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Sponsored and Funded by the National Cancer Institute

## **CONSENT FORM**

**CIRB N0147, A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5  
Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after  
Curative Resection for Patients with Stage III Colon Cancer**

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**CIRB N0147, A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5 Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer**

**PARTICIPANTS:**

**This is an important form. Please read it carefully. Your signature on this form also means that you agree and want to take part in this study.**

**Why is this study being done?**

This study is being done in patients who have had surgery for colon cancer.

The study is being done to:

- ◆ Find out if adding cetuximab to FOLFOX (a combination of the 3 drugs oxaliplatin, leucovorin and 5-fluorouracil) increases the effectiveness of FOLFOX in preventing your colon cancer from coming back.
- ◆ See whether patients get better results in one of these groups.
- ◆ Compare the side effects in the two groups of patients in the study.
- ◆ We will look at markers in tissue or blood specimens obtained from you to determine whether these markers can be used to predict whether your tumor responds to chemotherapy or the chance that your cancer will come back. These studies are for research purposes and have not been accepted into routine medical practice.

As of June 2008 it became apparent that a change within the genes of the tumor can better help predict who may be likely to benefit from cetuximab. Changes in a gene called KRAS have been shown to greatly lessen or prevent any benefit from the use of cetuximab. Based on this new finding this trial will now treat only new patients that have the normal (wild-type) version of the KRAS gene. In order to determine if you have a normal (wild-type) version of KRAS the assessment of KRAS in this trial uses a test that is a version of one widely used and generally considered reliable outside of clinical trials. However, it is important to note that no test for KRAS assessment has yet been approved by the Food and Drug Administration (FDA).

On the other hand, if the test shows that you have an abnormal (mutated) version of KRAS it means that you may not benefit from cetuximab and therefore will not receive treatment as part of this trial. It is important to note that the changes in the KRAS gene occur only in the tumor and not in normal cells of the body. As such, having a mutated gene for KRAS in your tumor does not mean that you received an abnormal gene from your parents or have the ability to pass the abnormal gene on to your children. The abnormal gene, when present, is only in the tumor.

Patients that have an abnormal (mutated) version of the KRAS gene may receive treatment outside of this study as determined by their physician. This study will not determine or provide treatment for these patients. Instead, yearly reports about the patient's treatment and health will be submitted for this study. Also, if KRAS status cannot be determined using the tissue that has been submitted, patients can receive treatment determined by their physician outside of this study, and yearly reports will be submitted for the study.

**The two drug combinations being studied in patients with a normal (wild-type) version of KRAS are listed below.** The drugs listed in Arm A, oxaliplatin (OXAL), 5-fluorouracil (5-FU) and leucovorin (CF) are considered standard of care. The combination of drugs in Arm D is considered experimental in the stage of colon cancer that you have because of the addition of cetuximab:

**Arm A:** OXAL, 5-FU, and CF

**Arm D:** Arm A + Cetuximab (*Cetuximab was discontinued as of November 25, 2009*)

Note: Arms B, C, E and F, which contained the drug irinotecan (CPT-11) are no longer part of the study as of June 1, 2005.

**Arm G of this study will include patients with an abnormal (mutated) version of KRAS, and patients whose KRAS status could not be determined from submitted tissue.** These patients may receive treatment determined by their physician (treatment is not given as part of this study). Yearly reports will be sent to NCCTG about the treatment that has been given, and the patient's overall health.

It is not possible at this time to know whether treatment given in this study will prevent your cancer from coming back.

#### **How many people will take part in the study?**

The plan is to have 3768 people take part in this study.

