

Northwest Community Clinical Oncology Program (NWCCOP)

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Sponsored and Funded by the National Cancer Institute

CONSENT FORM

CIRB R0232: A Phase III Study Comparing combined External Beam Radiation and Transperineal Interstitial Permanent Brachytherapy with Brachytherapy Alone for Selected patients with Intermediate Risk prostatic Carcinoma.

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CIRB R0232: A Phase III Study Comparing combined External Beam Radiation and Transperineal Interstitial Permanent Brachytherapy with Brachytherapy Alone for Selected patients with Intermediate Risk prostatic Carcinoma.

RISK PROSTATIC CARCINOMA.

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your friends and family. The National Cancer Institute (NCI) booklet, "Taking Part in Clinical Trials: What Cancer Patients Need To Know," is available from your doctor.

You are being asked to take part in this study because you have prostate cancer.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to compare the effects (good and bad) of two different radiation treatments in patients with prostate cancer. The effects of placing small radioactive pellets (hereinafter called seeds) inside your prostate (brachytherapy) after external radiation therapy will be compared to the effects of using brachytherapy alone in patients with prostate cancer.

This research is being done to see which treatment is better. This study will also look at your already biopsied prostate cancer tissue for information that may help to predict and treat prostate cancer in the future. In addition, the study will gather information about the effects of the treatment on your quality of life. A cost comparison between the two treatments, including long term costs thereafter, is also planned for participants under Medicare.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY

About **586** people in North America will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

SCHEMA

S	<u>Stage</u>	R		R	<u>Arm 1:</u> 45 Gy EBRT
	1. T1c				Partial pelvis (1.8 Gy/fraction M-F for
T	2. T2a – T2b	E	<u>Isotope</u>	A	five weeks) followed 2-4 weeks later
			1. I-125	N	by Pd-103 (100 Gy) or I-125 (110
R	<u>Gleason Score</u>	C		D	Gy)*
	1. ≤ 6		2. Pd-103		or
A	2. 7	O		O	
T	<u>PSA</u>	R		M	<u>Arm 2</u> Pd-103 (125 Gy) or I-125
	1. 0 - < 10				(145 Gy)*
I	2. 10-20	D		I	
F	<u>Neoadjuvant</u>			Z	
	<u>Hormonal</u>			E	
Y	<u>Therapy</u>				
	1. No				
	2. Yes				

*PROTOCOL TREATMENT MUST BEGIN WITHIN FOUR WEEKS AFTER STUDY ENTRY.

You will be “randomized” into one of the study groups (arms) described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group.

Treatment Arm 1: External Radiation Therapy and then Brachytherapy

External Radiation Therapy:

If you are randomized to receive this treatment, external radiation therapy to your prostate will be given once a day, five days a week, Monday to Friday, for five weeks. External radiation therapy treatments will be given on an outpatient basis at your institution.

Brachytherapy (Internal Radiation Therapy):

Two to four weeks after the completion of external radiation therapy, radioactive seeds will be implanted into your prostate. This procedure is done on an outpatient basis under anesthesia at your institution. Procedures that are done to deliver brachytherapy:

- **Local or general anesthesia will be given prior to and during the procedure.**

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-

- **With the help of ultrasound, thin needles with radioactive pellets will be inserted through the skin between your anus and scrotum into your prostate.**
- **As each seed is placed in the correct position, the needle is pulled out leaving the seed in your prostate.**

The number of needles and seeds varies depending on the size and shape of your prostate.

Treatment Arm 2: Brachytherapy Alone

Brachytherapy (Internal Radiation Therapy):

This is the same as the Brachytherapy described under Arm 1 above, except that the radioactive seeds will deliver a somewhat higher dose of radiation.

Treatment Arms 1 and 2:

If you take part in this study, you will have the following tests and procedures:

- A physical examination, including a digital rectal exam (DRE):
 - prior to beginning treatment,
 - weekly in Arm 1 during external radiation therapy (*NOTE: DRE is optional/at study doctor's discretion*);
 - at 4, 6, 9 and 12 months for the first year following treatment, (*NOTE: at 4 months is DRE optional/at study doctor's discretion*);
 - every 6 months for the next four years;
 - and then annually for the rest of your life.

The follow-up visits generally take 15 to 30 minutes (in addition to time for answering questionnaires described below).

