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Sponsored and Funded by the National Cancer Institute

## **CONSENT FORM**

**CIRB NSABP R-04: A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum.**

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**CIRB NSABP R-04: A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum.**

**Why have I been asked to take part in this research study?**

You are being asked to take part in this study because you have rectal cancer. At this time, it is thought that the best way to treat your cancer is to give you treatment with drugs (chemotherapy) and radiation (radiotherapy) to try to shrink the tumor. After chemotherapy and radiotherapy, you will have surgery to remove any tumor that is left.

It is up to you to decide whether or not to take part in this study. Please read this entire consent form and take your time to make your decision. We encourage you to talk to your doctor, your family, and/or your friends before you decide.

**Who is conducting the study?**

If you decide to join this study, you will be taking part in a clinical trial being conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP). Clinical trials are studies designed to find better ways to treat diseases like cancer.

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

There are several reasons why this study is being done:

- This study is being done to see if taking a drug called capecitabine as a pill, twice a day by mouth during the weeks you receive radiation therapy, is as good as the standard treatment with the drug 5-fluorouracil (5-FU) given continuously into your vein during the weeks you receive radiation therapy.
- This study is also being done to see if adding oxaliplatin to capecitabine and 5-FU can improve how well these drugs work.
- At this time we do not know which chemotherapy drugs, when combined with radiation therapy, are better for the type of cancer you have.
- This study will also look at the four different treatment options by obtaining important information regarding quality of life.
- The final reason for doing this study is that the U.S. Food and Drug Administration (FDA) considers the use of both capecitabine and oxaliplatin to be investigational when given before surgery to remove cancer such as yours. Capecitabine and oxaliplatin in combination with radiation therapy must be tested further in patients with your type of cancer.

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

About 1,606 patients from many cancer treatment centers will take part.

## What is involved in the study?

*Before you begin the study:* To find out if you can join the study, you will need to have the following exams and medical tests. If you have had any of them recently, your doctor may decide not to repeat them:

- physical exam
- blood tests
- chest x-ray or CT scan
- CT scan, combined PET/CT scan, or MRI of the abdomen and pelvis
- exam of rectum and colon
- Transrectal ultrasound or endoluminal ultrasound or MRI with endocoil. One of these procedures will be used and includes the use of a probe to examine the rectum and record pictures of the rectal tumor. Your doctor will decide which of these tests is the best for you.

These exams and tests are part of standard good medical care even if you do not join this study. If you do join, some of these procedures may be done more often than if you were not taking part in the study. They may be done on an outpatient basis at your doctor's office or clinic, or in a hospital.

If you have not already had a sample of tissue (a biopsy) collected in a solution called RNAlater, you will be asked if you are willing to have an additional biopsy so that a sample of your tissue can be collected in this solution and used for research. This will only be done if you agree to have an additional biopsy. If you do not agree to have an additional biopsy, you can still take part in this study. If you do agree to have an additional biopsy, you or your insurance company will not be charged for it.

*During the study:* If the tests and exams show that you can be in the study, and you agree to take part, you will be assigned by chance (by a process called randomization) to one of four treatment groups. This means a computer program will put you in Group 1, Group 2, Group 3, or Group 4 by chance. Neither you nor your doctor will choose the group for you. You will have an equal chance of being placed in any of the four groups. Patients in Group 1 will receive 5-FU by continuous venous infusion and radiation therapy. Patients in Group 2 will receive oxaliplatin through a vein, 5-FU by continuous venous infusion, and radiation therapy. Patients in Group 3 will take the drug capecitabine by mouth and receive radiation therapy. Patients in Group 4 will receive oxaliplatin through a vein, capecitabine by mouth, and radiation therapy.

*If you are in Group 1:* You will receive 5-FU through your vein continuously over 24 hours/day 5 days a week on the days you are scheduled to receive radiation therapy. You will receive radiation therapy 5 days a week (not on weekends) for 5 to 6 weeks. Your doctor will need to put a temporary tube into a vein in your chest or arm so that you can receive the 5-FU continuously.