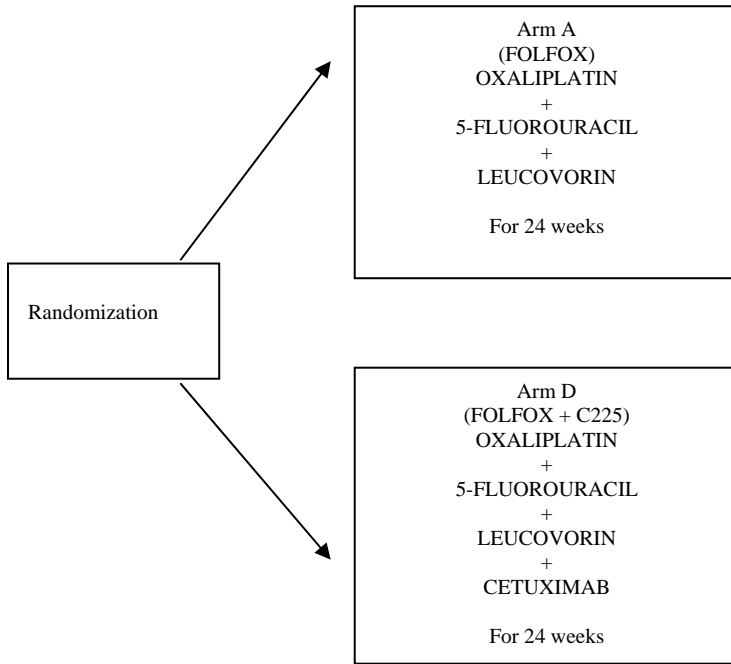
#### **What will happen in the study?**

**For all patients enrolled after July 2008:** You will first provide samples of your blood and tissue for use in this study. The tissue used will be from your surgery, so you will not have another procedure to collect this tissue. KRAS testing will be done on your tissue to determine whether you will be randomized to one of the two treatment arms (Arm A or D), or whether you will receive treatment outside of the study and have yearly reports submitted for the study (Arm G).

Besides KRAS testing, this study also involves other required tests using your blood and tissue blocks from your surgery. The required blood and tissue tests will be done for all patients (Arms A, D, and G). In addition, there is an optional tissue collection if your cancer comes back and you have surgery to remove it. The work to be done on these samples is described later in this consent form. You have the option to learn the result of one of the tests, called 'Immunohistochemistry testing' or 'IHC'. If you wish to receive this result there is a separate letter you will need to sign.

You also have the option to allow your samples to be kept by NCCTG for use in future research outside of this study. Your options regarding future use of your samples outside of this study are described later in this consent form.

**If your KRAS result is normal (wild-type)**, you will be put into one of the two study treatment groups by chance (as in the flip of a coin). This is called randomization. A computer will decide which group you will be in. One group will be treated with Oxaliplatin, 5-FU, and CF for 24 weeks. The other group will receive Oxaliplatin, 5-FU, and CF with cetuximab added to the treatment. Both groups will receive study drugs. That is, no placebo (sugar pill) will be used. Treatment will require the placement of an IV tube into a vein under the skin of the chest wall.



You will have two follow-up colonoscopies. These will be done one year and four years after your surgery.

**The following table tells you what tests, examinations, and treatments you will have if your KRAS result is “wild-type”.**

Within 30 days prior to randomization	<ul style="list-style-type: none"> <li>◆ Chest x-ray (may be done within 8 weeks before randomization)</li> <li>◆ US, CT or MRI scan (may be done within 8 weeks before randomization)</li> <li>◆ Discuss patient/physician fact sheet and patient instructions for preventing and treating diarrhea with doctor</li> <li>◆ Discuss IHC test results letter with doctor</li> </ul>
Within 28 days prior to randomization	<ul style="list-style-type: none"> <li>◆ Routine physical exam</li> <li>◆ Blood tests to verify eligibility</li> <li>◆ Collection of tissue blocks/slides</li> </ul>
Within 7 days prior to randomization	<ul style="list-style-type: none"> <li>◆ Blood pregnancy test for females who are able to become pregnant</li> </ul>
Groups A and D: Oxaliplatin/5-FU/CF Treatment Cycle	<ul style="list-style-type: none"> <li>◆ Day 1 treatment with Oxaliplatin and CF, IV (into a vein) for two hours</li> <li>◆ Day 1 5FU IV (into a vein) injection and then continuing with 5FU IV via a small portable pump for 46 hours</li> <li>◆ Treatment cycles are two weeks, treatment is for twelve 2-week cycles totaling 24 weeks.</li> </ul>
Follow-up (beginning after you have completed study treatment)	<ul style="list-style-type: none"> <li>◆ Research blood draw done only once during follow-up (Arm A or D only)</li> <li>◆ Routine physical exam, blood tests, every six months for the next five years or until recurrence, whichever occurs first.</li> <li>◆ Chest x-ray, or MRI scan every six months or CT at least yearly</li> <li>◆ Colonoscopy one year and four years after surgery.</li> </ul>

**If your KRAS result is “mutant” or not able to be determined,** you will be enrolled to Arm G and may receive treatment determined by your physician, outside of this study. Your physician will send yearly reports to NCCTG about your treatment and how you are doing. You will not need to have any additional procedures as part of this study.