- Blood tests prior to beginning treatment; weekly during radiation therapy if your doctor feels these tests are needed, and at each follow-up visit (except at the 4 and 9 month visits) as described above.
- An ultrasound examination of your prostate prior to brachytherapy. This is a brief, outpatient procedure in which an ultrasound probe is placed into your rectum to determine the precise size and shape of your prostate. This procedure determines where each needle and seed will be placed.
- Your doctor may want an examination of your bladder prior to treatment. This may include insertion of a small flexible tube through your penis into your bladder (cystoscopy).
- CT scan, MRI, or possible removal and biopsy of pelvic lymph glands, if indicated, to evaluate your cancer prior to treatment.

- If your disease worsens, your physician may request a needle biopsy of your prostate to see how your prostate has responded to treatment.
- A CT scan of your prostate, a pelvic x-ray, and two chest x-rays 3 to 5 weeks following radioactive seeds being implanted.
- You will be asked to complete four questionnaires about your sexual and urinary functioning and overall quality of life. These questionnaires should take about 25-30 minutes to complete. You will be asked to complete these forms prior to treatment, at 4 months, 12 months, and 24 months after treatment and once a year after that for three years.

HOW LONG WILL I BE IN THE STUDY?

If you receive Treatment 1, you will receive external radiation therapy once a day, five days per week for five weeks. Two to four weeks following radiation therapy, the radioactive seeds will be implanted into your prostate. Follow-up visits will continue for the rest of your life according to the above schedule.

If you receive Treatment 2, the radioactive seeds will be permanently implanted within 2 to 4 weeks from study enrollment. Follow-up visits will continue for the rest of your life according to the above schedule.

The researcher may decide to discontinue your treatment if it is in your medical best interest, your condition worsens, or new information becomes available and this information suggests the treatment will be ineffective or unsafe for you. It is unlikely, but the study may be stopped early due to lack of funding or of enough participants.

You can stop participating at any time. However, before you do this, we ask you to talk with the researcher and your regular doctor first.

WHAT ARE THE RISKS OF THE STUDY?

While on the study, you are at risk for these side effects. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and uncomfortable, such as medication to reduce irritation of the bowel, rectum, or bladder. Trouble with erections also can be successfully treated with medication in many circumstances. Many side effects go away shortly after the radiation therapy is stopped, but in some cases side effects can be serious or long-lasting or permanent. Some side effects do not become apparent for months or years after all treatment has been delivered.

Risks Associated with Implant Therapy

Very Likely

- Infection that can be treated with antibiotics
- Soreness in the implant area
- Temporary fatigue
- Temporary nausea
- Temporary diarrhea
- Abdominal cramps
- Bladder irritation with some bleeding
- Inability to achieve an erection
- Urinary tract infection (*UTI*)

Less Likely, But Serious

- Injury to the bladder, urethra, bowel or other tissues in your pelvis or abdomen
- Rectal bleeding that requires medication or burning/cutting of tissue or surgery to correct
- Intestinal or urinary obstruction
- Inability to control urination
- Movement of a radioactive seed to the lungs
- Serious infection
- Rectal fistula (breakdown of tissue between the urinary tract and rectum)

Risks Associated with External Radiation Therapy

Very Likely

- Tanning or redness of skin in treatment area
- Rash, itching or peeling of skin
- Temporary hair loss in the treatment area
- Temporary nausea
- Temporary diarrhea
- Abdominal cramps
- Bladder irritation with a stinging sensation
- Frequency or urgency of urination
- Inability to control urination (incontinence)
- Rectal irritation with more frequent bowel movements
- Fatigue
- Urinary Tract Infection (UTI)
- Inability to achieve an erection

Less Likely, But Serious

- Injury to the bladder, urethra, bowel or other tissues in your pelvis or abdomen
- Intestinal or urinary obstruction
- Rarely, rectal bleeding that requires medication or burning/cutting of tissue or surgery to correct

Risks Associated with External Radiation Therapy AND Seed Implant Therapy:

- Worsening of bowel, bladder or sexual dysfunction problems
- An overall decrease in your quality of life

Reproductive Risks:

If you are a man able to father children, the treatment you receive may risk harm to an unborn child unless you use a form of birth regulation (regulation highly effective: abstinence, IUD, birth control pills, tubal ligation or partner's vasectomy and less effective: condom, diaphragm or cervical cap) approved by your doctor. If you are unwilling to use adequate birth regulation (regulation highly effective: abstinence, IUD, birth control pills, tubal ligation or partner's vasectomy and less effective: condom, diaphragm or cervical cap) measures to prevent pregnancy, you should not participate in this study. If you suspect you have caused anyone to become pregnant while you are on this study, you must tell your doctor immediately.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other patients with prostate cancer in the future.

