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**Sponsored and Funded by the National Cancer Institute**

### CONSENT FORM

**CIRB R0848: A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma**

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## **CIRB R0848: A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma**

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 pancreatic cancer that was removed by surgery. You are eligible for this study because there was no visible cancer left behind and not more than 8 weeks have passed since your operation.

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

The standard treatment for patients with pancreatic cancer that was removed by surgery is to receive the chemotherapy drug gemcitabine. In this study, you will get either gemcitabine alone or gemcitabine combined with erlotinib. Erlotinib is a pill that may help treat cancers by blocking a gene that is important in cancer growth. The use of erlotinib to try to prevent the recurrence of pancreatic cancer after surgery is investigational. This study will compare the effects, good and/or bad, of the drug erlotinib in combination with gemcitabine to gemcitabine alone for patients with pancreatic cancer that was removed by surgery to find out which is better.

Following completion of 5 months of gemcitabine (with or without erlotinib), all patients will be evaluated by CT scan to see if the tumor has not grown back (progressed). We expect that most patients will not have signs of progression although a few patients may show signs of progression at this point. Patients showing progression will no longer receive treatment on this study. For patients who remain without evidence of progression, half will then get one additional month of gemcitabine (with or without erlotinib). The other half will get one additional month of gemcitabine (with or without erlotinib) and then will get radiation treatments with a fluoropyrimidine for about 5 ½ weeks. (A fluoropyrimidine is a type of chemotherapy drug that may help radiation be more effective). Therefore, this study will also determine the effects, good and/or bad, of radiation for patients who remain disease-free after gemcitabine chemotherapy.

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

About 950 people will take part in this study.

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

### Before you begin the study

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Physical Exam
- Blood Tests
- Abdominal/Pelvic CT/MRI Scan
- Chest X-Ray or Chest CT
- Pregnancy Test

### During the study

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

- Physical Exam                      Monthly during gemcitabine and weekly during radiation treatment
- Blood tests                              Weekly while you are on the study
- Abdominal CT/MRI                      After 5 months of gemcitabine with or without erlotinib
- Chest X-ray or CT                      After 5 months of gemcitabine with or without erlotinib

When you enter the study, it is required that the study doctor send the block of tumor tissue obtained at the time of your surgery and some blood (2 tablespoons) to the central tissue bank. Scientists will study your tumor tissue and blood to try to learn more about pancreatic cancer and determine what characteristics of pancreatic cancer cells predict cancer growth.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in any group. Treatments are given in an outpatient setting.

**If you are in group 1 (Arm 1):** Gemcitabine weekly by vein over 30 minutes for 3 weeks, then 1 week off, for 5 months. (1 cycle = 1 month)

**If you are in group 2 (Arm 2):** Gemcitabine weekly by vein over 30 minutes for 3 weeks, then 1 week off, for 5 months and erlotinib, 1 pill per day on an empty stomach for 5 months

When you have completed 5 months of treatment you will have a CT scan and chest x-ray. If your cancer has grown back you will be removed from the study and your doctors will discuss with you what options are best for you.

When you have completed 5 months of treatment, you will have a CT scan and chest x-ray. If your cancer has grown back, you will be removed from study treatment; you will not be randomized again to one of two treatments. Your doctors will discuss with you what options are best for you, and you will be seen in follow-up visits as described below.

If after 5 months of chemotherapy your cancer has not grown back you will be randomized again to one of two treatments. The chances of receiving either treatment are about equal. You will be treated with one of the following:

**If you are in group 3 (Arm 3):** One additional cycle of the same chemotherapy you received in the first 5 months of this study (either gemcitabine alone or gemcitabine with erlotinib).

**If you are in group 4 (Arm 4):** One additional cycle of the same chemotherapy you received in the first 5 months of this study (either gemcitabine alone or gemcitabine with erlotinib). In addition, you will receive radiation and fluoropyrimidine. Radiation will be given to the area where your tumor was once a day, Monday through Friday for 5 ½ weeks (*28 radiation treatments*). Fluoropyrimidine will be given with the radiation. Fluoropyrimidine is a chemotherapy drug that helps radiation work better. There are two forms of fluoropyrimidine. You may receive a pill form of fluoropyrimidine called capecitabine, which is taken twice a day, Monday through Friday on radiation days for 28 days. Alternatively, you may receive the form called 5-FU, which is given by vein continuously, 7 days per week, for 5 ½ weeks throughout radiation. If you receive the intravenous 5-FU you will need a special IV tube placed into a large vein in your arm, neck or chest and a small pump to give the drug. This pump weighs about seven ounces and would be worn by you throughout the 5 ½ weeks. You and your doctor will decide which form of fluoropyrimidine (capecitabine or 5-FU) is best for you.