**How long will I be in the study?**

This study will have an eight-year follow-up for all patients (Arms A, D, and G).

If you receive study treatment on Arm A or D, the length of time that you receive study treatment will depend on how you do with the drugs and how your cancer acts. Even if you stop taking the study drugs, the study doctors will still want to keep in touch with you as described in the ‘Follow-up’ row of the table above.

### **Are there reasons I might leave the research study early?**

Taking part in this research study is your decision. You may decide to stop at any time. You should tell the researcher if you decide to stop and you will be informed if any additional tests may need to be done for your safety.

In addition, the researchers may stop you from taking part in this study at any time if it is in your best interest, if you do not follow the study rules you will be given, or if the study is stopped.

### **What are the risks of the study?**

**For all patients:** Possible risks related to drawing blood may involve discomfort, a risk of bleeding, bruising, or infection at the needle site.

**Risks for older patients (age 70 and greater):** There is a higher likelihood of severe or life-threatening side effects, or death, for patients 70 years of age and older in both Arm A and Arm D compared to younger patients. However, this risk is greater for those 70 and older who receive treatment as part of Arm D. These side effects may develop shortly after starting therapy or may occur toward the end of the planned 6 months of therapy. The potential side effects from the treatment are outlined in detail below. However, if you experience diarrhea that is not easily controlled with a medication such as Imodium you should contact your doctor right away or go to an emergency room. It is also important to let your doctor know if you start to have any breathing problems. Breathing problems may occur toward the end of the 6 months of treatment or even after you have finished all of the treatment. Finally, should you have any concerns about how the therapy is making you feel it is important that you talk to your doctor. It is very important to identify side effects while they are still mild and treat them so they do not become severe or life-threatening.

### **(The following risks apply to patients in Arms A and D)**

If you receive study treatment on Arm A or D in this study, you are at risk for these side effects. You should talk to the researcher and/or your medical doctor about these side effects. There also may be other side effects that are not known. Side effects may range from mild to life-threatening. Other drugs may be given to make side effects less serious and uncomfortable. As with any medication, allergic reactions are a possibility. Many side effects go away shortly after the study drugs are stopped, but in some cases side effects can be serious, long lasting, or may never go away. Although small, there is always a risk of death.

While you are receiving oxaliplatin you should avoid cold drinks, very cold food, and being in cold air as it may make some of your side effects, such as numbness, worse.

### **FOLFOX Side Effects (Arm A, Arm D)**

#### Very Likely

- Low white blood cells (may make you more likely to get infections)
- Low platelets (may make you more likely to have bruising or bleeding)
- Anemia (Low red blood cells which may make you feel tired or weak)
- Fatigue or difficulty sleeping
- Nausea and vomiting lasting 24-48 hours following completion of the chemotherapy
- Diarrhea
- Loss of appetite/weight loss
- Mouth sores

- Numbness or tingling of the hands, feet, mouth and/or throat that can be made worse by cold weather, very cold food, or cold drinks
- Joint or muscle pain
- Abdominal pain or cramps
- Irritation of intestines
- Irritation of the esophagus (swallowing tube)
- Infection
- Fever
- Involuntary movement/restlessness
- Dehydration
- Nail changes
- Skin darkening
- Hearing changes or ringing in the ears, which could include ear pain or dizziness
- Change in taste
- Cough or hiccups
- High blood pressure
- Hot flashes/flushes
- Bleeding
- Dizziness or fainting
- Depression
- Allergic reaction or hypersensitivity to the drug infusion

