

**Northwest Community Clinical Oncology Program (NWCCOP)**  
**MultiCare Health Research Institute**  
**315 Martin Luther King Jr. Way**  
**Tacoma, WA 98405**  
**Phone: (253) 403-1461**  
**Fax: (253) 403-1615**  
Sponsored and Funded by the National Cancer Institute

### CONSENT FORM

**CIRB S0600: Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab (NSC-714692) or Bevacizumab (NSC-704865) as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with Either FOLFOX, OPTIMOX or XELOX.**

#### INVESTIGATORS:

Lauren K. Colman, MD, Chris Chen, MD, Xinda Wang, MD, Daniel Moore, MD, Troy Wadsworth, MD, Katharine Barford, MD and Umesh Chitale, MD, 1003 South 5th Street-3<sup>rd</sup> Floor, Tacoma, WA 98405 (253) 403-1677.

Robert McCroskey, MD, Sibel Blau, MD, Andrea Rose, MD, 400-15<sup>th</sup> Avenue SE, Puyallup, WA 98372 (253) 841-4296.

Frank Senecal, MD, Thomas Baker, MD, Lorrin Yee, MD, Moacyr Oliveira, MD 1624 South I Street, Tacoma, WA 98405 (253) 383-3366.

Paul Robertson, MD, Steven Gorton, MD, James Lechner, MD, Harry Griffith, MD, Xingwei Sui, MD, 4525 Third Ave. SE, Suite 200, Lacey, WA 98503 (360) 754-3934.

Dustan Osborn, MD, Robert Witham, MD, Nicole Grous, MD, Min Kang, MD, 3920 Capital Mall Drive SW, Suite 100, Olympia, WA 98502 360-753-4700 and 222-2<sup>nd</sup> Street NE, Suite B, Auburn, WA 98002 (253) 887-9333.

John Rieke, MD, Suraj Singh, MD, Carolyn Rutter, MD, 1003 South 5<sup>th</sup> Street, 1st Floor, Tacoma, WA 98405 (253) 403-4994.

Michael Liao, MD, 400 -15<sup>th</sup> Ave SE, Puyallup, WA 98372 (253) 697-4829

Oliver A. Batson, MD, James Congdon, DO, Mark Coughenour, MD, Peter Y.Z. Jiang, MD, Elie P. Saikaly, MD, Luke N. Walker, MD, Xiaowen Wang, MD, Steve F. Adam, MD, B. Sharon Cole, MD, Darren J. Little, MD, William Wisbeck, MD, Thomas J. Smith, MD, 1717 13<sup>th</sup> Street, Third Floor, Research, Everett, WA 98201 (425) 297-5532

James Pelton, MD, William Reece, MD, Tanya Wahl, MD, Kathryn Crossland, MD, 11135 116<sup>th</sup> Avenue NE #230, Third Floor, Research, Bellevue, WA 98201 (425) 454-2148

**CIRB S0600: Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab (NSC-714692) or Bevacizumab (NSC-704865) as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with Either FOLFOX, OPTIMOX or XELOX.**

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 colorectal cancer that has spread and that has not responded to prior treatment that included bevacizumab.

### **Why is this study being done?**

**The purpose of this study is to compare the effects, good and/or bad, of bevacizumab or cetuximab when added to an irinotecan-based treatment. We want to know the effects of these drugs on you and your colorectal cancer to find out which is better.**

**Bevacizumab is considered investigational in this study. The other drugs used in this study are not considered investigational.**

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

About 620 people will take part in this study.

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

#### **Treatment Plan**

You will either receive irinotecan by itself or “FOLFIRI”, which is a combination of drugs. It is up to you and your study doctor whether you receive irinotecan or FOLFIRI.

If your doctor suggests irinotecan by itself, this will be given to you every 3 weeks by an IV (into your vein) over 90 minutes.

If your doctor chooses FOLFIRI, this will be given to you every 2 weeks. FOLFIRI includes the following drugs: irinotecan (IV for 90 minutes), then leucovorin (IV for 2 hours), then a 2-4 minute injection of 5-FU, then 5-FU (IV for 46-48 hours). The 46-48 hours of 5-FU will be a continuous IV infusion given through an outpatient infusion pump. You may require placement of a special central venous catheter. Should you need a catheter, your doctor will discuss the risks associated with catheter placement.

In addition to receiving irinotecan or FOLFIRI, 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 a one in two chance of being placed in either group. (12/29/08) You will be told what group you are in.