### **When treatment is finished you will need the following**

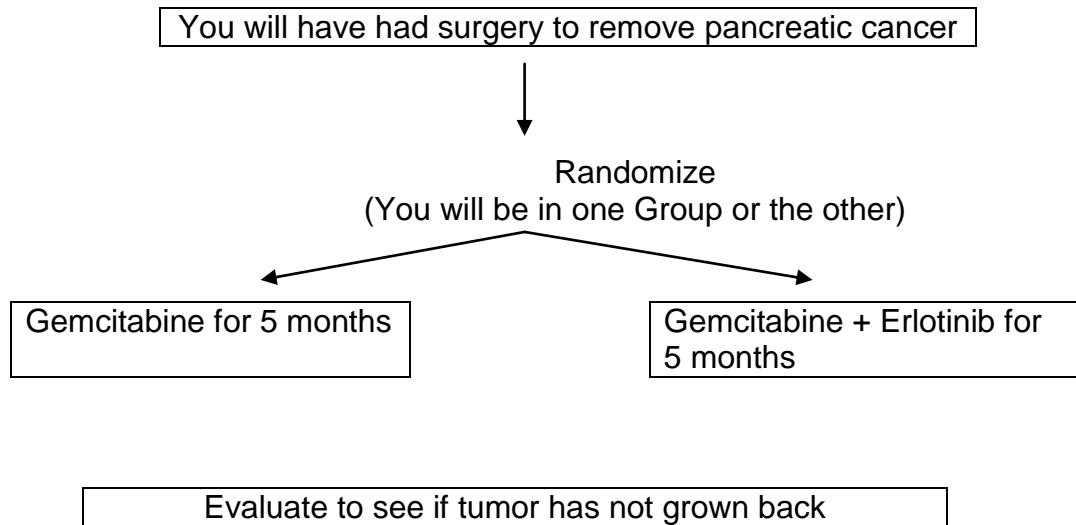
#### **For patients who do not receive Arm 3 or 4 treatment:**

- Physical Exam                      Every 6 months for 2 years then annually

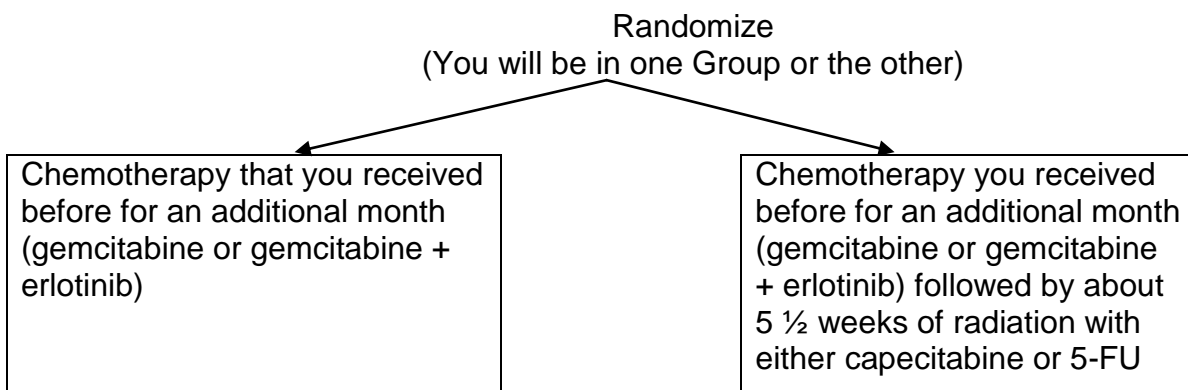
#### **For patients who receive Arm 3 or 4 treatment:**

- Physical Exam                      Every 3 months for 2 years, every 6mo x 3yrs then annually
- Abdominal CT/MRI                Every 3 months for 2 years, every 6mo x 3yrs then annually
- Chest X-ray or CT                 Every 3 months for 2 years, every 6mo x 3yrs then annually

**Study Plan** Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



If there is no evidence of progression:



If there is evidence of progression: You will no longer receive treatment on this study, but you will be seen in follow-up visits.