#### Less Likely

- Flu-like symptoms such as fevers, chills, and muscle aches
- Dry or watery eyes, nasal stuffiness
- Pain or irritation of the vein or skin in the area where the drug is injected
- Allergic skin reaction (hives, welts or wheals)
- Temporary vision changes, especially when exposed to cold
- Eye pain
- Temporary blindness
- Damage or dysfunction of the liver or kidney
- Constipation
- Shortness of breath or wheezing
- Rash or redness of the skin
- Dry skin/itching
- Headache
- Intestinal blockage
- Flatulence (intestinal gas)
- A loss of phosphorus, sodium, magnesium, phosphate, calcium and/or potassium from the blood that may cause a sense of weakness or muscle cramps. If symptoms occur, replacement may be necessary using either pills or intravenous treatment.
- High or low levels of sugar in the blood (hyperglycemia/hypoglycemia)
- Inflammation of the lungs
- Blistering of the palms of the hands and soles of the feet (hand-foot skin reaction)
- Swelling of the head and neck, arms or legs
- Low blood pressure
- Problems with blood clotting
- Sweating
- Weight gain
- Dry mouth
- Difficulty swallowing (dysphagia)
- Inflammation of the stomach or pancreas
- Heartburn/dyspepsia
- Ulcer
- Anxiety

- Voice changes
- Frequent/urgent urination
- Temporary hair loss

Rare, but serious

- Death
- Confusion or memory loss
- Speech impairment, such as slurred speech
- Damage or build-up of scar tissue in lungs, which could interfere with breathing
- Stroke
- There have been 3 deaths reported in older patients who had developed weakness, diarrhea, and low blood pressure. These deaths may have been the result of dehydration that was caused by the diarrhea, and an infection. It is important that the occurrence of diarrhea be promptly reported to your physician.
- A breakdown of red blood cells and kidney failure known as the hemolytic uremic syndrome.
- Heart attack or chest pain
- Lung failure
- Blood clot, which can go to the lungs
- Abnormal heartbeat
- A rare serious side effect, veno-occlusive disease of the liver (VOD), occurred when oxaliplatin and 5-fluorouracil were given in combination. VOD is a disease that sometimes occurs after high-dose chemotherapy or radiation in which the blood vessels that carry blood through the liver become swollen and clogged.
- Disseminated intravascular coagulation (DIC), a condition where abnormal blood clotting and bleeding occurs

**Oxaliplatin Side Effects:**

Likely:

- Increased blood level of a liver enzyme (ALT/SGPT or AST/SGOT)
- Inflammation (swelling, irritation, or redness) or deterioration of your nerves outside of brain and spinal cord which may cause numbness, tingling, or burning

Less Likely:

- Irritation or sores in the lining of the mouth or difficulty/limitation in ability to open mouth
- Inflammation in the middle ear
- Seizures
- Destruction of tissue or ulcer somewhere in the digestive tract
- Loss of muscle coordination; awkward, uncoordinated walk or walking difficulties, such as limp
- Pain: stomach, joint, back, bone, muscle, or chest (not heart related)
- Temporary blindness of one eye due to blockage (or decreased blood flow) in the blood vessels leading to that eye
- Inflammation of a vein, or damage to the tissue in the area where the drug is injected
- Skin rash with the presence of macules (flat discolored area) and papules (raised bump)
- Hives
- Sudden reddening or swelling of the face and/or neck
- Depression
- Weight loss
- Chills
- Dehydration
- Fever, including a fever associated with dangerously low levels of a type of white blood cell (neutrophils)
- Hot flashes

