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Sponsored and Funded by the National Cancer Institute

CONSENT FORM

CIRB R0436: A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients With Esophageal Cancer Who Are Treated Without Surgery.

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CIRB R0436: A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients With Esophageal Cancer Who Are Treated Without Surgery

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 esophageal cancer that is considered appropriate for treatment with a combination of chemotherapy and radiation. Based on the fact that your cancer started in the esophagus and you have not yet received any treatment for your cancer, you may be eligible for participation.

Why is this study being done?

In this study, you will get either radiation, chemotherapy, and cetuximab or radiation and chemotherapy. The purpose of this study is to compare the effects, good and/or bad, of radiation therapy and chemotherapy (paclitaxel and cisplatin) with or without the addition of cetuximab to find out which treatment is better.

Cetuximab may delay or prevent tumor growth by blocking certain cellular chemical pathways that lead to tumor development. Cetuximab is approved for the treatment of colorectal and head and neck cancers but is experimental for esophageal cancer. Cetuximab is investigational in this study.

How many people will take part in the study?

About 420 people will take part in this study.

What will happen if I take part in this research study? (2/13/09)

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.

- History and physical exam
- One of the following:
 1. Chest/abdominal CT (computed tomography) scan (a CT scan is a study that uses x-rays to look inside of your body) OR

2. A PET (positron emission tomography) scan [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.] OR
3. A combination of a PET and CT scan of your body (a PET-CT scan)
 - EKG (electrocardiogram) (an EKG is a test of your heart function)
 - Endoscopy with biopsy or fine needle aspiration. During an endoscopy, your study doctor will insert a tube into your throat that will allow him/her to look at your esophagus. Your study doctor will remove some of the cancerous tissue (biopsy) or extract cells (fine needle aspiration) during this procedure.
 - Blood tests (about 2-3 teaspoons of blood will be taken from your vein)
 - This will include a blood pregnancy test if you are a woman of child-bearing potential
 - Assessment of your daily caloric intake to be sure you are able to eat enough to provide enough energy for your body
 - If you agree, blood and urine tests will be collected for research purposes. This will be discussed later in this consent form.

You will also be asked to report any use of over-the-counter (OTC) or herbal products to your study doctor, so that he or she can make sure you are not taking any products that interact with any of the study drugs. You cannot be in this study if you are having frequent chest pains ("angina"), have had frequent chest pains, or have been hospitalized for heart failure within the last 3 months. You cannot be in this study if you had a heart attack in the past 6 months. Tell your study doctor if you think any of these may apply to you.

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. They will be done every week while you are receiving treatment.

- History and physical exam
- Evaluation of your 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 experiencing

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

All patients will receive radiation. Radiation treatment will be given once a day, 5 days a week, for 5 and a half weeks. All radiation treatments will be given as an outpatient at your institution. In general, each treatment will last about 30 minutes.

All patients will also receive chemotherapy with paclitaxel and cisplatin. Starting the same day as your radiation treatments, you will receive paclitaxel and cisplatin once a week for 6 weeks (6 cycles). Paclitaxel and cisplatin will be injected into a vein (intravenously). You will be given intravenous fluids and medicines to prevent nausea. You will also be given diphenhydramine, ranitidine, and dexamethasone to prevent an allergic reaction. Your chemotherapy treatments will be given as an outpatient at your institution. The treatment will last for about 3 and a half hours, once a week.

If you are in group 1 (often called "Arm 1") ... You will also receive the drug cetuximab. Starting the same day as your first dose of radiation and paclitaxel plus cisplatin, you will be given cetuximab by vein as an outpatient. Then you will receive paclitaxel and cisplatin. You will get cetuximab, paclitaxel, and cisplatin once a week for 6 weeks with the radiation. If you are randomized to this arm, you should wear sunscreen and a hat to limit sun exposure, because cetuximab causes skin problems and sun exposure can make these problems worse.

If you are in group 2 (often called "Arm 2")... You will not receive cetuximab. You will be treated with radiation and paclitaxel plus cisplatin.

