part in this study.

What will happen if I take part in this research study?

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
- One of the following:
 - Chest x-ray
 - Or CT (Computed Tomography) scan of your chest: A study using x-rays to look at one part of your body
 - Or the combination of a PET (Positron Emission Tomography) and CT scan 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.

- CT scan or an MRI (Magnetic Resonance Imaging) of your head and neck or a PET/CT scan of your body (MRI: Imaging using a strong magnetic field to look at one part of your body)
- Tests of your heart function: One of two common tests of heart function will be used to make sure that your heart can handle the stress of fluid loads given with chemotherapy: a Multiple Gated Image Acquisition scan (MUGA) or an echocardiogram.
 - A MUGA scan is performed by injecting a small amount of radioactive substance mixed with your own blood. A camera records the path of the radioactive tracer like a movie, and computer analysis estimates the efficiency of the heart in pumping blood.
 - An echocardiogram accomplishes the same analysis by using sound waves bounced off the walls of the heart using a small instrument held against the chest wall.
- Blood tests (about 2-3 teaspoons of blood will be taken from your vein)
- For women able to have children, a pregnancy test
- If your study doctor recommends:
 - A dental evaluation before receiving radiation
 - A hearing test
 - An evaluation of your diet and ability to chew and swallow to see if a feeding tube is needed

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 **during the study**. They are part of regular cancer care.

- Physical examination by your several doctors
- Evaluation of your weight and ability to carry out daily activities
- Blood tests every week during treatment (about 7 times); about 2-3 teaspoons of blood will be taken from your vein
- Evaluation of any side effects you may be having
- An evaluation of your diet and ability to chew and swallow to see if a feeding tube is needed

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.

At 4 weeks after treatment

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

At 8-9 weeks after treatment

- A physical examination
- For patients with remaining large tumors, a CT scan or MRI of the head and neck; these patients may also have a PET/CT scan.

At 6, 9, and 12 months from the start of treatment

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

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

- A physical examination
- Blood tests (about 2-3 teaspoons of blood will be taken from your vein)

At 6 months for year 1, then annually:

- Chest x-ray or CT scan of the chest or PET/CT scan of your body

At 6 months after treatment, then annually:

- CT scan or MRI of your head and neck or PET/CT scan of your body

You 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 doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

If you are in Group 1 (often called "Arm 1"), you will receive radiation therapy and chemotherapy (cisplatin).

All patients will receive radiation therapy for 6 weeks. Each radiation treatment will take about 30 minutes. There are several ways to receive radiation therapy in this study. Your study doctor will discuss with you how your radiation therapy will be given:

- You may receive radiation therapy once a day, Monday through Friday, for about 3 ½ weeks and then twice a day, Monday through Friday, for the remaining 2 ½ weeks. There will be at least 6 hours between the two daily treatments.
- Or you may receive radiation therapy once a day for four days of the week (Monday through Thursday) and twice a day on the fifth day (Friday) for 6 weeks. When given twice a day on the fifth day, there will be at least 6 hours between treatments.
- Or you may receive radiation therapy once a day, Monday through Saturday for 6 weeks.

All patients also will receive chemotherapy (cisplatin), through the vein, on days 1 and 22 of treatment. This will take 60 minutes. Some patients may stay overnight in the hospital after each chemotherapy treatment to receive medicines to replace body fluids. Your study doctor will discuss this with you.

If you are in group 2 (often called "Arm 2"), you will receive cetuximab (C225), radiation therapy, and chemotherapy (cisplatin).

Before your first dose of C225, you will be given some medicine through your vein to prevent an allergic reaction to C225. Then you will be given the first dose of C225 through your vein for approximately two hours. You will not receive chemotherapy or radiation therapy on the day you receive the first dose of C225.

Your blood pressure and overall physical condition will be closely monitored while you receive C225 and for at least one hour afterwards. If you have a severe allergic reaction to the first dose of C225 or any later doses, the study doctor will treat you for the reaction, and you may not receive further C225 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 C225 well, the following week you will begin receiving C225 before radiation therapy and chemotherapy. You will receive C225 once a week for 7 weeks.