- Decreased number of white blood cells (lymphocyte, neutrophil/granulocyte) or total number of white blood cells (leukocytes)
- Destruction of red blood cells
- Abnormal reaction of the body to substances, called allergens, that are contacted through the skin, inhaled into the lungs, swallowed, or injected (allergic reaction)
- Increased blood level of a liver enzyme (GGT), a liver or bone enzyme (alkaline phosphatase), or a liver pigment (bilirubin), which is often a sign of liver problems
- Increased blood level of creatinine (a substance normally eliminated by the kidneys into the urine)
- Increased INR (measure of the ability of the blood to clot properly) which increases the risk of bleeding
- More acid than normal in the blood, including uric acid (a waste material from food digestion)
- Decreased levels of a blood protein called albumin
- Problems with eye lids
- Inflammation around the nerve in the back of the eye, which could lead to problems with vision
- Inflammation of the conjunctiva (the outermost layer of the eye and the inner surface of the eyelids). This is commonly called “pink eye”.
- Temporary vision problems caused by the cold
- Confusion
- Feeling of imbalance, lightheadedness, or unsteadiness (dizziness)
- Hearing loss
- Taste changes
- Loss of appetite
- Sinus problems
- Accumulation of fluid in the abdomen (ascites)
- Stomach pain
- Bleeding with a decreased number of blood cells that help to clot blood (platelets)
- Bleeding in the respiratory tract, kidney, prostate, reproductive organs (e.g., vagina, testes), digestive tract or brain
- Inflammation of the esophagus (tube that carries food from the mouth to the stomach), the stomach lining, the small or large bowel (colon), or pancreas (otherwise known as pancreatitis)
- Partial or complete blockage of the small and/or large bowel. Ileus is a functional rather than actual blockage in the bowel.
- Weakness or paralysis (loss of muscle function) caused by damage to peripheral nerves outside brain and spinal cord, including facial, head and neck muscles
- Decreased blood flow to the brain which may lead to stroke
- Problems with speech, such as restless, repetitive, or involuntary movements and rapid speech
- Increases/decreases in blood pressure
- Inability to fall or remain asleep
- Sleepiness
- Blood in the urine
- Difficulty emptying or retaining urine in the bladder
- Inflammation or damage (scarring) to the lung, which could interfere with breathing
- Sneezing
- Cough
- Hiccups
- Sudden constriction of the muscles in the walls of the bronchioles (small airways of the lung)
- Higher risk of blood clots including formations of clots that can break loose, move through the blood stream, and block another blood vessel

- Abnormal heartbeat that could include slow, fast, regular or irregular rhythm. **May be life-threatening, needs immediate attention.**
- Infections (bacterial, fungal, viral, or other unusual infections) that could be life-threatening
- Liver and/or kidney damage or failure

Rare, but serious

- Formation of blood clots in small blood vessels around the body that leads to a low platelet count
- Gas in the intestinal (bowel) wall
- Inflammation of the gallbladder possibly associated with gall stones
- Sudden or traumatic injury to the kidney
- Swelling and redness of the skin on the palms of the hands and soles of the feet
- Severe potentially life-threatening damage to the lungs, which could lead to fluid in the lungs

**Cetuximab Side Effects (Arm D) (*discontinued as of November 25, 2009*)**

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 macules (flat discolored area) and papules (raised bump)

Less Likely

- Lack of enough red blood cells (anemia)
- Inflammation (swelling and redness) of the skin of outer ear and canal
- Noise in the ears, such as ringing, buzzing, roaring, clicking
- Inflammation (swelling and redness) of the conjunctiva (the outermost layer of the eye and the inner surface of the eyelids). Commonly called "pink eye".
- Dry eye
- Inflammation (swelling and redness) of the middle layer of the eye (uvea)
- Excessive tearing in the eyes
- Belly pain
- Inflammation (swelling and redness) 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.
- 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
- Sore 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.
- 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 that can be life-threatening
- Swelling and redness of the skin on the palms of the hands and soles of the feet

Additional risk information for protocols involving chemotherapy and cetuximab in patients with advanced NSCLC

- In clinical trials involving patients with advanced, non-small cell lung cancer, the combination of cetuximab and chemotherapy may increase the risk of life-threatening complications, some of which may be fatal, in elderly patients (65 years old or more), particularly those with pre-existing cardiac disease.

**Intravenous Injection Side Effects:** If the drug leaks from the vein the shot is given into, it may cause sores on the skin or severe local redness, pain, and/or swelling.

**Allergic Reactions:** As with any medication, there is the chance of an allergic reaction.

**This study may hurt an unborn or breast-fed child.** There is not enough medical information to know what the risks might be to a breast-fed infant or to an unborn child of a man or woman who takes part in this study. Men who are able to father a child and women who can become pregnant must use birth control plans while you are receiving study treatment ***and for at least 60 days after the last dose of cetuximab.*** Breast-feeding mothers must stop breast-feeding to take part in this study. Women who can become pregnant must have a pregnancy test before taking part in this study. If you are a woman who can become pregnant, blood will be taken from a vein in your arm with a needle within 7 days before you enter the study. You will be told if you are pregnant or not.