When you are finished receiving treatment on this study...

You will need to have the following exams, tests, and procedures. They are being done to see how the treatment you received affected you and your cancer.

- At the end of treatment
 - Blood tests (about 2-3 teaspoons of blood will be taken from your vein)
 - History and physical exam

- At 6-8 weeks after you've finished treatment
 - Endoscopy: If it looks like your cancer is still present, your study doctor will also do a biopsy to confirm this. Your study doctor may also do a biopsy even if it doesn't look like your cancer is still present in order to find out how well your cancer has responded to the study treatment.
 - PET/PET-CT scan or chest/abdominal CT scan
 - Surgery/Additional Treatment: If it looks like your cancer is still present but has not grown outside of your esophagus, your doctor *may* talk to you about removing your esophagus in order to prevent the tumor from possibly growing. In addition, if it looks like your cancer is still present, you may need to switch to a different treatment, such as another chemotherapy regimen.
 - If you agree, blood and urine tests will be collected for research purposes. This will be discussed later in this consent form.

- During follow up
 - History and physical exam: every 4 months from the start of your treatment for 2 years, then every 6 months for 2 more years, then every year
 - If your cancer has gone away a PET/PET-CT scan or chest/abdominal CT scan:
Beginning at 8 months from the start of your treatment and then every 4 months for 2 years, then every 6 months for 2 more years, then every year.
If your cancer goes away and then appears to have returned your doctor may talk to you about an additional biopsy.

How long will I be in the study?

You will receive treatment with radiation and drug therapy for approximately 6 weeks. After you are finished the treatment, your study doctor will ask you to visit the office for follow-up exams every 4 months for 2 years, every 6 months for 2 years, and then every year indefinitely.

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 he/she can evaluate any risks from the treatment. 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?

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 taking the treatment. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death. In addition, side effects of chemotherapy may be increased when it is given with radiation.

As of 8/19/10, patients 75 years or older are not allowed to participate in this study. This decision was based on the Study Chairs' review of toxicity data for the patients enrolled to the study. Their review revealed that patients 75 or older experienced more severe side effects than patients younger than 75. The Study Chairs' decision to exclude patients 75 years or older is to ensure adequate safety for all patients participating in this study.

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

Risks and side effects related to the radiation include those that are:

Likely

- Fatigue
- Decrease in blood counts, which can cause infection, bleeding, and bruising
- Tanning and redness of the skin in the treatment area

Less Likely

- Growth of fibrous tissues similar to scar tissue underneath your skin
- Nausea/vomiting
- Diarrhea
- Weight loss

Rare but Serious

- Inflammation of the muscle tissue of the heart
- Inflammation and/or scarring of the lung tissue
- Inflammation of the esophagus
- Inflammation of the spinal cord
- Narrowing of the esophagus, which can cause problems with swallowing
- Hole in the esophagus

Risks and side effects related to paclitaxel include those that are:

Likely

- Fatigue
- Hair loss
- Nausea
- Vomiting
- Diarrhea
- Abdominal pain
- Decrease in blood counts, which can cause infection, (white blood cell count) or bleeding or bruising (platelet count)
- Anemia (decrease in red blood cell count)
- Tanning and redness of the skin in the treatment area
- Hardening or tenderness of the skin in the treatment area

Less Likely

- Mouth sores
- Tingling or numbness in your hands and feet
- Stiffness or pain in your joints and muscles
- Ulceration of the skin at the injection site, including redness, tenderness, swelling, and cellulitis (infection of the skin)
- Inflammation of the liver with a rise in liver function tests
- Tearing of the eyes

- Inflammation of the lining of the eye
- Low blood pressure
- Slowing of the heart rate
- Premature heart beats
- Changes in skin or nail color
- Fragility of nails
- Swelling of the legs or ankles
- Constipation