All patients will receive radiation therapy for 6 weeks. Each radiation treatment will take about 30 minutes. There are several ways to receive radiation therapy in this study. Your study doctor will discuss with you how your radiation therapy will be given:

- You may receive radiation therapy once a day, Monday through Friday, for about 3 ½ weeks and then twice a day, Monday through Friday, for the remaining 2 ½ weeks. There will be at least 6 hours between the two daily treatments.
- Or you may receive radiation therapy once a day for four days of the week (Monday through Thursday) and twice a day on the fifth day (Friday) for 6 weeks. When given twice a day on the fifth day, there will be at least 6 hours between treatments.
- Or you may receive radiation therapy once a day, Monday through Saturday for 6 weeks.

All patients also will receive chemotherapy (cisplatin), through the vein, on days 1 and 22 of treatment. This will take 60 minutes. Some patients may stay overnight in the hospital after each chemotherapy treatment to receive medicines to replace body fluids. Your study doctor will discuss this with you.

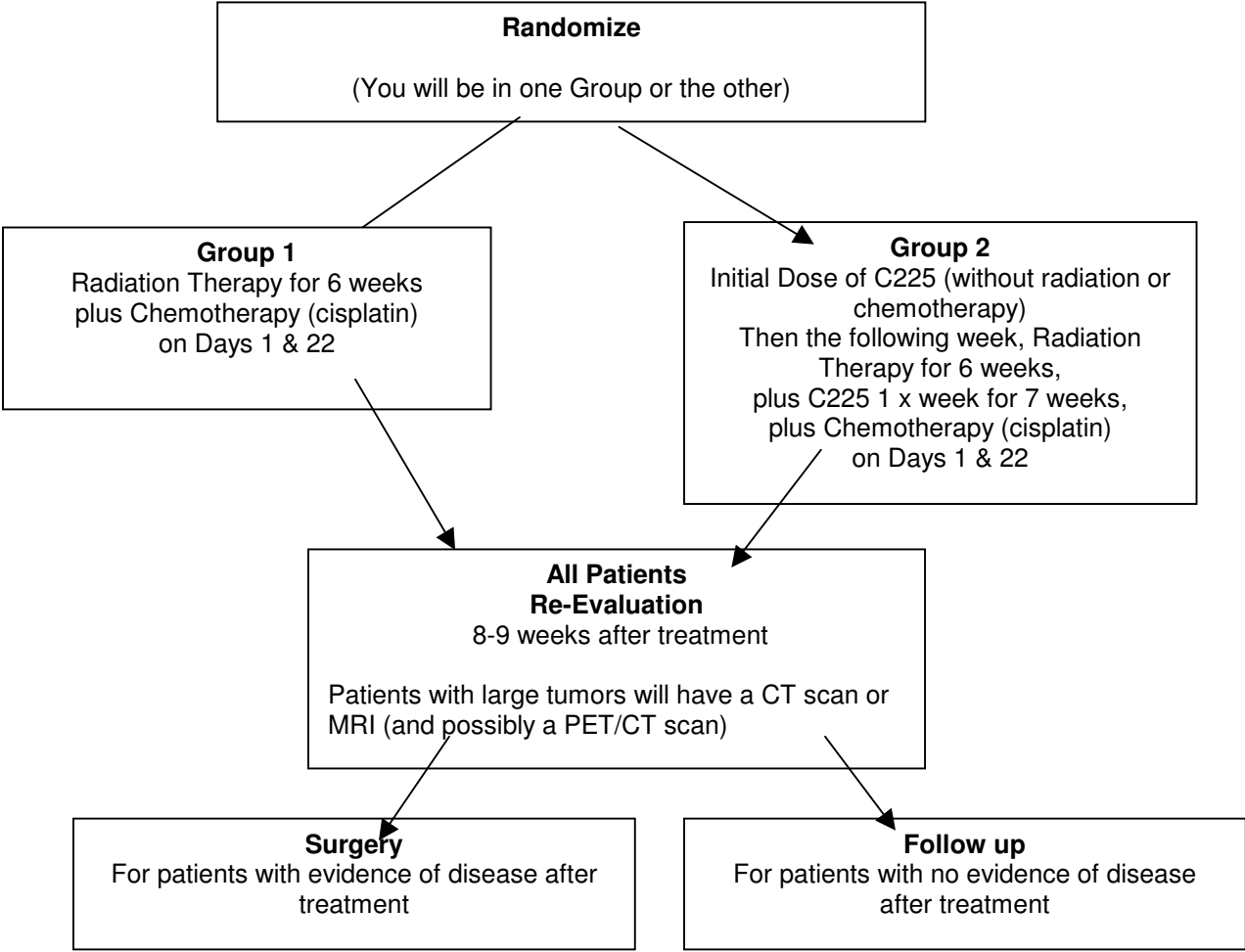
Both Groups: Evaluation of Treatment

Eight to nine weeks after treatment, patients with large tumors will have a CT scan or MRI of the head and neck (and may have an additional PET/CT scan) to evaluate the effect of treatment on their cancer.