*If you are in Group 2:* You will receive oxaliplatin through a vein once every week for 5 weeks beginning on the first day of radiation therapy. You will also receive 5-FU through your vein continuously over 24 hours/day 5 days a week on the days you are scheduled to receive radiation therapy. You will receive radiation therapy 5 days a week (not on weekends) for 5-6 weeks.

Your doctor will need to put a temporary tube into a vein in your chest or arm so that you can receive the 5-FU continuously.

*If you are in Group 3:* You will take capecitabine twice a day by mouth (within 30 minutes after eating breakfast and dinner) 5 days a week on the days you are scheduled to receive radiation therapy. Your doctor may ask you to write in a diary or on a calendar each dose of capecitabine that you take. You will receive radiation therapy 5 days a week (not on weekends) for 5 to 6 weeks.

*If you are in Group 4:* You will receive oxaliplatin through a vein once every week for 5 weeks beginning on the first day of radiation therapy. You will take capecitabine twice a day by mouth (within 30 minutes after eating breakfast and dinner) 5 days a week on the days you are scheduled to receive radiation therapy. Your doctor may ask you to write in a diary or on a calendar each dose of capecitabine that you take. You will receive radiation therapy 5 days a week (not on weekends) for 5 to 6 weeks.

*For all patients:* You will have a physical exam and blood work every week while you are receiving therapy.

**Summary of study treatment:**

<b>Group 1</b>	<b>Group 2</b>	<b>Group 3</b>	<b>Group 4</b>
radiation therapy (RT) 5 days a week for 5-6 weeks  +  5-FU (given continuously through a vein 5 days a week throughout RT)  <i>followed by</i>  surgery	radiation therapy (RT) 5 days a week for 5-6 weeks  +  5-FU (given continuously through a vein 5 days a week throughout RT)  +  oxaliplatin (given through a vein once every week for 5 weeks throughout RT)  <i>followed by</i>  surgery	radiation therapy (RT) 5 days a week for 5-6 weeks  +  capecitabine (taken by mouth twice a day 5 days a week on the days you receive RT)  <i>followed by</i>  surgery	radiation therapy (RT) 5 days a week for 5-6 weeks  +  capecitabine (taken by mouth twice a day 5 days a week on the days you receive RT)  +  oxaliplatin (given through a vein once every week for 5 weeks throughout RT)  <i>followed by</i>  surgery

*For all patients:* Before you start your treatments, toward the completion of your radiation treatments, and 1 year after your surgery, you will be asked to complete a paper and pencil questionnaire that asks how you are functioning physically and emotionally, and about any symptoms you may be having from the cancer or the treatments. It should take you about 20-30 minutes to complete the questionnaire which can be done while you are waiting to see the doctor

in the office. This type of questionnaire focuses on quality of life issues, as we feel it is best to learn directly from you how the treatments are affecting your everyday activities. You may skip any questions you do not want to answer. If you do not answer some or all of the questions, it will not affect the care or treatment you receive in the study.

Also, before you begin your treatment, a blood sample will be collected if you agree to the collection and use of your blood and tissue samples for research. This sample will be compared to a blood sample collected after your treatment ends but before your surgery.

*After the treatment:* After you complete your chemotherapy and radiation therapy, you will undergo surgery to remove any remaining tumor. After surgery, your doctor will ask you to come in for physical examinations every 6 months for 5 years. You will have blood tests before your surgery and then every 6 months for 5 years after surgery. You will need to have an exam of the area of your rectum where your tumor had been at 1, 2, and 3 years after surgery. You will need to have a CT scan (which may include a PET scan) or MRI of your abdomen and pelvis at 1 and 2 years after surgery.

You should talk to your doctor about receiving additional treatment (chemotherapy) after you receive surgery.

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

Your chemotherapy and radiation therapy will last about 6 weeks. Even if your chemotherapy and radiation therapy are delayed due to side effects, they will not continue beyond 9 weeks. We will want to keep track of your medical condition for five years after your surgery.

Your doctor may take you off the study drugs if one of the following happens:

- the study treatment does not work for your cancer;
- you develop a serious side effect that you cannot tolerate or that cannot be controlled with other medications;
- your health gets worse;
- you are unable to meet the requirements of the study (for example, you cannot take the medicine as prescribed or cannot return for follow-up visits);
- new information about the study drugs or other treatment for rectal cancer becomes available.