WHAT OTHER OPTIONS ARE THERE?

Other options that could be considered for your condition instead of this study may include the following: (1) external radiation therapy alone, whether standard, three dimensional conformal, or intensity modulated radiation therapy (IMRT); (2) internal radiation therapy (brachytherapy) like this study, or by temporary insertion of radioactive rods, called high dose rate therapy; (3) hormone therapy; (4) surgery to remove your prostate (radical prostatectomy); (5) watchful waiting with regularly scheduled monitoring with digital rectal exams (DRE) and PSA blood draws; or (6) no treatment except medications to make you feel better. With the latter choice, your tumor would continue to grow and your disease would likely eventually spread. The treatments (1) through (4) could be given either alone or in combination with each other.

Your doctor can tell you more about your condition and the possible benefits of the different available options.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Records of your progress while on the study will be kept in a confidential form at this institution and in a computer file at the headquarters of the Radiation Therapy Oncology Group (RTOG). Your personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Food and Drug Administration (FDA), the National Cancer Institute (NCI) or its authorized representatives, the Cancer Trials Support Unit (CTSU), qualified representatives of applicable drug manufacturers, and other groups or organizations that have a role in this study.

WHAT ARE THE COSTS?

Taking part in this study may lead to added costs to you or your insurance company. If you are randomized to receive Treatment 1, the combination of external radiation with implant may result in higher costs to you or your insurance company than an implant alone. Please ask about any expected added costs or insurance problems.

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. Although no funds have been set aside to compensate you in the event of injury or illness related to your treatment or procedures, 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 continuing medical care and/or hospitalization. Medicare should be considered a health insurance provider.

You will receive no payment for taking part in this study.

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.nci.nih.gov/ClinicalTrials/insurance> (and click on printable version).

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. If you choose to stop participating in the study, you should first discuss this with your doctor. In order to provide important information that may add to the analysis of the study, he/she may ask your permission to submit follow-up data as it relates to the study. You may accept or refuse this request. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

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 the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For information about your disease and research-related injury, you may contact

For information about this study, you may contact the number listed on the cover sheet.

For information about your rights as a research subject, you may contact the MultiCare Health System Investigational Review Board at 253-403-3877.

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

WHERE CAN I GET MORE INFORMATION?

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

Visit the NCI's Web sites

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

for cancer information go to <http://cancer.gov/cancerinformation>

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

SIGNATURE

I have read all the above, asked questions, and received answers concerning areas I did not understand. I have had the opportunity to take this consent form home for review or discussion.

I willingly give my consent to participate in this program. Upon signing this form I will receive a copy. Upon request, I will also receive a copy of the protocol (*full study plan*).

Patient's Name

Signature

Date

Name of Person Obtaining Consent

Signature

Date

CONSENT FORM FOR USE OF TISSUE FOR RESEARCH

ABOUT USING TISSUE FOR RESEARCH

We would like to keep some of the tissue that remains from the biopsy you underwent in the diagnosis of your cancer for future research. If you agree, this tissue 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 is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

All possible methods will be used to ensure your privacy and confidentiality. Identifying information will be taken off anything associated with your tissue before it is given to a researcher. Reports about research done with your tissue 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 for future research is up to you. **No matter what you decide to do, it will not affect your care or participation in the primary study.**

If you decide now that your tissue 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, and then any tissue that remains will no longer be used for research.

In the future, people who do research may need to know more about your health. While doctor/institution may give researchers reports about your health, your doctor/institution will not give researchers your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes tissue is 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. However, the research done with your tissue may help to develop new products in the future, or your tissue may be used to establish a cell line that could be patented and licensed. If this occurs, you will not be paid for this use.

BENEFITS

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

RISKS

There is a very small chance that information from your health records could be incorrectly released. All possible methods will be used to protect your privacy and ensure confidentiality. Unless you have given your specific permission, your (doctor/institution) will not release your personal results or information to third parties such as employers or insurers.