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

You will be asked to take 5 months of gemcitabine (with or without erlotinib). Radiation and fluoropyrimidine takes 5 1/2 weeks if you are in an arm receiving the radiation and 5-FU treatment. If you are in group 1 (Arm 1) or 2 (Arm 2), you will have follow-up exams every six months for two years and then every year for your lifetime to record whether your cancer grows back.

If you are in group 3 (Arm 3) or 4 (Arm 4), you will have follow-up exams every three months for two years, every six months for three years, and then every year for your lifetime to record whether your cancer grows back.

### **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 or radiation can be evaluated. Another reason to tell your study doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

### **What side effects or risks can I expect from being in the study?**

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the drugs and/or radiation. 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 Gemcitabine include those which are:**

#### **Likely**

- Low blood counts, which could lead to an increased risk of infection, weakness, and/or in bleeding and bruising easily
- Nausea
- Diarrhea
- Loss of appetite
- Tiredness
- Fever
- Headache and chills
- Skin rash that may cause itching
- Swelling of the foot, leg, and ankle

**Less Likely**

- Muscle aches
- Vomiting
- Constipation
- Change in liver function that could cause jaundice (yellowing of skin)
- Excess protein in the urine
- Abnormal kidney function tests

**Rare but serious**

- A severe skin reaction called Stevens-Johnson Syndrome, a painful red or purplish rash that spreads and blisters, eventually causing the top layer of your skin to die and shed
- Inflammation or scarring of the lung with shortness of breath and cough
- Kidney and liver failure
- Cardiac dysfunction such as heart attack, congestive heart failure (heart unable to pump enough blood throughout the body), and atrial fibrillation (problem with the speed or rhythm of the heartbeat).

**Risks and side effects related to the Erlotinib include those which are:**

**Likely**

- Fatigue or tiredness
- Rash/flaking or shedding of outer layer of skin
- Loss of appetite
- Diarrhea
- Vomiting

**Less Likely**

- Dry skin
- Hair loss
- Nail changes
- Itching
- Acne; pimples
- A condition in which your body does not have as much water and fluid as it should (dehydration, which can be caused by severe diarrhea and/or vomiting)
- Dry mouth
- Heartburn
- Irritation or sores in the lining somewhere in the digestive tract
- Nausea, the urge to vomit
- Taste changes
- Nosebleed
- Bleeding in some organ(s) of the digestive tract
- Infection(s) somewhere in the body
- Increased level of a liver enzyme (ALT/SGPT; AST/SGOT)
- Abnormal liver or bone enzyme level (alkaline phosphatase)
- Elevation of a liver pigment (bilirubin) in the blood indicative of liver dysfunction
- Dry eye

- Damage to the surface of the eye
  - In-grown eyelashes/thickening of eyelashes
  - Belly pain
  - Head pain/headache
  - Cough
  - Shortness of breath
  - Inflammation of the lungs (pneumonitis, which can rarely be life-threatening or fatal)
- If you develop a cough or difficulty breathing, you should stop taking erlotinib and call your doctor.** If you are found to have interstitial pneumonitis that is thought to be from erlotinib, you will not receive further erlotinib.

### **Rare but serious**

- Severe reaction of the skin and gut lining that may include rash and shedding, or death of tissue
- Inflammation of the skin on the palms of the hands and soles of the feet
- A hole in a part(s) of the digestive tract (which commonly requires surgery and can be life-threatening or fatal). This risk may be increased if at the same time you are taking anti-angiogenic agents (drugs that prevent the growth of new blood vessels into a solid tumor), corticosteroids (such as cortisone), NSAIDs (nonsteroidal anti-inflammatory drug such as ibuprofen), and/or taxane-based chemotherapy, or have a prior history of peptic ulcers or diverticular disease (small pouches that bulge outward through colon or large intestine and can become inflamed or infected).
- Bleeding in the brain or spinal cord
- Liver problems/liver failure
- Inflammation of the cornea of the eye
- A hole or sore in the outer layer of the eye (caused by severe inflammation or dry eye syndrome)

**Dangerous interaction between erlotinib and warfarin (Coumadin®):** If you are taking warfarin or Coumadin® (medicine to prevent blood clotting), erlotinib may change the way your blood clots. If you need to take warfarin, your doctor will regularly check for changes in blood clotting time.

Patients who will be taking erlotinib, should wear sun screen protection, hat, and long sleeve shirt as the sun can make the skin rash worse.

