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

## CONSENT FORM

**CIRB C90203: RANDOMIZED PHASE III STUDY OF NEO-ADJUVANT DOCETAXEL AND ANDROGEN DEPRIVATION PRIOR TO RADICAL PROSTATECTOMY VERSUS IMMEDIATE RADICAL PROSTATECTOMY IN PATIENTS WITH HIGH-RISK, CLINICALLY LOCALIZED PROSTATE CANCER.**

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**CIRB C90203: RANDOMIZED PHASE III STUDY OF NEO-ADJUVANT DOCETAXEL AND ANDROGEN DEPRIVATION PRIOR TO RADICAL PROSTATECTOMY VERSUS IMMEDIATE RADICAL PROSTATECTOMY IN PATIENTS WITH HIGH-RISK, CLINICALLY LOCALIZED PROSTATE CANCER.**

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 prostate cancer and are at risk of cancer recurrence after surgery to remove your prostate. You are at increased risk for cancer recurrence because of your PSA (prostate specific antigen) blood test, prostate biopsy Gleason score (the way your cancer looks under a microscope), and/or your clinical stage.

**Why is this study being done?**

The purpose of this study is to compare the effects (good and bad) of the combination of chemotherapy and hormone therapy followed by radical prostatectomy (surgery to remove your prostate) with radical prostatectomy alone on you and your prostate cancer to see which is better.

This research is being done because many men with your type of prostate cancer are at risk of having the cancer come back if they are treated only with surgery. We are trying to find out if giving chemotherapy with hormone therapy before surgery makes the chance of being cured of prostate cancer better.

We are also going to study whether anything in your diet or lifestyle predicts how well you do overall with your cancer.

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

About 750 men 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.

- A complete history and physical exam including a digital rectal exam
- Blood tests, including chemistries, liver function tests, and PSA tests (three tablespoons of blood)
- CT or MRI scan of the abdomen and pelvis
- Bone Scan

If the exams, tests and procedures show that you can be in the study and you choose to take part, then 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 an equal chance of being placed in either group.

## **Group 1**

If you are in Group 1 (often called "Arm A") you will be treated with chemotherapy and hormone therapy (an LHRH agonist such as Lupron or Zoladex) followed by radical prostatectomy (removal of the entire prostate gland and surrounding tissue).

The **chemotherapy** will be a drug called docetaxel (also called Taxotere(r)), which will be given through a vein in your arm for one hour every three weeks. Each 3-week period of chemotherapy is also called a "cycle." A total of 6 cycles (18 weeks) of chemotherapy will be given prior to your surgery. At the time you are receiving docetaxel you will also be given a steroid called dexamethasone in a pill form to be taken by mouth to help decrease the side effects of the treatment.

The **hormone therapy** will be drugs called LHRH agonists. These are drugs that lower the male hormone, testosterone. You will probably receive either goserelin acetate (Zoladex®) or leuprolide acetate (Lupron®). If you receive goserelin acetate, the injection will be under the skin of the abdomen; if you receive leuprolide acetate, the injection will be in the thigh or buttocks muscle. These injections may be given either every 4 weeks or every 12 weeks. You will receive these injections for at least 18 weeks (about 4 months). Sometimes you may be given only one shot that may last for a four month time period.

**While you are receiving chemotherapy** you will need the following tests and procedures every 3 weeks to make sure you are not having any side effects from the chemotherapy and hormone therapy. They are part of regular cancer care for patients receiving chemotherapy.

- History and physical exam,
- Blood tests, including chemistries, liver function tests, and PSA tests

After you have completed 6 cycles of chemotherapy, you will have the radical prostatectomy. Your surgeon will discuss the details of the radical prostatectomy surgery with you.

## Group 2

If you are in Group 2 (often called "Arm B") you will be treated with radical prostatectomy (removal of the entire prostate gland and surrounding tissue) without chemotherapy or hormone therapy. Your surgeon will discuss the details of the radical prostatectomy surgery with you.

## Both Groups

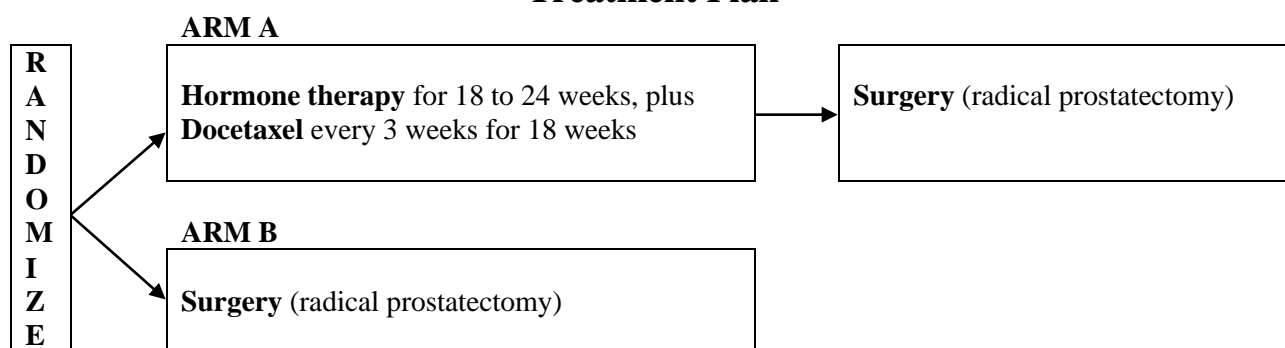
Before the radical prostatectomy you will have the following routine tests to make sure that it is safe for you to go to surgery:

- A history and physical exam
- Blood tests, including chemistries, liver function tests, a PSA test and a testosterone test (three tablespoons of blood)
- Electrocardiogram (EKG)

**When you have completed surgery**, you will be seen within 1 month and within 3 months after surgery, then every 3 months for the first three years after surgery, then every 6 months for the next 3 years, then every year until 15 years after you have started the study. If your cancer worsens, your visits required for this study may become less frequent. At each doctor's visit you will have a history and physical exam and blood drawn to measure PSA and testosterone levels.

You will also be asked to complete a questionnaire about your urinary and sexual functioning every 6 months for 3 years.

## Treatment Plan



Portions of the prostate tissue removed at the time of your original diagnosis and at the time of your surgery will be sent to the CALGB Pathology Coordinating Office at the Ohio State University for confirmation of your diagnosis.

## How long will I be in the study?

You should be in the study for several years. If you are randomized to Arm A, you will be asked to have chemotherapy and hormone therapy for about 18 weeks and then have surgery within 2 months after completing chemotherapy and hormone therapy. If you are randomized to Arm B, you will have the surgery within 2 months of randomization. For both arms of the study, the treatment part of the study ends after the surgery to remove your prostate. After you have finished the surgery, the study doctor will ask you to visit the office regularly for the first six years after surgery, then every year for up to 15 years after you started the study.

## **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 treatment 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, may never go away, or may cause death.

Because we do not know the effect of the chemotherapy drugs on your cancer, if you are assigned to Group A, there is some risk that your cancer will worsen while you are taking the drugs before surgery. 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 therapy we are studying include:

### **Arm A: Chemotherapy (Docetaxel and Dexamethasone) and Hormone Therapy**

#### **LIKELY:**

- Hair loss
- Fluid retention/edema
- Fatigue (feeling tired)
- Upset stomach
- Soreness and/or weakness of muscles and/or joints
- Increases in blood sugar levels, which may cause increased thirst, urination, and fatigue
- Lowered white blood cell count that may lead to an increased risk of infection
- Lowered platelet count that may lead to increased bruising or bleeding
- Lowered red blood cell count that may cause tiredness or shortness of breath (if the counts get too low, you may need a transfusion)
- Impotence (inability to achieve erections satisfactory for intercourse)
  - Hot Flashes
  - Decreased libido
  - Weight gain
  - Lethargy (feeling tired) or fatigue
  - Decreased testicular size
  - Breast swelling or tenderness

**LESS LIKELY:**

- |                        |  |
|------------------------|--|
| Diarrhea               | Darkening or lightening of fingernail beds       |
| Nausea and vomiting    | Peeling skin on hands and feet                   |
| Mouth and throat sores | Insomnia (difficulty falling asleep)             |
| Loss of appetite       | Numbness and/or tingling of the fingers and toes |
| Loss of reflexes       | Pain swelling or redness at the injection site   |
| Skin rashes            | Bruise at the injection site                     |
| Vomiting               | Heartburn  |
| Low blood pressure     | Heart problems                                   |

- Loss of bone mass, which may lead to osteoporosis

**RARE BUT SERIOUS:**

- Stomach ulcers and/or bleeding
- Heart failure with fluid in the lungs
- Severe allergic reaction (life-threatening breathing problems)
- Development of diabetes
- Heart attack
- Stroke

**Arm A and Arm B: Radical Prostatectomy (Surgery)**

Your doctor will talk to you about the risks of surgery. Listed below are the likely side effects that happen in more than 5% of the men and the unlikely side effects that will happen in 5% or less of the men that have radical prostatectomy.

**LIKELY:**

- Time away from work
- Pain
- Permanent scarring or bending of the skin in the area of the incision
- Blood loss
- Urinary incontinence (occasional leaking of urine)
- Frequency or urgency to urinate that may last for several months after the surgery
- Impotence (inability to achieve erections satisfactory for intercourse)
- Inability to ejaculate

**LESS LIKELY:**

- Wound infection
- Edema (swelling) in the pelvis/scrotal area or leg
- Urinary incontinence (leaking of urine), possibly permanent, that is frequent and may require the use of a pad
- Urinary retention (not able to pass urine) that may need to have catheter placed in the bladder for several weeks
- Injury to adjacent organs (rectum, nerve tissue, blood vessels, ureter [tube draining the kidney to the bladder])

- Lymphocele (collection of lymph fluid in the pelvis)
  - Blood clot in the leg (deep venous thrombosis or pulmonary embolism (blood clot in the lung))
- RARE BUT SERIOUS:**
- Death

**Unanticipated side effects** may occur which have not been reported. If you have any unusual symptoms, report them immediately to your doctor.