In addition, your participation in this study may be ended because the NSABP finds it must limit or stop the study.

You can stop taking part at any time. If you decide to stop, you should talk to your study doctor first.

## What are the risks to me of being in the study?

There are risks involved in taking the drugs in this study, and there may be side effects. Most of these are listed here, but they will vary from person to person. **There may be other side effects that we cannot predict.** Your doctor may be able to give you other medications to prevent or reduce some of the side effects.

Many side effects go away shortly after the drugs are stopped, but in some cases, side effects may be very serious, long-lasting, and/or life-threatening. Talk with your study doctor about this. If you want to learn more about these study drugs, please ask your doctor or pharmacist for more information.

During the study, we will do blood tests to see if the amount of some of the drugs you are receiving during your chemotherapy should be changed or delayed. The tests will also help monitor any side effects you may have. You may need to be hospitalized if you have serious side effects.

**Group 1 and Group 2 Patients:** Side effects that are *likely* to occur from therapy with 5-FU. (*Likely means these effects occur in 10% or more of patients taking 5-FU.*)

- Diarrhea (can be very severe and life-threatening)
- Nausea
- Vomiting
- Loss of appetite
- Sores in mouth, throat, and esophagus (*these may cause difficulty in swallowing and/or heartburn*)
- Low white blood cell count
- Infection
- Fever
- Skin problems (*rash, itching, dryness, sensitivity to sunlight, etc.*)
- Hair thinning or loss
- Weight gain
- Depression
- Change in ability to perform activities of daily living
- Time away from work
- Redness, swelling, pain, numbness, tingling, cracking, blistering, and peeling of the hands and feet (hand-foot syndrome)

**Possible** side effects that may occur from therapy with 5-FU. (*Possible means these effects occur in 3-9% of patients taking 5-FU.*)

- Low platelet count that might interfere with blood clotting
- Changes in blood test results that indicate possible liver injury
- Weakness
- Weight loss
- Headache
- Constipation
- Skin discoloration
- Nail changes
- Mood changes
- Dehydration
- Eye problems
- Changes in blood pressure
- Gastrointestinal ulcers and bleeding
- Bowel wall changes (*that may require hospitalization*)
- Darkening of veins
- Blood clots in the veins
- Allergic reactions (*including itching, hives, flushing, shortness of breath, wheezing, chest tightness, skin rashes, fever, chills, muscle stiffening, severe breathing problems*)

In **rare** circumstances (*effects seen in 2% or less of patients receiving 5-FU*), you may experience:

- Poor coordination and balance
- Irregular heartbeats
- Heart problems
- Chest pain
- Shortness of breath
- Disorientation
- Confusion
- Skin damage (due to leakage of drug)

Some of these effects may be serious and life-threatening.

**Group 3 and Group 4 Patients:** Side effects that are **likely** to occur from the therapy with capecitabine. (*Likely means these effects occur in 10% or more of patients taking capecitabine.*)

- Diarrhea (*can be very severe and life-threatening*)
- Nausea
- Vomiting
- Loss of appetite
- Sores in mouth, throat, and esophagus (*these may cause difficulty in swallowing and/or heartburn*)
- Redness, swelling, pain, numbness, tingling, cracking, blistering, and peeling of the hands and feet (hand-foot syndrome)
- Eye problems
- Tiredness
- Hair loss
- Abdominal pain
- Fever
- Constipation
- Skin problems (*rash, itching, and dryness*)
- Changes in liver function tests
- Time away from work
- Change in ability to perform activities of daily living
- Low white blood cell count

**Possible** side effects that may occur from the capecitabine. (*Possible means these effects occur in 3-9% of patients taking capecitabine.*)

- Dehydration
- Weakness
- Dizziness
- Headache
- Nail changes
- Cough
- Shortness of breath
- Depression
- Decreases in hemoglobin (the part of the blood cells that carry oxygen)
- Fever with a low white blood cell count
- Skin discoloration
- Gastrointestinal bleeding
- Mood changes
- Taste changes
- Tingling in the arms and feet (peripheral neuropathy)

In **rare** circumstances (*effects seen in 2% or less of patients taking capecitabine*), you may experience:

- Heart problems
- Chest pain
- Low platelet count that might interfere with blood clotting
- Infection
- Changes in blood pressure
- Blood clots

Some of these effects may be serious and life-threatening.