### GROUP 1

If you are in Group 1 (often called "Arm A"), you will receive cetuximab weekly. (12/29/08) When it is given on the same day as irinotecan or FOLFIRI it will be given first. This will be given to you by IV. The first time the cetuximab is given, it will take 2 hours. After that, it will only take 1 hour. The summary below may help explain the treatment schedule.

<u>EITHER:</u>	<u>OR:</u>
<ul style="list-style-type: none"><li>• Cetuximab (1-2 hours) every week</li></ul>	<ul style="list-style-type: none"><li>• Cetuximab (1-2 hours) every week</li></ul>
<ul style="list-style-type: none"><li>• Irinotecan (90 minutes) every 3 weeks</li></ul>	<ul style="list-style-type: none"><li>• Irinotecan (90 minutes) every 2 weeks</li></ul>
	<ul style="list-style-type: none"><li>• Leucovorin (2 hours) every 2 weeks</li></ul>
	<ul style="list-style-type: none"><li>• 5-FU (2-4 minutes) every 2 weeks</li></ul>
	<ul style="list-style-type: none"><li>• 5-FU (46-48 hours) every 2 weeks</li></ul>

### GROUP 2

If you are in Group 2 (often called "Arm B"), you will receive bevacizumab. If you are receiving irinotecan, bevacizumab will be given every 3 weeks. If you are receiving FOLFIRI, bevacizumab will be given every 2 weeks. The bevacizumab IV takes 30 minutes, but if you had previous infusion-related adverse events with bevacizumab, your IV infusion may take longer. The summary below may help explain the treatment schedule.

<u>EITHER:</u>	<u>OR:</u>
(12/29/08)	(12/4/08)
<ul style="list-style-type: none"> <li>• Bevacizumab (30 minutes) every 3 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• Bevacizumab (30 minutes) every 2 weeks</li> </ul>
<ul style="list-style-type: none"> <li>• Irinotecan (90 minutes) every 3 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• Irinotecan (90 minutes) every 2 weeks</li> </ul>
	<ul style="list-style-type: none"> <li>• Leucovorin (2 hours) every 2 weeks</li> </ul>
	<ul style="list-style-type: none"> <li>• 5-FU (2-4 minutes) every 2 weeks</li> </ul>
	<ul style="list-style-type: none"> <li>• 5-FU (46-48 hours) every 2 weeks</li> </ul>

### 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. These tests will all be performed in an outpatient setting.

- Physical exam
- Blood pressure
- X-rays and scans
- Blood tests for blood counts, clotting time, and kidney and liver function
- Urine tests for kidney function

### 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 may need the following tests and procedures. They are part of regular cancer care. These tests will all be performed in an outpatient setting.

- Physical exam – every 3 weeks if you are receiving irinotecan by itself (not FOLFIRI); every 2 weeks if you are receiving FOLFIRI
- Blood pressure
- X-rays and scans – every 6 weeks
- Blood tests – every 3 weeks if you are receiving irinotecan by itself (not FOLFIRI); every 2 weeks if you are receiving FOLFIRI
- Urine tests – before every other treatment with bevacizumab

### When I am finished taking the study drugs...

After you are finished taking the study drugs, you will have follow-up visits with the study doctor for up to 5 years from the time you started the study. If your disease did not get worse while you were on the study drugs, you will continue to have scans every 6 weeks during this

time. Otherwise, you will see the doctor every 6 months for the first 2 years, then every 12 months for 3 more years for lab tests and a physical exam.

If you are randomized to Arm B (the group that received bevacizumab), your doctor may decide to start treatment with cetuximab after you finish this study treatment.

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

You will be asked to continue taking the study drugs as long as your disease does not get worse and the side effects are not too bad. After you are finished taking the study drugs, the study doctor will ask you to visit the office for follow-up exams for up to 3 years, as explained above.