In the case of injury or illness resulting from participating in this research, emergency medical treatment is available but will be provided at the usual charge. Although no funds have been set aside to compensate you in the event of injury or illness related to your participation in this research, you do not waive any of your legal rights to compensation, if any, by signing this form.

MAKING YOUR CHOICE

If you have any questions about the research involving your tissue or about this form, please talk to your doctor or nurse, or call the institution's research review board at 253-403-3877.

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". **No matter what you decide to do, it will not affect your care or participation in the primary study.**

1. My tissue may be used for the research in the current study.

Yes **No** **Initials:** _____

2. My tissue may be kept for use in research to learn about, prevent, or treat cancer.

Yes **No** **Initials:** _____

3. My tissue 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).

Yes **No** **Initials:**_____

4. Someone from doctor's office/institution may contact me in the future to ask me to take part in more research.

Yes **No** **Initials:** _____

Participant statement:

I have read and received a copy of this consent form. I have been given an opportunity to discuss the information with my doctor/nurse, and all of my questions/concerns have been answered to my satisfaction. My answers above and my signature below indicate my voluntary participation in this research.

Patient's Name

Signature

Date

Witness statement:

I have explained the information in this consent form to the patient and have answered any questions raised. I have witnessed the patient's signature.

Name of Person Obtaining Consent

Signature

Date

CONSENT FORM FOR USE OF COST DATA FOR RESEARCH
(Limited to Participants Whose Health Care is Covered at Least in Part by Medicare)

ABOUT USING COST INFORMATION FOR RESEARCH

In comparing different treatments for prostate cancer, very little is known about long-term costs of different kinds of treatment. This study compares two different kinds of treatment that are different in their initial costs. However, the long-term costs of the two different treatments are not known. Obtaining this information would allow us to study both the cost and the benefits of the treatments involved in this study. This information would help patients; physicians and providers make more informed decisions about these therapies in the future.

We would like to obtain information about both the short-term and the long-term costs of treatment for your prostate cancer. To do this, we would like to use computerized information from the Medicare system to estimate the costs of your medical care. You are being asked to provide your name and Social Security Number so that we may link your treatment and outcomes to the cost data involved in both your treatment and follow-up care.

This information is private and confidential. We must have your permission to use a personal identifier to obtain your specific Medicare information. **The specific information about you that is collected will not be given to any other party, including your physician, the hospital, or any other third party. These reports will not be put in your health record.** The Medicare data will be aggregated with data from all patients participating in this portion of the study, and only reported in aggregate form. No personal identifying information will be made public.

This cost information will be used only for research.

THINGS TO THINK ABOUT

The choice to let us have access to your Medicare information is up to you. **No matter what you decide to do, it will not affect your care or participation in the primary study.**

If you decide now that your Medicare data may be used 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 information, and your information will be removed from the study database.

BENEFITS

The benefits of research using costs data include learning how to achieve the most effective treatments for cancer while avoiding added costs and decreased quality of life for patients. This information would help patients like you; physicians and providers make more informed decisions about these therapies in the future.

RISKS

There is a very small chance that information from your billing information could be incorrectly released. If you give your permission for us to use your Medicare information, that information will be furnished to the RTOG directly by Medicare, and will not be made available to any third party, including your physician, hospital, employer, or other insurer. All possible methods will be used to protect your privacy and ensure confidentiality.

MAKING YOUR CHOICE

If you have any questions about the research involving your cost data or about this form, please talk to your doctor or nurse, or call the institution's research review board at 253-403-3877.

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". **No matter what you decide to do, it will not affect your care** or participation in the primary study.

My Medicare data may be used for the research in the current study.

Yes

No Initials: _____

Participant statement:

I have read and received a copy of this consent form. I have been given an opportunity to discuss the information with my doctor/nurse, and all of my questions/concerns have been answered to my satisfaction. My answers above and my signature below indicate my voluntary participation in this research.

Patient's Name

Signature

Date

Witness statement:

I have explained the information in this consent form to the patient and have answered any questions raised. I have witnessed the patient's signature.

Name of Person Obtaining Consent

Signature

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 R0232: A PHASE III STUDY COMPARING COMBINED EXTERNAL BEAM RADIATION AND TRANSPERINEAL INTERSTITIAL PERMANENT BRACHYTHERAPY WITH BRACHYTHERAPY ALONE FOR SELECTED PATIENTS WITH INTERMEDIATE RISK PROSTATIC CARCINOMA.

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.

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: _____