**Group 2 and Group 4 Patients:** Side effects that are **likely** to occur from therapy with oxaliplatin. (Likely means these effects occur in 10% or more patients receiving oxaliplatin.)

- Nerve problems that are usually temporary, but some may be long-lasting. These may be made worse by exposure to cold temperature and cold objects
  - Pain, tingling, burning, or numb feeling (pins and needles) in hands, feet, or area around mouth or throat, which may cause problems walking or performing the activities of daily living.
  - Trouble swallowing or saying words, jaw tightness, odd feelings in the tongue, chest pressure, or a feeling of not being able to swallow or breathe without having any physical reason for this.
- Abdominal pain or cramps
- Cough
- Time away from work
- Temporary loss of hair
- Nausea
- Vomiting
- Diarrhea
- Loss of appetite
- Fatigue
- Changes in blood tests that may indicate liver injury
- Fever
- Infection
- Sores in mouth, throat, and esophagus, which is the tube that goes from the mouth to the stomach
- Low platelet count (which may lead to increased bruising or bleeding)
- Lowered red blood cell count (anemia) (may lead to tiredness, weakness and shortness of breath)
- Low white blood cell count (may lead to infection)

**Possible** side effects that may occur from therapy with oxaliplatin. (Possible means these effects occur in 3-9% of patients receiving oxaliplatin.)

- Headache
- Blistering, peeling, redness, swelling, tingling, numbness, and/or pain of the palms of hands and bottoms of feet
- Rash
- Inflammation of the veins
- Allergic reaction (including itching, hives, skin rash, fever, chills, muscle stiffening, sinus congestion, or swelling or puffiness of the face, especially eyelids)
- Intestinal blockage
- Bowel wall changes (that may require hospitalization)
- Irritation of the intestines
- GI ulcers and bleeding
- Problems with hearing
- Visual changes (including blindness that lasts less than a minute)
- Constipation
- Taste changes
- Shortness of breath
- Pain in muscles, bones, or joints
- Changes (high or low) in blood pressure
- Hot flashes/flushing
- Dehydration
- Fever with a low white blood cell count
- Chest pain
- Dizziness
- Mood changes (including depression)
- Blood clots
- Changes in blood test that may indicate kidney damage
- Hiccups
- Weight loss
- Eye problems (including redness and irritation)
- Poor coordination and balance

In *rare* circumstances (*effects seen in 2% or less of patients receiving oxaliplatin*), you may experience the following serious side effects:

- Changes in the lungs (including inflammation, thickening, scarring, and possible lung failure)
- A breakdown of red blood cells and kidney failure known as hemolytic uremic syndrome
- Severe allergic reaction including shortness of breath, low blood pressure, wheezing, chest tightness, and severe breathing problems
- Clots that form in the blood and use up the substances needed to stop bleeding
- Liver damage that may be permanent, including a serious form called “veno-occlusive disease” which can cause swelling of the abdomen, painful swelling of the liver and yellowing of the skin
- Skin and tissue damage in the area surrounding the catheter where the chemotherapy is injected
- Irregular heartbeat

Some of these effects may be serious and life-threatening.

You are at risk for any of these side effects with any of these drugs as long as you are receiving treatment as part of this study. There may be other side effects that we cannot predict. You should discuss risks and side effects with the researcher or with your regular doctor.

*Risks related to radiation therapy:* Your radiation doctor will explain the side effects that may result from your radiation therapy. The drugs given in this study may make these side effects more severe. You may also be asked to sign a consent form for your radiation therapy.

*Risks related to surgery:* Your surgeon will explain the risks that are related to your surgery. You may also be asked to sign a consent form for your surgery.

*Risks related to pregnancy:* Because the drugs in this study can affect an unborn baby, you should not become pregnant or father a baby while on this study. You should not nurse your baby while on this study.

Both male and female patients should ask about counseling and more information about preventing pregnancy. Female patients or sexual partners of male patients, who feel they might be pregnant even though they practiced birth-control, must notify the study doctor immediately and a pregnancy test may be performed.