Rare but Serious

- Problems with your heart, including irregular or rapid heart beat, high blood pressure, and fainting
- Heart attack
- Congestive heart failure (heart muscle weakness, swelling, and shortness of breath)
- Blood clots in the veins
- Severe allergic reaction with low blood pressure, shortness of breath, rash, swelling of the face, redness in the face, chest pain, and shock
- Death from allergic reaction
- Death from infection due to low white blood cell count, including sepsis (blood infection), peritonitis (infection of the stomach lining), and pneumonia
- Visual changes including flashes of light
- Hearing loss
- Muscle weakness
- Liver failure
- Intestinal obstruction
- Intestinal perforation
- Pancreatitis (inflammation of the pancreas)
- Ischemic colitis (impaired blood flow to the bowel)
- Lung inflammation or fibrosis (hardening of tissue)
- Pulmonary embolism (blood clot in lung)
- Seizure
- Balance or coordination difficulty

Risks and side effects related to cisplatin include those that are:

Likely

- Decrease in blood counts, which can cause infection, (white blood cell count) or bleeding or bruising (platelet count)
- Anemia (decrease in red blood cell count)
- Nausea
- Vomiting
- Diarrhea
- Loss of appetite and taste
- Fatigue

- Weight loss
- Hair loss
- Changes in body calcium, potassium, sodium, phosphate, and magnesium levels, which can cause muscle cramps, weakness, and abnormal heart rhythms

Less Likely

- Mouth sores
- Restlessness
- Tingling or numbness in your hands and feet
- Muscle cramps
- Weakness
- Hiccups
- Increase in blood uric acid level
- Inflammation of the liver resulting in rise in liver function tests
- Blurred vision

Rare but Serious

- Leukemia (another type of cancer that is likely to be fatal)
- Involuntary movements, loss of coordination, and seizures
- Severe allergic reaction with low blood pressure, shortness of breath, rash, swelling of the face, chest pain, and shock
- Damage to the ears, including hearing loss and ringing in the ears
- Kidney failure
- Death from allergic reaction
- Death from infection due to low white blood cell count
- Heart attack
- Stroke
- Irregular heart beat
- Blindness

Risks and side effects related to cetuximab include those that are:

Likely:

- Diarrhea
- Nausea or the urge to vomit
- Fatigue or tiredness
- Fever
- Headache or head pain
- Dry skin
- Acne
- Skin rash with the presence of flat discolored areas (macules) and raised bumps (papules)

Less Likely:

- Lack of enough red blood cells (anemia)
- Swelling and redness (inflammation) of the skin of outer ear and canal
- Noise in the ears, such as ringing, buzzing, roaring, clicking
- Swelling and redness (inflammation) of the outermost layer of the eye and the inner surface of the eyelids (conjunctiva); commonly called "pink eye".
- Dry eye
- Swelling and redness (inflammation) of the middle layer of the eye (uvea)
- Excessive tearing in the eyes
- Belly pain
- Swelling and redness (inflammation) of the lip
- Constipation
- Dry mouth
- Heartburn
- Irritation or sores in the lining of the mouth
- Vomiting
- Chills
- Swelling of the arms and/or legs
- Flu-type symptoms (including body aches, fever, chills, tiredness, loss of appetite, cough)
- Reaction that can occur during or following infusion of the drug. The reaction may include fever, chills, rash, low blood pressure, and difficulty breathing.
- Chest pain not heart-related
- Allergic reaction by your body to the drug product that can occur immediately or may be delayed. The reaction may include hives, low blood pressure, wheezing, swelling of the throat, and difficulty breathing. 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.
- Infection
- Decreased number of a type of white blood cell (neutrophil/granulocyte)
- Weight loss
- Decrease in the total number of white blood cells (leukocytes)
- Loss of appetite
- Dehydration (when your body does not have as much water and fluid as it should)
- Decreased blood level of calcium
- Decreased blood level of magnesium
- Joint pain
- Back pain
- Muscle pain
- Fainting
- Stuffy or runny nose, sneezing
- Sudden constriction of the small airways of the lung that can cause wheezing and shortness of breath