Patients with remaining large tumors after treatment will have surgery to remove the cancer, if it is found that surgery can be done to remove the remaining cancer. The study doctor and surgeon will discuss the need for this re-evaluation and surgery with you.

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?

If you are in Group 1, you will receive treatment for about 6 weeks. If you are in Group 2, you will receive treatment for about 7 weeks. Patients with remaining large tumors after treatment will have surgery 9-10 weeks after treatment, if it is found that surgery can be done to remove the remaining cancer.

After you are finished with treatment, the study doctor will ask you to visit the office for follow-up exams at 6, 9 and 12 months after treatment, every 3 months in year 2, every 6 months in years 3-5, then annually.

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 that any risks from the radiation therapy, chemotherapy, or C225 (if you receive C225) can be evaluated by the study doctor. Another reason to tell the 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?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors 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, chemotherapy, or C225 (if you receive C225). 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 include:

Combining cisplatin with radiation to the head and neck can increase the effectiveness of radiation therapy on your cancer, but also can increase the side effects of radiation on normal tissue in treatment area. In addition, receiving a combination of cisplatin with radiation can result in the side effects described below being more likely or more severe.

Risks Associated with Radiation to the Head and Neck

Very Likely

- 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 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
- Loss of teeth, or cavities in the teeth, if strict dental care is not followed and/or hypersensitivity of teeth

Less Likely, But Serious

- 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.
- Serious ear infections and/or hearing loss
- Damage to the spinal cord leading to permanent weakness and/or symptoms like a “stroke”
- Permanent hair loss (of the face/chin/neck)

Risks Associated with PET/CT scans

A PET/CT scan involves exposure to a low dose of radiation from an injection of a radioactive substance (a tracer). The risk from this level of radiation exposure is about 60% of the allowable annual dose for radiation workers (such as an x-ray technician) and is small when compared with other everyday risks. Ask the study doctor if you would like more information about radiation exposure.

Less Likely

- Discomfort from lying still on an enclosed scanning table
- Bruising or bleeding at the site of the injection of the tracer
- Infection at the injection site

Rare but Serious

- An allergic reaction to the radioactive substance

Risks Associated with cisplatin

Very Likely

- Decrease in blood counts, which can lead to a risk of infection, decreased healing after surgery, and/or bleeding
- Anemia
- Loss of appetite and/or taste; metallic taste in your mouth
- Nausea and/or vomiting
- Fatigue
- Generalized loss of strength
- Hearing loss, ringing in the ears
- Loss of muscle or nerve function that may cause weakness or numbness in your hands and feet
- Loss of appetite and weight loss
- Low magnesium in the blood, which could result in muscle cramps and/or weakness
- Low calcium in the blood
- Kidney damage

Less Likely

- Allergic reactions (sweating, difficulty breathing, rapid heartbeat)
- Muscle cramps or spasm
- Facial swelling
- Loss of taste
- Loss of coordination
- Involuntary movement
- Restlessness
- Loss of hair, which is temporary
- Blood clots
- Low blood pressure

Less Likely, But Serious

- Seizures

- A severe allergic reaction, which could be life threatening
- Decrease in the kidneys' ability to handle the body's waste, which may be permanent
- Calcium or potassium levels so low that it may affect heart function
- Decrease in liver function
- Another cancer called acute leukemia
- A condition called hemolytic uremic syndrome that involves decreased red blood cells and platelets, fever, and kidney failure

Risks Associated with Cetuximab (C225)

Very Likely

- Weakness
- Headache
- Fever
- Dry skin
- Localized acne-like skin reactions, rash, itching
- Low calcium in the blood
- Low magnesium in the blood, which could result in muscle cramps and/or weakness