*Risks related to completion of the quality of life questionnaire:* Rarely, people may get upset after answering questions about their symptoms and their feelings. If this happens to you, then you should discuss it with your doctor or nurse so you can receive some assistance. You may choose not to complete the questionnaire if it is too difficult for you.

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

There may or may not be direct medical benefits to you from your taking part in this study. All of the drugs used in this study have been given to patients with rectal cancer, but it is not known which combination of drugs and radiotherapy works best. We hope the information learned from this study will help patients with rectal cancer in the future.

### **What other treatment options are there?**

Instead of being in this study, you can decide to have:

- radiation therapy;
- chemotherapy with these or other drugs known to be effective for treating rectal cancer;
- surgery;
- some combination of the options above; or
- comfort care only, where treatments are directed only at reducing symptoms, relieving suffering, and maximizing comfort, dignity, and control. In comfort care only, treatment is not directed at curing, slowing, or reversing your disease.

These options are available to you at this center or other centers, even if you do not take part in this study. Talk with your doctor about these and other options before you enter the study and about other options that may become available during the trial.

### **How will information about me be kept private?**

We will try to keep your personal information as private as we can. We cannot guarantee total privacy. Your personal information may be disclosed if required by law. If these study results are published, steps will be taken so that no one will be able to tell you took part. Your research records will include your medical history, results of your blood tests and exams, reports from your surgery and treatment and reports of your office visits. Some of the information collected as part of the research will also be included in your medical records. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include:

- the National Surgical Adjuvant Breast and Bowel Project (NSABP);
- Roche Laboratories, Inc., which is supplying the study drug capecitabine free of charge;
- Sanofi-Synthelabo, Inc., which is supplying the study drug oxaliplatin free of charge;
- your local Institutional Review Board (IRB), a group of people who review the research study to protect your rights;
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials; and
- government agencies including the NCI, the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and Health Canada. Information may be provided to these agencies in a way that maintains your privacy according to the United States and Canadian regulations. These agencies may review the research to see that it is being done safely and correctly.

### **What are the costs?**

Capecitabine and granisetron (Kytril), a prescription medicine that helps protect cancer patients from the nausea and vomiting that often follows chemotherapy and radiation therapy, will be provided free of charge by Roche Laboratories, Inc. Oxaliplatin will be provided free of charge by Sanofi-Synthelabo, Inc. 5-FU will be provided for the usual and customary costs and must be paid for by you or your insurance company.

The follow-up tests and exams are part of regular cancer care except for the proctoscopy or sigmoidoscopy done at years 2 and 3, which are being done for study purposes only and will be paid for by the study.

Taking part in this study may lead to added costs for you or for your insurance company. Medicare should be considered a health insurance provider. Please ask your doctor about any added costs or health insurance problems. If you are injured or become ill from taking part in this study, emergency medical treatment is available and will be provided at the usual charge. No funds have been set aside to pay you in case you are injured, but you do not waive any of your legal rights to compensation, if any, by signing this form. You or your insurance company will be charged for medical care and/or hospitalization.

You will not be paid for taking part in this study. If during the study, capecitabine or oxaliplatin is no longer provided free of charge, you may have to pay for the amount of drug needed to complete the study. However, we do not expect this will happen.

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://www.cancer.gov/clinicaltrials/understanding/insurance-coverage> (and click on printable version).

### **Do I have to be part of the study?**

You are free to choose to take part or not to take part in this research study.

If you have any questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

### **What are my rights as a study participant?**

Even after you agree to take part in this study, you may withdraw at any time. Before you withdraw, you should first talk to one of the researchers or nurses involved. This will allow them to inform you of any medical problems that could result from stopping your treatment.

You can choose to withdraw one of two ways. In the first, you can stop your study treatment, but still allow the study doctor to follow your care. In the second, you can stop your study treatment and not have any further contact with the study staff. Either way, there will be no penalty to you.

Your decision will not affect your medical treatment, or your relationship with those treating you or with this institution. If you withdraw from the study, you will still be offered all available care that suits your needs and medical condition.

The Data Monitoring Committee (DMC), an independent group of experts, will be reviewing the data from this research on an ongoing basis. If any important new information about the study develops that may affect your health, welfare, or willingness to stay on the study, your doctor will tell you. You may be asked to sign another consent form at that time.