- Cough
- Shortness of breath
- Hoarseness
- Hair loss
- Loss of some or all of the finger or toenails
- Increased skin sensitivity to sunlight
- Itching
- Area of bleeding within the skin causing a reddish purple discoloration
- Sores or destruction of skin
- Hives
- Low blood pressure
- Formation of a blood clot that plugs the blood vessel; blood clots may break loose and travel to another place, such as the lung

Rare but Serious:

- Serious, life-threatening allergic reaction requiring immediate medical treatment by your doctor. The reaction may include extremely low blood pressure, swelling of the throat, difficulty breathing, and loss of consciousness. 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.
- Inflammation of the lining of the brain and spinal cord
- Inflammation of the lungs that may cause difficulty breathing and can be life-threatening
- Fluid build-up in the lungs that is not due to a heart problem and that can be life-threatening
- Swelling and redness of the skin on the palms of the hands and soles of the feet

Reproductive risks: The drugs in this study can affect an unborn baby. You should therefore not become pregnant or father a baby while on this study and, if you are receiving cetuximab, for at least 60 days after the last cetuximab dose. Women should not breastfeed a baby while on this study and, if you are receiving cetuximab, for at least 60 days after the last cetuximab dose. It is important you understand that you need to use birth regulation (highly effective: abstinence, IUD, birth control pills, tubal ligation or partner's vasectomy and less effective: condom, diaphragm or cervical cap) while on this study. Check with your study doctor about what kind of birth regulation (highly effective: abstinence, IUD, birth control pills, tubal ligation or partner's vasectomy and less effective: condom, diaphragm or cervical cap) methods to use and how long to use them. Some methods might not be approved for use in this 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 researchers hope radiation therapy, chemotherapy, and cetuximab will be more useful against cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help researchers learn more about this therapy combination 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. This may include surgery in some cases, either by itself or with chemotherapy and/or radiation. You could also receive chemotherapy and radiation with the same or different chemotherapy drugs as used in this study without being part of this 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 study doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private?

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

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

- The Radiation Therapy Oncology Group (RTOG)
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- Qualified representatives of ImClone and Bristol-Myers Squibb, manufacturers and distributors of cetuximab
- 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

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 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 study doctor in person or call him/her at the number listed on the cover page.

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 Safety Monitoring Board will be regularly meeting to monitor safety and other data related to this study. The Board 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 at the number listed on the cover page.

For questions about your rights while taking part in this study, call the MultiCare Health System Institutional Review Board (a group of people who review the research to protect your rights) at 253-403-3877.

*You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only).

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 studies. Below, please mark your choice for each question.

Quality of Life Study

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

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

You will be asked to complete 2 questionnaires on 4 occasions.

You will complete the questionnaires before you begin treatment, within 1 week after you having your post-treatment endoscopy, 1 year after you start treatment, and 2 years after you start treatment. It takes about 10 minutes to fill out each of the questionnaires.

If any questions make you feel uncomfortable for any reason, skip those questions.

If you decide to take part in this study, the only thing you will be asked to do is fill out the questionnaires. 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.

YES

NO

Use of Tissue, Blood, and Urine for Research

About Using Tissue, Blood, and Urine for Research

You have had a biopsy (or surgery) to see if you have cancer. Your doctor 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 was left over for future research. If you agree, this tissue 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.rtog.org/tissue%20for%20research_patient.pdf

As a result of your participation in the trial, you also will have blood tests performed before you start treatment and 6-8 weeks after you have finished treatment. We would like to keep for future research about three teaspoons of the blood taken at each of these times. If you agree, this blood will be kept and may be used in research to learn more about cancer and other diseases.

In addition, we would like to keep some of your urine for future research. We would collect your urine at the following times: before you start treatment and 6-8 weeks after you have finished treatment. If you agree, the urine will be kept and may be used in research to learn more about cancer and other diseases.

The research that may be done with your tissue, blood, and urine 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, blood, and urine 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 your tissue, blood, and urine 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, blood, and urine 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, blood, and urine. Then any material that remains will no longer be used for research. Any tissue that remains will be returned to the institution that submitted it, and any blood or urine that remains will be destroyed.