Less Likely

- Inflammation under fingernails and/or toenails, which can last for several months after C225 is stopped
- Mouth sores
- Nausea and/or vomiting
- Diarrhea
- Constipation
- Upset stomach
- Reduced appetite, which could lead to weight loss
- Stomach pain
- Chills
- Dehydration
- Trouble sleeping
- Tiredness and/or sluggishness
- Feeling depressed
- Muscle aches
- Joint or back pain
- Build up of fluid in ankles, feet, and/or legs
- Shortness of breath
- Cough
- Hair loss
- Inflammation of the lining of the eye

Less Likely, But Serious

- Reduced white blood cell count which could lead to an increased risk of infection, weakness, and/or in bleeding and bruising easily; this lowering of blood counts can lead to need for treatment with antibiotics, transfusions, or hospitalization if severe.
- Calcium or potassium levels so low that it may affect heart function
- Blood clots within a blood vessel in the lungs, legs, pelvis, or other places
- Kidney failure, which could lead to being hospitalized, or rarely, to death

Rare

- Scarring of lung tissue, which could be life threatening or lead to death

Possible allergic reactions to Cetuximab

Cetuximab also may cause allergic reactions such as hives, itching, and/or skin rash. Some patients have had allergic reactions with the first dose of cetuximab, but some patients have had reactions with later doses. The allergic reactions also can be severe, involving shortness of breath, wheezing, difficulty swallowing, lightheadedness, very low blood pressure, and rarely, heart attack and/or death.

Your condition will be closely monitored during doses of cetuximab and for at least one hour afterwards. If you have a severe reaction, your doctor will treat you for the reaction, and you will not receive further treatment on this study. If you have a delayed severe reaction after receiving cetuximab, you must immediately tell your doctor.

Risks Associated with Cisplatin, Cetuximab (C225), and Radiation Therapy

The combination of cetuximab with chemotherapy and radiation therapy could increase the likelihood and/or severity of the side effects of chemotherapy and 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.

Risks Associated with Neck Surgery

Patients with remaining large tumors after treatment will have surgery to remove the cancer, if it is found that surgery can be done to remove the remaining cancer. The study doctor and surgeon will discuss the need for surgery with you. You will need to review and sign a separate permission form from your doctor/hospital for this surgery.

The serious risks of surgery are infection, bleeding, poor healing of the skin and/or muscles in the neck, clots in the legs and/or lung, pneumonia, heart attack stroke, and/or death.

These risks may be more likely or severe for people in this study than for someone having neck surgery without having had chemotherapy and/or radiation therapy before surgery.

Reproductive risks: You should not become pregnant or father a baby while on this study because the drugs and scans 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 and for at least 60 days after the last study treatment. It is important you understand that you need to use birth control while on this study and for at least 60 days after the last study treatment. 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. There is a risk of not being able to have children in the future due to the chemotherapy. If you think that you may want to have children in the future, discuss this with the study doctor.

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, chemotherapy, and C225 (if you receive C225) may keep your head and neck cancer from growing, 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 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
- Receiving cetuximab without being in a study
- Taking part in another study
- Getting no treatment
- Getting 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 doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private?

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.

Records of your progress and medical images while on this study will be kept in confidential form at Marquette General Health System and in computers at The Radiation Therapy Oncology Group (RTOG) and The American College of Radiology Imaging Network (ACRIN). Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- RTOG
- ACRIN
- Qualified representatives of Bristol-Myers Squibb, makers of cetuximab (C225)
- 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 research group sponsored by the National Cancer Institute (NCI) to provide patients and doctors greater access to cancer trials
- Other qualified researchers studying new methods to analyze your medical images; at this time it is not known what type of studies these might be. Your name and any other information that identifies you will not be provided to these researchers.

Research studies may be conducted on aspects of the data and medical images collected during this study. At this time, it is not known what type of studies may be conducted. These studies may affect patient care or future studies of a medical or non-medical nature.

What are the costs of taking part in 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.

Bristol-Myers Squibb is supplying cetuximab (C225) 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, _____, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____.

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.

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

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.

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 _____ at _____ .

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

You can say “yes” or “no” to each of the following studies. 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.