### **Who can I call if I have questions or problems?**

For questions about the study or a research-related injury, contact your physician from the number on the cover sheet. For questions about your rights as a research participant, call Multicare Investigational Review Board at 253-403-3844.

You may also call the Project Office of the NCI Central Institutional Review Board (CIRB) at 1-888-657-3711 (from the continental US only).

### **What about the use of my blood and tissue for research?**

One of the goals of this study is to look at tumor samples collected before you receive study treatment (chemotherapy and radiation therapy). Another goal of this study is to look at blood samples collected before you receive study treatment (chemotherapy and radiation therapy) and at the end of study treatment. This may allow the researchers to find something in the blood or tumor sample that will show if someone might benefit from the chemotherapy and radiation therapy before they receive it. This won't help you, but may help others who are treated for cancer in the future.

The NSABP is asking that you allow us to look at tumor samples that are collected by your hospital pathology department. This will not involve any additional procedures for you. You may make your decision by answering yes or no to this question at the end of this consent form. The NSABP would also like to look at tumor samples that are put in a solution called RNAlater. RNAlater is a special salt solution that preserves genetic material so that it can be examined in a laboratory. Any tests that are done with these samples are experimental, so you and your doctor will not be told the results.

**Note: You should answer either question #1 in section A or question #2 in section B. You do not need to answer both question #1 and question #2.**

#### **A. For patients who have not had a biopsy specimen collected in RNAlater**

##### *Consent for additional biopsy*

Before you were told about this study, you already had a biopsy which showed you had rectal cancer. The NSABP would like you to have an additional biopsy that will allow some of your tumor to be collected and put in a solution called RNAlater. This tissue sample will be sent to the NSABP. This will give them a sample of your tumor before you begin receiving treatment for your cancer.

Possible risks and side effects of the additional biopsy include discomfort during the biopsy, bleeding at the biopsy site, and rarely an infection following the biopsy.

**Does not apply because a biopsy sample has already been collected in RNAlater**

1. I agree to undergo an additional biopsy so that a sample of my tumor can be collected in RNAlater solution and sent to the NSABP to be used for the R-04 study.

YES                      NO

**B. For patients who had a biopsy specimen collected in RNAlater**

Before you were told about this study, you already had a biopsy which showed you had rectal cancer. You were asked if the sample could be collected in RNAlater and sent to the NSABP. The sample was sent to the NSABP with a code number and the NSABP cannot link this to you. However, if you give your permission, your doctor can send the NSABP the code number to link to your R-04 study identification number (the identification number assigned to you in this study). The NSABP would then like your permission to use that previous biopsy tissue in the R-04 study.

**Does not apply because a biopsy sample was not collected in RNAlater**

2. I agree to let my doctor release the coded link to my R-04 study identification number so my biopsy sample that was collected in RNAlater may be used in the R-04 study.

YES                      NO

**C. For all patients – consent for blood and tumor sample collection**

The NSABP would also like to keep some of the blood and tissue that is taken during this study for all patients but is not needed for other tests. If you agree, the blood and tissue samples will be kept and may be used for the purpose of the R-04 study. Some of the research tests will be done soon, but others will be done in the future when the best methods are ready to test the samples. The NSABP will study the samples and may give them to other researchers approved by the NSABP only for the purposes of the R-04 study. Any research study using your samples must also be approved by an IRB. The research that may be done with your samples is not designed to specifically help you. It might help people who have cancer in the future. Reports about research done with your samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your blood and tissue samples will not affect your care. These blood and tissue samples will not be used for genetic research about diseases that are passed on in families.

The choice to let the NSABP keep the blood and tissue samples for research related to this study is up to you. No matter what you decide to do, it will not affect your care in this study. If you decide now that your blood and tissue samples can be kept for research, you can change your mind at any time. Just contact your study doctor and let him or her know that you do not want the NSABP to use your blood and tissue samples and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until the NSABP decides to destroy them.

People who do research with your blood and tissue samples may need to know more about your health. While the NSABP may give them reports about your health, they will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

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

The possible benefits of research from your blood and tissue include learning more about what causes cancer, how to prevent it and how to treat it. The greatest risk to you is the release of information from your health records. The NSABP will protect your records so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any blood and tissue collected and stored by the NSABP.