## **Can I stop being in the study?**

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the drugs can be evaluated by your doctor. Another reason to tell your 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 taking the drugs. 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 related to the irinotecan, 5-FU and leucovorin include those that are:**

#### ***Likely:***

- **decrease in the number of white blood cells, red blood cells and platelets that may lead to an increased risk of infection, fatigue, bruising and bleeding**

- **nausea, vomiting or diarrhea**
- **flu-like symptoms such as headache, fever, back pain, chills and cough**
- **tearing**
- **sweating**
- **loss of appetite**
- **bleeding from the gastrointestinal tract**
- **soreness or painful sores in the mouth, throat or esophagus**
- **loss of hair**
- **skin sensitivity when exposed to sunlight**
- **skin irritation around area where drug is given**
- **thinning of the skin**
- **dry skin, redness, rash**
- **nosebleed**
- **fingernail changes**
- **tingling of hands and feet followed by pain, redness and swelling**
- **dizziness**
- **confusion or disorientation**
- **changes in mood**
- **slurred speech**
- **uncontrolled eye movements, changes in vision, watering eyes**
- **pain, bruising, bleeding or infection at the site of the intravenous catheter**

*Less Likely:*

- **decrease of blood supply to the heart**
- **shortness of breath and painful breathing**
- **allergic reaction including rash and difficulty breathing**
- **swelling**
- **constipation**
- **sores in your mouth**
- **mild liver irritation**
- **abdominal cramps**
- **decrease in kidney function**

**Additional risks from bevacizumab:**

*Likely:*

- **Diarrhea**
- **Nausea or the urge to vomit**

- **Vomiting**
- **Fatigue or tiredness**
- **Headache or head pain**
- **High blood pressure**

*Less Likely:*

- **Lack of enough red blood cells (anemia)**
- **Fast heartbeat usually originating in an area located above the ventricles**
- **Feeling of spinning or whirling**
- **Belly pain**
- **Inflammation (swelling and redness) of the large bowel (colon)**
- **Constipation**
- **Heartburn**
- **Bleeding in some organ(s) of the digestive tract**
- **Partial or complete blockage of the small and/or large bowel. Ileus is a functional rather than actual blockage of the bowel.**
- **Irritation or sores in the lining of the mouth**
- **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**
- **Pain**
- **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**
- **Infection (collection of pus) around the rectum**
- **Premature opening of a wound along surgical stitches after surgery**
- **Increased blood level of a liver enzyme (ALT/SGPT)**
- **Increased blood level of a liver or bone enzyme (alkaline phosphatase)**
- **Increased blood level of a liver enzyme (AST/SGOT)**
- **Increased blood level of a liver pigment (bilirubin) often a sign of liver problems**
- **Increased blood level of a heart muscle protein (troponin I) indicating damage to the heart muscle**
- **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**
- **Joint pain**
- **Muscle pain**
- **Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)**
- **Fainting.**

- **Sudden decrease of kidney function.**
- **Blood in the urine.**
- **More protein leaking into the urine than usual, often a sign of kidney disease**
- **Bleeding in the vagina**
- **Cough**
- **Shortness of breath**
- **Nose bleed**
- **Hoarseness**
- **Stuffy nose**
- **Itching**
- **Skin rash**
- **Hives**
- **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:**

- **Damage of or clots in small blood vessels in the kidney that can cause complications, some of which are serious including abnormal destruction of red blood cells (hemolysis) or platelets (that help to clot blood) and kidney failure**
- **Collection of signs and symptoms that indicate sudden heart disease in which the heart does not get enough oxygen. Sudden symptoms such as chest pain, shortness of breath, or fainting could indicate heart disease and should be reported right away. Signs such as abnormal EKG and blood tests can confirm damage to the heart.**
- **Heart failure: inability of the heart to adequately pump blood to supply oxygen to the body**
- **Decrease in heart's ability to pump blood during the "active" phase of the heartbeat (systole)**
- **Heart attack caused by a blockage or decreased blood supply to the heart**
- **Irregular heartbeat resulting from an abnormality in the one of the lower chambers of the heart (ventricle)**
- **Ventricular fibrillation: irregular heartbeat that involves the lower chambers of the heart (ventricles) that results in uncoordinated contraction of the heart; life threatening and potentially fatal, needing immediate attention**
- **Gastrointestinal fistula: Abnormal hole between an organ of the digestive tract and another organ or tissue**
- **Gastrointestinal perforation : A tear or hole in the stomach or gut that can lead to serious complications and may require surgery to repair**
- **Sore (ulcer) somewhere in the digestive tract**
- **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.**