Although it is not known for sure, docetaxel might interact with other drugs. If you are randomized to Arm A, you should tell your doctor about any medications you are taking, both prescription and non-prescription, before starting your treatment.

**Reproductive risks:** If you are randomized to Arm A, you should not father a baby while you are receiving chemotherapy and hormone therapy and for at least 2 months after the last dose of chemotherapy and hormone therapy because the drugs in this study can affect an unborn baby. It is important you understand that you need to use birth regulation (regulation highly effective: abstinence, IUD, birth control pills, tubal ligation or partner's vasectomy and less effective: condom, diaphragm or cervical cap) while on this study. Check with your study doctor about what kind of birth regulation 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 the researcher at the number listed on the cover page.

### **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 treatment with chemotherapy and hormones before surgery will be more useful against cancer compared to surgery without chemotherapy and hormones, there is no proof of this yet. We do know that the information from this study will help doctors learn more about chemotherapy before surgery as a treatment to reduce cancer recurrence. This information could help future cancer patients.

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

Your other choices may include:

- Getting treatment or care for your cancer without being in a study. This might include having surgery without chemotherapy, receiving hormonal therapy, or receiving radiation therapy with or without hormonal therapy
- Taking part in another study
- Getting no treatment

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 Cancer and Leukemia Group B
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- Sanofi-Aventis pharmaceutical company, the makers of docetaxel

## **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 drug company, Sanofi-Aventis is supplying the docetaxel through the National Cancer Institute at no cost to you. However, you or your health plan may need to pay for the supplies and personnel who give you the docetaxel.

Every effort will be made to ensure adequate supplies of docetaxel, free of charge, for all participants. If docetaxel becomes commercially available for this indication, there is a remote possibility that you may be asked to purchase subsequent supplies. Your doctor will discuss this with you should this situation arise.

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.

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 new information or changes in the study that may affect your health or your willingness to continue in the study.

It may be necessary to contact you at a future date regarding new information about the treatment you have received. For this reason, we ask that you notify the institution where you received treatment on this study of any changes in address. If you move, please provide your new address to the following person:

(name) \_\_\_\_\_ (title) \_\_\_\_\_  
(address) \_\_\_\_\_ (phone number) \_\_\_\_\_.

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).

## RELATED STUDIES

**Please note: The following section of the informed consent form is about additional research studies that are being 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 any of these additional studies.**

The results of these research studies will not be provided to you or your doctor, nor will the results have any effect on your treatment. It is unlikely that what we learn from these studies will have a direct benefit to you. However, the information learned from these studies may benefit other patients in the future.

The results from these studies may be published, but individual patients will not be identified in these publications.

There will be no charge to you for participating in these research studies. Your sample will only be used for research and will not be sold. The research done with your sample may help to develop new products in the future.

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 is very small.

If you decide now to participate and then change your mind at any time about participating in these studies for any reason, you should contact your institution and let them know that you do not want the researchers to use your sample. The sample will then no longer be used for research. It will either be destroyed or returned to your institution for storage. The sample will also be returned to your institution upon request if needed for any other medical or legal reasons.

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

### *Diet and Lifestyle Study*

The study investigators would like to ask you to fill out a survey about your diet and lifestyle, which includes questions about your physical activity and smoking history. This questionnaire should take about 1 hour to complete and will be given to you at your first clinic visit, 3 months after your surgery.

- 1) I choose to take part in the diet and lifestyle study and agree to complete the diet and lifestyle questionnaire:

\_\_\_\_\_ Yes

\_\_\_\_\_ No

Initials \_\_\_\_\_



## 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 C90203: RANDOMIZED PHASE III STUDY OF NEO-ADJUVANT DOCETAXEL AND ANDROGEN DEPRIVATION PRIOR TO RADICAL PROSTATECTOMY VERSUS IMMEDIATE RADICAL PROSTATECTOMY IN PATIENTS WITH HIGH-RISK, CLINICALLY LOCALIZED PROSTATE CANCER.**

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

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

- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
- National Cancer Institute of Canada Clinical Trials Group (NCIC CTG), the research group coordinating this study.
- The company that makes the study drugs and are supporting the study.
- NCI US (National Cancer Institute in the United States)
- Therapeutic Products Program of Health Canada (because it oversees the use of drugs in Canada)
- The Northwest CCOP
- 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; Northwest CCOP  
315 Martin Luther King Jr., Way  
Tacoma, WA 98405  
(253) 403-1461

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

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

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

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

**Signatures**

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

Signature of Patient or Patient's Legal Representative: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name of Legal Representative (if any): \_\_\_\_\_

Representative's Authority to Act for Patient: \_\_\_\_\_

Signature of Person Obtaining Authorization: \_\_\_\_\_

Printed Name of Person Obtaining Authorization: \_\_\_\_\_