### **Risks Associated with Fluoropyrimidine:**

You and your doctor will decide whether it is best for you to receive the pill form of fluoropyrimidine (capecitabine) or the IV form (5-FU). The leaders of this study believe the effectiveness of the IV and pill forms are the same. The general side effects of the pill (capecitabine) and IV (5-FU) forms of fluoropyrimidine are similar. However, in some patients, capecitabine may cause more diarrhea and nausea. These potential gastrointestinal side effects of capecitabine are balanced by the inconvenience of a continuous 5-FU infusion and the need for the minor surgical placement of a special type of intravenous (PICC line or port-a-cath) and the need to carry a small pump for 5 ½ weeks.

**Risks and side effects related to the fluoropyrimidine include those which are:**

**Likely**

- Nausea
- Diarrhea
- Mouth sores
- Loss of appetite and weight loss
- Weakness
- Tiredness
- Redness and/or drying of the skin, especially the hands and feet.
- Skin or nail darkening
- Skin rash or peeling of skin on hands and feet
- Low blood counts which could lead to an increased risk of infection, weakness, and/or in bleeding and bruising easily
- Infection

**Less Likely**

- Vomiting
- Muscle aches
- Constipation
- Hair loss
- Change in liver function that could cause jaundice (yellowing of skin)
- Unsteadiness

**Rare but serious**

- Chest pain or irregular heartbeat

**Dangerous interaction between capecitabine and warfarin (Coumadin®):** If you are taking warfarin or Coumadin® (medicine to prevent blood clotting), capecitabine may change the way your blood clots. The interaction between warfarin and capecitabine is very large and could result in severe bleeding. If you need to take warfarin, your doctor will regularly check for changes in blood clotting time. The IV drug 5-FU does not interact as significantly with warfarin.

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

**Likely**

- Stomach pain and intestinal discomfort, which usually occur during the last three weeks of radiation and generally go away within 2 months after the treatment is finished
- Nausea
- Diarrhea
- Fatigue
- Tanning, redness of skin, and hair loss within the radiation area, which is temporary

- Permanently dry skin in the radiation treatment area
- Low blood counts, which could lead to an increased risk of infection, weakness, and/or in bleeding and bruising easily
- Loss of appetite and weight loss
- Mild muscle aches in the area treated

### **Less Likely**

- Vomiting
- Infection

### **Rare but serious**

- Change in liver or kidney function, which is unlikely to cause symptoms.
- Bowel obstruction, which could result in abdominal pain, nausea and vomiting and may require surgery.
- Gastric, duodenal or small-bowel ulcer formation that can result in abdominal pain, nausea and vomiting, and bleeding, and may require surgery.

**Reproductive risks:** You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. 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. Some of the drugs in the study may make you unable to have children.

**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. It has been proven that gemcitabine will reduce the chance that this cancer will come back and that this will increase your lifespan. It is not proven whether the addition of erlotinib to gemcitabine or the addition of radiation and fluoropyrimidine following gemcitabine will reduce the risk of pancreatic cancer recurring for patients with pancreatic cancer that has already been removed. Based on other studies there are reasons to believe that these treatments may be helpful and this trial is being done to try to find out whether they really are. We do know that the information from this study will help researchers learn more about the treatment of pancreatic 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

**Talk to your study doctor about your choices before you decide if you will take part in this study.**

**Will my medical information be kept private?**

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

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

- The Radiation Therapy Oncology Group
- The Southwest Oncology Group
- The European Organization for the Research and Treatment of Cancer
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- The Cancer Trials Support Unit (CTSU), a service sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
- OSI Pharmaceuticals, the company that makes erlotinib

**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.

The NCI will supply the study agent, erlotinib, at no charge while you take part in this study. The NCI does not cover the cost of getting the erlotinib ready and giving it to you, so you or your insurance company may have to pay for this.

Even though it probably won't happen, it is possible that the manufacturer may not continue to provide the erlotinib to the NCI for some reason. If this would occur, other possible options are:

- You might be able to get the erlotinib from the manufacturer or your pharmacy but you or your insurance company may have to pay for it.
- If there is no erlotinib available at all, no one will be able to get more, and the study would close.

If a problem with getting erlotinib occurs, your study doctor will talk to you about these options.