One of the questionnaires requires data from Medicare on reimbursement amounts. If your health care is covered at least in part by Medicare, you will be asked to provide your social security number. Your social security number will not be used for any other purposes. We will do our best to make sure that your personal information is kept private; the chance that this information will be given to someone else is very small.

You will be asked to complete 2 questionnaires. In addition, you will be asked some questions about what you are able to eat at home and in public and how clear your speech is.

You will complete one of the questionnaires and answer the questions at your first visit, during the 5-6th week of treatment, at 3 and 12 months from the start of treatment, then annually for years 2-5. It takes about 5-10 minutes to fill out the questionnaire and about 5-10 minutes to answer the questions.

You will be asked to complete the other questionnaire at your first visit and then annually in years 1 and 5. It takes about 5-10 minutes to fill out this questionnaire.

If any questions make you feel uncomfortable, talk with your study doctor or nurse about skipping those questions and not giving 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 some questions. You may change your mind about participating 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 2 Quality of Life Questionnaires and answer some questions about my speech and my eating abilities.

YES

NO

Use of Tissue and Blood for Research

About Using Tissue and Blood for Research (6/1/06)

You will have or have had a biopsy (or surgery) to see if you have cancer. Your doctor will remove or 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. If your tumor comes back after you complete study treatment, we would like to keep some of that tumor tissue as well. If you agree to allow us to keep your tissue, it 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://www.cancerdiagnosis.nci.nih.gov/specimens/patient.pdf>

In addition, you will have blood tests before you start treatment. We would like to keep about one tablespoon of your blood for future research.

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 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 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.

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 or blood. Then any tissue or blood that remains will no longer be used for research and will be returned to the submitting institution.

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 or 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 products in the future.

Benefits

The benefits of research using tissue 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.

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

Yes No

2. My tissue and 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

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?

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

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

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.

CONTACT PERSONS:

Whom can I call if I have questions or problems?

If injury occurs as a result of this research, treatment will be available. You understand, however, you will not be provided with reimbursement for medical care other than what your insurance carrier may provide nor will you receive other compensation. For more information concerning the research and research-related risks or injuries, you can notify Dr. _____ the investigator in charge at Dickinson County Health System at 906-776-5975. During evenings, weekends, and holidays you may phone Dickinson County Health System at 906-774-

1313 and ask to speak with the Radiation Oncologists on call. In addition, you may contact the Patient Advocate at Marquette General Hospital at (906) 228-9440 for information regarding patients' rights in research studies.

COSTS AND PAYMENTS:

You understand that the Group and Marquette General Hospital furnish no funds providing medical treatment for, or financial compensation to, human subjects in the event the investigational therapy results in loss or injury. You will be responsible for the cost of emergency medical treatment provided by this institution and/or by your physician. You are also aware that the ...Group and Marquette General Hospital will not take financial responsibility for non-acute medical problems.

Lab tests (blood), x-rays and other diagnostic tests will be done frequently to check the effects of the investigational therapy. You understand that the costs of your medication and treatment may exceed what your insurance company is willing to pay, and that you will be responsible for payment. In many instances, however, all or a portion of those costs may be reimbursed by your insurance company.

INSTITUTIONAL FUNDING:

Funds are provided from the study sponsor to Marquette General Hospital on a per patient basis to help with the institution's costs of participating in this study.

VOLUNTARY CONSENT:

You certify that you have read the preceding or it has been read to you and that you understand its contents. Any questions you have pertaining to the research or research related injuries have been and will be answered by Dr. _____ or his/her associates, who may be reached by phoning the office at _____. During evenings, weekends, or holidays you may phone Marquette General Hospital at (906) 228-9440, and request to speak with the radiation oncologist on call. Any questions you have concerning your rights as a research subject will be answered by the Patient Advocate at Marquette General Hospital, who may be reached by phoning (906) 228-9440. You will be given a copy of this consent form.

Your signature below means that you have freely agreed to participate in this investigational study.

Patient's Signature

Date

Signature of person conducting
Informed consent discussion

Date

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this research study have been explained to the patient indicated, and that any questions about this information have been answered.

Investigator's Signature

Date

Your signature below means that you do not wish to participate in this investigational study.

Patient's Signature

Date

Signature of person conducting
Informed consent discussion

Date

Investigator's Signature

Date

IRB approved amendment #2 3/14/07