- **Leakage from stomach due to breakdown of an anastomosis (surgical connection of two separate body structures)**
- **Bleeding in the brain**
- **Stroke caused by decreased blood flow to the brain**
- **Abnormal changes in the brain that can cause a collection of symptoms including headache, confusion, seizures, and vision loss associated with MRI imaging findings (RPLS)**
- **A condition in which the kidneys leak a large amount of protein into the urine that can cause complications including swelling and kidney failure**
- **Kidney failure**
- **Abnormal hole between part of the urinary system and another organ or tissue**
- **Abnormal hole between the vagina and another organ or tissue**
- **Abnormal hole between the lower breathing tube and the body cavity that surrounds the lungs**
- **Bleeding from the lungs**
- **Hole in the wall that separates the nostrils of the nose**
- **Abnormal hole between the breathing tube (windpipe) and the tube that goes from mouth to stomach through which food passes (esophagus). This is life-threatening and potentially fatal.**
- **Blockage or narrowing of a blood vessel (artery) that can cause damage or loss of function including a heart attack or stroke**
- 

**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 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**

**Rare but serious incidents of heart problems such as chest pain, decreased heart function, heart attack, and irregular heart beats as well as blood tests that indicate possible damage to the liver have been observed in clinical trials with cetuximab, but we do not know if these incidents are related to cetuximab.**

**Reproductive risks: You should not become pregnant or father a baby or breast-feed a baby while on this study or within 4 months after you stop taking bevacizumab and cetuximab because they can affect an unborn or nursing baby. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.**

**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 these combinations of drugs 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 doctors learn more about these drugs as a treatment for cancer. This information could help future cancer patients.**

## What other choices do I have if I do not take part in this study?

**Your other choices may include:**

- **Getting treatment or care for your cancer without being in a study**
- **Taking part in another study**
- **Getting no treatment**
- **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.

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

- The Southwest Oncology Group
- The National Cancer Institute (NCI) and other government agencies, like the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), involved in keeping research safe for people
- Qualified representatives of the drug manufacturers Genentech and Bristol Myers Squibb/ImClone
- The Cancer Trials Support Unit (CTSU), a research group sponsored by the NCI to provide greater access to clinical 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.

Administration of the drugs will be *charged in the usual way*. The parts of the research consisting of keeping research records will be paid by those organizing and conducting the research. The research requires that you receive certain standard medical tests and examinations. These standard tests and examinations will be *charged in the usual way*.

Genentech will provide you with the bevacizumab free-of-charge for this study through the National Cancer Institute. Bristol-Myers Squibb/ImClone will provide you with the cetuximab free-of-charge for this study through the National Cancer Institute. Every effort will be made to ensure adequate supplies of both the bevacizumab and cetuximab, free-of-charge, for all patients. However, if you should need to take the study agent much longer than is usual, it is possible that the free supply of study agent given to the NCI could run out. If this happens, your study doctor will discuss with you how to obtain additional drug from the manufacturer and you may be asked to pay for it.

Irinotecan, 5-FU and leucovorin are commercially available.

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 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 and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about important new information from this or other studies that may affect your health, welfare, or willingness to stay in this 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 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: The following question is about additional research studies that may be 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 these additional studies.

You can say "yes" or "no" to the following question.  
Please mark your choice for each study.

### **Future Contact**

**I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.**

**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.

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: \_\_\_\_\_

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

### ***1. What is the purpose of this form?***

The **Southwest Oncology Group** 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 Southwest Oncology Group 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 Southwest Oncology Group 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 Southwest Oncology Group if you enter a Cooperative Group research study, or to evaluate your eligibility for a study. The Southwest Oncology Group researchers will use your information for the following cancer research study(ies).

**S0600**, "Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab (NSC-714692) with or without Bevacizumab (NSC-704865) as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with either FOLFOX, OPTIMOX or XELOX."

The purpose of this study is to compare the effects, good and/or bad, of not adding bevacizumab or of adding either a lower dose or a higher dose of bevacizumab to cetuximab plus an irinotecan-based treatment. We want to know the effects of these doses on you and your colorectal cancer to find out which is better.

Bevacizumab is considered investigational in this study. The other drugs used in this study are not considered investigational.

Bevacizumab is the common name for the commercial drug Avastin. The bevacizumab used in this trial, however, is for use in research studies only and may be made at locations different from those where Avastin is made. Although some differences may exist, bevacizumab for research use and the commercial drug, Avastin, are manufactured by a similar process, meet similar standards for final product testing, and are expected to be very similar in safety and effectiveness.

#### ***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 Southwest Oncology Group  
the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute 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 Southwest Oncology Group research efforts.  
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 Southwest Oncology Group 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 Southwest Oncology Group 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  
Program Coordinator  
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 Southwest Oncology Group 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: \_\_\_\_\_