If you are pregnant, you will not be able to take part in the study. In addition, the effects of cetuximab last up to 2 months (60 days). It is therefore important that if you take part in this study and receive cetuximab that you do not try to become pregnant or father a child for at least 60 days after completing your therapy.

**Are there benefits to taking part in this research study?**

No benefit can be guaranteed by taking part in this study and the chance of knowing whether or not you will receive any benefits from the study is not able to be accurately predicted.

**What other choices do I have if I don't take part in this research study?**

- The standard recommended treatment for your cancer is to perform the surgery you have already undergone and then to take treatment with FOLFOX chemotherapy for six to seven months.
- All of the drugs in this study are approved for use in people with colon cancer in North America outside of enrollment in this study (although cetuximab is not approved for the stage of colon cancer that is being looked at in this study). Therefore you can get access to standard and alternative treatments without enrolling in this trial.

**Will I need to pay for the tests and procedures?**

**For all patients:** The costs of drawing blood for research purposes and performing KRAS, IHC, and all other research testing, will be covered by the study.

**For patients on Arm A or D:**

The drug cetuximab will be provided free of charge through NCI; however, you may still need to pay for the cost of having cetuximab made ready for your use.

Oxaliplatin will be provided through NCI for patient's enrolled before 7/8/09. For patients enrolled on or after 7/8/09, oxaliplatin will be obtained commercially. If your insurance does not cover the cost of oxaliplatin, Sanofi-Aventis has a program to provide it for you free of charge. Information regarding the PACT+ program is available on the world wide web at <http://www.oncology.sanofi-aventis.us/docs/pdf/Pact+SM%20Program%20Services.pdf>.

You and/or your health plan will need to pay for all costs associated with the FOLFOX (5-fluorouracil and leucovorin) treatment. You and your health plan might also have to pay for other drugs or treatments that are given to help you control side effects. Before you take part in this study, you should call your health insurer to find out if the cost of these tests and/or procedures will be paid for by the plan. Some health insurers will not pay for these costs. You will have to pay for any costs not covered by your health insurer.

You may find a National Cancer Institute guide: "Clinical Trials and Insurance Coverage – a Resource Guide" helpful in this regard. You may ask your doctor for a copy, or it is available on the world wide web at <http://cancer.gov/clinicaltrials/insurance>.

Every effort will be made to ensure that adequate supplies of cetuximab are available free of charge for all who take part. If, however, cetuximab becomes commercially available for how it is used in this study while you are being treated, there is a possibility that you and/or your health plan would be asked to purchase subsequent supplies.

### **What happens if I am injured because I took part in this research 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 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 this medical treatment.

### **What are my rights if I take part in this research study?**

Taking part in this research 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 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. 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?**

You may talk to your study doctor at any time about any questions or concerns you have on this study.

You can get further information about policies, the conduct of this study, or the rights of research subjects from the MultiCare Health System Investigational Review Board at 253-403-3877.

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

### **Where can I get more information about clinical trials?**

You may call the NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615.

Visit the NCI Web site: [For clinical trials go to http://cancer.gov/clinicaltrials](http://cancer.gov/clinicaltrials)  
[For cancer information go to http://cancer.gov/cancerinformation](http://cancer.gov/cancerinformation)

### **What about confidentiality?**

Information from this study may be published or presented at scientific meetings. However, your name and other identifying information will not be sent outside of NCCTG without written permission unless the law allows it. Your medical record will be used by the researchers in this study. Representatives of North Central Cancer Treatment Group (NCCTG) will be able to look at your medical records to check the accuracy of the forms completed for the study. Information from your medical records may also be made available to the Food and Drug Administration, the Cancer Trials

Support Unit (CTSU; a research group sponsored by the National Cancer Institute [NCI] to provide greater access to cancer trials), the National Cancer Institute (NCI) and its authorized representatives and its collaborators, NCI Central Institutional Review Board, other U.S. government agencies including the Office for Human Research Protections or other offices within the Department of Health and Human Services, and/or the Office of the Inspector General.