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, blood, and urine are used for genetic research (about diseases that are passed on in families). Even if your tissue, blood, and urine is used for this kind of research, the results will not be put in your health records.

Your tissue, blood, and urine will be used only for research and will not be sold. The research done with your tissue, blood, and urine may help to develop new products in the future.

Benefits

The benefits of research using tissue, blood, and urine 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 253-403-3877. No matter what you decide to do, it will not affect your care.

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

Yes No

2. My tissue, blood, and urine 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.

Signature

I have been given a copy of all 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.

Patient's name (printed or typed)

Patient's Signature Date

Physician name (printed or typed)

Physician Signature Date

Signature of person conducting the
Informed consent discussion

Date

Authorization to Use or Disclose (Release) Identifiable Health Information For Research

Participant's Name: _____

Birthdate: _____

1. What is the purpose of this form?

The Cancer Trials Support Unit (CTSU) is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your identifiable health information, you must sign and date this form to give them your permission.

2. What health information do the researchers want to use?

The researchers want to abstract and use the portions of your medical record that they will need for their research. If you enter a CTSU research study, information that will be used and/or released may include your complete medical record, and in particular, the following:

- the history and diagnosis of your disease
- specific information about treatments you received
- information about other medical conditions that may affect your treatment
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, X-rays, photographs of radiation therapy target areas, and pathology results
- information on side effects (adverse events) you may experience, and how these were treated
- long-term information about your general health status and the status of your disease
- tissue and/or blood samples, associated data related to the analysis of the samples

You may request a blank copy of the CTSU data forms from the Northwest CCOP to learn what information will be shared.

3. Why do the researchers want my health information?

The Northwest CCOP will collect your health information and share it with the CTSU if you enter a Cooperative Group research study, or to evaluate your eligibility for a study. The CTSU researchers will use your information for the following cancer research study(ies). You are being asked to take part in a study known as CIRB R0436: A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients With Esophageal Cancer Who Are Treated Without Surgery

4. *Who will be able to use my health information?*

The Northwest CCOP will use your health information for research. As part of this research, they may give your information to the following Groups taking part in the research. The Northwest CCOP may also permit staff from these Groups to review your original records as required by law for audit purposes.

the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
Radiation Therapy Oncology Group (RTOG)
public health agencies and other government agencies (including non-U.S.) as authorized or required by law
other people or organizations assisting with CTSU research efforts and the Food and Drug Administration
central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed above.

5. *How will information about me be kept private?*

The CTSU will keep all identifiable health information confidential to the extent possible, even though they and other federal research groups are not subject to the same federal privacy laws governing clinical centers. The CTSU will not release identifiable health information about you to others except as authorized by this form, or required by law. If your identifiable health information must be shared with other organizations, the privacy laws that govern those organizations would apply.

6. *What happens if I do not sign this authorization form?*

If you do not sign this authorization form, you will not be able to take part in a research study for which you are being considered.

7. *If I sign this form, will I automatically be entered into the research study?*

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a separate research consent form.

8. *What happens if I want to withdraw my authorization?*

You can change your mind at any time and withdraw this authorization. This request for withdrawal must be made in writing. Beginning on the date you withdraw your authorization, no new identifiable health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your authorization, you will be removed from the research study at that time.

To withdraw your authorization, please contact the person below. She will make sure your written request to withdraw your authorization is processed correctly.

Karyn Hart, RHIT, CCRP
Clinical Research Associate Supervisor
Northwest CCOP
315 Martin Luther King Jr., Way
Tacoma, WA 98405
(253) 403-1461

9. How long will this authorization last?

If you agree by signing this form that researchers can use your identifiable health information, this authorization has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding my identifiable health information?

You have the right to refuse to sign this authorization form. You have the right to review and/or copy records of your health information kept by the Northwest CCOP. You do not have the right to review and/or copy records kept by the CTSU or other researchers associated with the research study.

Signatures

I agree that my identifiable health information may be used and disclosed for research purposes described in this form.

Signature of Patient or Patient's Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Authorization: _____

Printed Name of Person Obtaining Authorization: _____