**You will not be paid for taking part in this study.**

**For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at**

**<http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.**

**Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.**

**What happens if I am injured because I took part in this study?**

**It is important that you tell your study doctor if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call him/her at the number listed on the cover page.**

**You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.**

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

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

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

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

**Who can answer my questions about the study?**

**You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor at the number listed on the cover page.**

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

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

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

**You can say “yes” or “no” to the following study. Below, please mark your choice [for each study].**

**Consent Form for Quality of Life Study**

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

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

You will be asked to complete 2 questionnaires: before treatment, and then at 5-6, 9, 12 and 24 months after your treatment has started. It takes about 5 minutes or less to fill out each questionnaire.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

If you decide to take part in this study, the only thing you will be asked to do is fill out the 2 questionnaires. You may change your mind about completing the questionnaires at any time.

Just like in the main study, we will do our best to make sure that your personal information will be kept private.

Please circle your answer.

I choose to take part in the Quality of Life Study. I agree to fill out the two Quality of Life Questionnaires.

YES

NO

## **Consent Form for Use of Tissue, Blood, and Urine for Research**

### **About Using Tissue, Blood, and Urine for Research**

Your cancer has been removed by surgery. To participate in the main part of this study, you must agree to have your tumor tissue and blood sample sent to the tissue bank to be used for studies that are essential components of this clinical trial. Therefore, permission to use the tissue block and blood sample is mandatory for your participation in the main study.

We would like to keep some of the tissue that is left over for future research. The use of your tissue, blood and urine for future research is optional. If you agree, this tissue will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How is Tissue Used for Research" to learn more about tissue research. This information sheet is available to all at the following web site:

[http://cdp.cancer.gov/humanSpecimens/ethical\\_collection/patient.htm](http://cdp.cancer.gov/humanSpecimens/ethical_collection/patient.htm)

If your cancer comes back and an additional biopsy is needed, your doctors ask permission to send additional tumor tissue and blood to a research lab but this is not required.

In addition, we would like to keep some of your urine for future research. We would collect about 5 tablespoons of your urine before you start treatment. If you agree, the urine will be kept and may be used in research to learn more about cancer and other diseases.

The research that may be done with your tissue, blood, urine is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your tissue, blood, urine will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

### **Things to Think About**

The choice to let us keep the left over tissue and blood and urine for future research is up to you. No matter what you decide to do, it will not affect your care or your participation in the main part of the study.

If you decide now that your tissue, blood, urine can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue, blood, and urine. Then any tissue that remains will no longer be used for research and will be returned to the institution that submitted it and leftover blood and urine will be destroyed. However, tissue, blood, and urine already used and data obtained from it will remain part of the study data.

In the future, people who do research may need to know more about your health. While your doctor/institution 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.

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

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

### **Benefits**

The benefits of research using tissue, blood, and urine include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

### **Risks**

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

### **Making Your Choice**

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our Institutional Review Board at 253-403-3877.

No matter what you decide to do, it will not affect your care.

1. *My specimens may be kept for use in research to learn about, prevent, or treat cancer, as follows:*
  - Tissue Yes No
  - Blood Yes No
  - Urine Yes No
  
2. *My specimens may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease), as follows:*
  - Tissue Yes No
  - Blood Yes No
  - Urine Yes No
  
3. *Someone may contact me in the future to ask me to take part in more research.*  
Yes No
  
4. *If my cancer comes back, specimens may be kept for use in research to learn about, prevent, or treat cancer, as follows:*
  - Tissue Yes No
  - Blood Yes No

5. *If my cancer comes back, my specimens may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease), as follows:*

- Tissue  Yes  No
- Blood  Yes  No

**Where can I get more information?**

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

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

**You may also visit the NCI Web site at <http://cancer.gov/>**

- For NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials/>
- For NCI's general information about cancer, go to <http://cancer.gov/cancerinfo/>

**You will get a copy of this form. If you want more information about this study, ask your study doctor.**

**Signature**

**I have been given a copy of all pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.**

\_\_\_\_\_  
Patient's name (printed or typed)

\_\_\_\_\_  
Patient's Signature      Date

\_\_\_\_\_  
Physician name (printed or typed)

\_\_\_\_\_  
Physician Signature      Date

\_\_\_\_\_  
Signature of person conducting the  
Informed consent discussion

\_\_\_\_\_  
Date

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

Participant's Name: \_\_\_\_\_

Birthdate: \_\_\_\_\_

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

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

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

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

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

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

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

**The Northwest CCOP will collect your health information and share it with the CTSU if you enter a Cooperative Group research study, or to evaluate your eligibility for a study. The CTSU researchers will use your information for the following cancer research study(ies). You are being asked to take part in a study known as: CIRB R0848: A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**9. How long will this authorization last?**

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

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

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

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