**What is being done with my blood and tissue samples?**

*This section applies to all patients – Arms A, D, and G (except for optional recurrent tissue)*

Before it is determined which arm of the study you will be in, samples of your blood (about two tablespoons) and tissue blocks from your surgery will be collected. After you go off or complete treatment, samples of your blood (about two tablespoons) will be collected at your next follow-up visit (Arm A or D patients only). These samples are required for the study and will be used to look at characteristics of your tumor that may be the result of your genes. Also, if your cancer comes back (Arm A or Arm D patients only) and you have surgery to remove it, we would like to use leftover tissue samples from this surgery for additional research. You will not need an additional biopsy done. These tissue samples from surgery to remove cancer that has come back are not required, but we strongly encourage you to provide them. Because the research tests in this study are not used for regular medical care, the test results will not be put in your medical record. You will be given the option of learning the results of some testing (IHC) that researchers are doing on part of your colon tumor. If you wish to receive this result there is a separate letter you will need to sign. Your physician will tell you how to get genetic counseling, if this is needed. You are being offered this test result because the test result may be useful in selected families. All results from such tests will be kept confidential and known only to the principal investigators for the clinical and research portions of the study and the lead statistician.

*Please read the following statement and mark your choice:*

If my cancer comes back and I have surgery to remove it, I agree to provide tissue sample(s) to NCCTG for research testing planned as part of this study.

Yes       No      Please initial here: \_\_\_\_\_      Date: \_\_\_\_\_

**Will any biological sample(s) be stored and used in the future for other studies by the North Central Cancer Treatment Group (NCCTG)?**

Yes, if you agree to let us do so. Another part of this research study is storing samples of your blood and tissue for future research studies. Future research studies may be done to learn more about colorectal cancer or other diseases. The samples may be stored indefinitely. You can decide whether or not your stored samples are used in future research outside of this study. You can still take part in this treatment study without having your samples be used for future research outside of this study.

If you change your mind about allowing your samples to be stored for future research outside of this study, and want the sample to be destroyed or returned to you contact your study doctor.

Your samples will be stored safely at NCCTG and will be given a code (rather than your name) when used in research. This code will allow your samples to be used without anyone knowing that it is yours just by looking at the label.

Your samples will be used only for research and will not be sold. You will not be paid for allowing your samples to be used in research even though the research done on the samples may help to develop new products in the future.

Sometimes blood and tissue are used for genetic research (research about diseases that are passed on in families). Even if your samples are used for genetic research, the findings will not be linked with your medical records and they will not be given to people outside of the research process.

***Please read the following statements and mark your choice:***

1. I permit my samples (blood and tissue) to be stored and used in future research of colorectal cancer.

Yes       No      Please initial here: \_\_\_\_\_      Date: \_\_\_\_\_

2. I permit my samples (blood and tissue) to be stored and used in future research to learn about, prevent, or treat any other health problems:

Yes       No      Please initial here: \_\_\_\_\_      Date: \_\_\_\_\_

NCCTG has the right to end storage of the sample without telling you.

The samples will be stored at NCCTG. Outside researchers may one day ask for a part of your samples for studies now or future studies.

Researchers from universities, hospitals, and other health organizations do research using blood and tissue. They may contact NCCTG and ask for samples for their studies. NCCTG looks at the way that these studies will be done, and decides if any of the samples can be used. NCCTG sends the blood and tissue samples and some general information about you and your health (such as stage/disease, age, sex, etc.) to the researcher. NCCTG will not send your name, address, phone number, social security number, or any other identifying information to the researcher. If you allow your samples to be given to outside researchers, it will be given to them with a code number. If researchers outside NCCTG use the samples for future research, they will decide if you will be contacted and, if so, they would have to contact you through the researchers at NCCTG.

3. I permit NCCTG to give my samples to outside researchers:

***Please mark one box:***

Yes       No      Please initial here: \_\_\_\_\_      Date: \_\_\_\_\_

**I have had an opportunity to have my questions answered. I have also been given a copy of this form. I agree to take part in this research study.**

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Printed Name of Participant)

\_\_\_\_\_  
(Signature of Participant)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Printed Name of Individual Obtaining Consent)

\_\_\_\_\_  
(Signature of Individual Obtaining Consent)

## **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 CTSU N0147: A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer.

**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
- 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: \_\_\_\_\_