Even if you answered "no" to having an additional biopsy in order to send your tumor sample to the NSABP, you can still allow your blood to be collected and your hospital's pathology department to send a sample from the biopsy that showed you have rectal cancer to the NSABP by answering "yes" to question 3. The choice is up to you.

Please read each sentence below and think about your choice. After reading each sentence, circle "yes" or "no". If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and use of your blood and tissue, you may still take part in the R-04 trial.

By signing this form, you are agreeing that:

3. My blood and tissue samples may be kept by the NSABP and used for the purposes of the R-04 study.

YES                  NO

4. My study doctor (or someone he or she chooses) may contact me in the future to ask me to take part in more research.

YES                  NO

**Where can I get more information about cancer and its treatment?**

You can call the Cancer Information Service at 1-800-4-CANCER or visit the National Cancer Institute's Cancer Trials Websites:

- for cancer information go to <http://cancer.gov/cancerinformation>
- for clinical trials information go to <http://cancer.gov/clinicaltrials>.

You can also visit the NSABP Website at <http://www.nsabp.pitt.edu>.

### Cancer Fax

Includes NCI information about cancer treatment, screening, prevention, and supportive care. To obtain a contents list, dial (301) 402-5874 or 1-800-624-2511 from a fax machine handset and follow the recorded instructions.

If you would like additional information about the drugs used in this trial and their side effects, you should ask your doctor or pharmacist.

You can also get information at any time from the doctor in charge of your medical care in this study.

You will get a copy of this form.

### Signatures

You are deciding whether or not to take part in this study. If you sign, it means that you have decided to volunteer to take part in this study (including submission of preserved tissue for laboratory testing outlined previously), and that you have read and understood all the information on this form.

\_\_\_\_\_  
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 (Permission) to Use or Disclose (Release) Identifiable Health Information for Research**

Patient's Name: \_\_\_\_\_ Birth Date: \_\_\_\_\_

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

The NSABP 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 personal health information, you must sign and date this form to give them your permission.

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

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter an NSABP research study, information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, such as laboratory test results; pathology results; and reports of physical exams, diagnostic tests, x-rays, and tumor measurements;
- 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;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that will identify you, such as your social security number and medical record number.

You may request a blank copy of the NSABP data forms from the study doctor or his/her research staff to learn what information will be shared.

### ***3. Why do the researchers want my personal health information?***

The Northwest CCOP will collect your health information and share it with the NSABP Biostatistical Center and the NSABP Operations Center if you enter a cooperative group research study. The NSABP centers will use your information in their cancer research study. You are being asked to take part in a study known as; **CIRB NSABP R-04: A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum.**

### ***4. Who will be able to use my personal 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 these groups to come in to review your original records that are kept by the Northwest CCOP so that they can monitor their research study.

- the NSABP Operations Center;
- the NSABP Biostatistical Center;
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute that supports the research of the NSABP;
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- other people or organizations assisting with NSABP research efforts (including other groups who review the research to protect the rights and ensure the safety of patients);
- Genentech, Inc. (the company providing support for the study); and
- central laboratories, central review centers, and central reviewers. The central laboratories, centers, and review agencies may also give your health information to those groups listed above.

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

The NSABP will keep all patient information private to the extent possible, even though the NSABP is not required to follow the federal privacy laws. Only researchers working together with the NSABP will have access to your information. The information will only be shared in a manner that will protect your identity. The NSABP will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

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

If you do not sign this permission form, you will not be able to take part in the 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 specific research consent form.

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

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal 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 permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. He/she will make sure your written request to withdraw your permission is processed correctly.

Karyn Hart, RHIT, CCRP  
Program Coordinator  
Northwest CCOP  
315 Martin Luther King Jr., Way  
M/S 315-C2-CCO  
Tacoma, WA 98405  
(253) 403-1461

**8. How long will this permission last?**

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

**9. What are my rights regarding access to my personal health information?**

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

**Signatures**

I agree that my personal health information may be used for the 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 Permission: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name of Person Obtaining Permission: \_\_\_\_\_  
the informed consent discussion