

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

Study Title: RTOG 0526: A Prospective Phase II Trial of Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent Prostate Adenocarcinoma Following External Beam Radiotherapy

This is a clinical trial, a type of research study. Your study doctors, Mack Roach III, M.D., I-Chow Joe Hsu, M.D., Alexander Gottschalk, M.D., Joycelyn Speight, M.D. from the UCSF Department of Radiation Oncology, 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 that has come back in your prostate after being treated with external beam radiotherapy.

Why is this study being done?

The purpose of this study is to evaluate the safety and effectiveness of brachytherapy (radiation seed implants) as treatment for prostate cancer that has come back in the prostate after external radiotherapy. The study will examine the side effects of the implants as well as the ability of the implants to get rid of the cancer.

It is important for you to realize that sometimes when prostate cancer comes back in the prostate after radiation, it may be very slow growing and may not cause you symptoms or problems for years. Sometimes just monitoring your condition and not undergoing repeat treatment is appropriate. The treatment offered in this study may cause side effects. The side effects are discussed in this consent form, and you should read that section carefully and discuss it with your study doctor.

How many people will take part in this study?

About 96 men will take part in this study nationwide. About 5 men will take part in this study at UCSF.

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.

Before starting any treatment, your study doctor needs to know that your prostate cancer grew back in your prostate gland and that it has not spread to other parts of your body. You will therefore need to have the following tests:

- A transrectal ultrasound (TRUS) will be done to measure the size of the prostate and see if cancer has spread to the nearby tissues. Small tissue samples will be taken by a needle biopsy done through the rectum into the prostate gland. If this shows prostate cancer, other tests will be done.
- About 2 tablespoons of blood will be taken from a vein. Tests will be done to determine the level of prostate-specific antigen (PSA) and may be done to check for low hemoglobin (anemia), the number of infection-fighting (white cells) and blood-clotting (platelets) cells, and how well your kidneys are working.
- A bone scan will check for cancer spread to your bones.
- Computed tomography (CT) or magnetic resonance (MR) imaging of the pelvis and abdomen will be done to see if the cancer has spread.
- We may need to biopsy areas other than the prostate or do surgery to see if the cancer spread to certain lymph nodes.

In addition, your study doctor will need to send to a central study office a slide of the tumor tissue obtained at the time that you had surgery to find out if your prostate cancer came back. There, a pathologist will confirm that your tumor is the type of prostate cancer that the study doctors are evaluating in this study.

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 these tests and procedures.

- A second TRUS may be done to measure the size of the prostate and to plan the prostate seed implantation. This may be done either at the time of the seed implant or within four weeks before the implant. This is done on either an inpatient (stay overnight) or outpatient (go home the same day) basis. The implantation will be done in the following way:
 - General or spinal anesthesia will be given before and during the implantation.
 - A tube (catheter) is inserted through the penis into the bladder, so urine can be drained.
 - Using TRUS for guidance, thin needles will be inserted through the skin between the anus and scrotum and positioned in the prostate.
 - The radioactive seeds will be put into the prostate as the needles are removed.
 - You will be taken to a recovery area after the seed implantation is done and may then go home, or you may stay overnight in the hospital.
 - The tube will be removed from the bladder either before you leave for home or within a day or two.

After the prostate seed implantation is complete...

- Although the seeds are permanent, they release radiation only for a period of time. The amount of radiation you will give off following the implant is very low, so that you can leave the hospital immediately after the implant procedure. However, it is also recommended that you try to keep a 6-foot distance from babies, pregnant women, and small children for 3 weeks to 2 months after the procedures, depending on the type of implant your doctor uses. Your study doctor can tell you more details about the specific time period for which you should stay at a distance.
- You will come back to the study office three to five weeks later to have a CT scan of the prostate seed implantation area.
- You will have follow-up visits every three months for the first year, every six months for the next four years, and then every year for the rest of your life. Your study doctor will examine you and your prostate and will check your PSA (by a blood test) during these visits. Depending on the result of your PSA test, your study doctor may also see if other tests such as a bone scan or a biopsy of the prostate gland are needed at certain times.
- At each follow-up visits (until the end of the third year of the study), you will also be asked to answer a questionnaire that looks at urinary symptoms.

How long will I be in the study?

After the prostate seed implantation, this study will follow you for life and your medical records will also be reviewed until this study is terminated. You will visit your study doctor every three months for the first year after implantation, every six months for the next four years, and then every year for the rest of your life.

Can I stop being in the study?

Yes. You can stop being in the study at any time. Tell the study doctor if you are thinking about stopping or you 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 him or her. Another reason to tell your study doctor that you are thinking about stopping is to discuss what follow-up care and testing would be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he or 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 from this treatment. 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. You may not have any of these side effects. Your health care team may give you medicines to help lessen side effects. Many side effects go away within a few weeks of the seed implant. In some cases, side effects may be serious, long lasting, or may never go away. We may need to use drugs to help these problems, but they may not cure the problem. There 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.

Prostate seed implantation is done with anesthesia. Risks and side effects related to the anesthesia include those that are

Likely

- Nausea
- Vomiting
- Headache
- Sore throat

Rare but serious

- Blood pressure or heart rhythm problems
- Problems breathing
- Heart attack
- Allergic reaction
- Stroke
- Death

Risks and side effects related to the seed implant include those that are:

Likely

- Weak (slow) stream of urine
- Frequent urination
- Strong urges to urinate
- Pain when urinating

These problems are common, but they may improve or go away in many patients with time or the use of medicines.

Less Likely

- Need for use of a urinary catheter for an indefinite duration after the implant
- Blood in the urine shortly after brachytherapy (this usually clears up) or some months or years later
- Leakage of urine (incontinence)
- Pain in the implantation area (mild)
- Bladder infections that require antibiotics
- Injury to the rectum that may cause pain, bleeding, or leakage of stool
- Injury to the bladder, urethra, bowel, or other tissues in the pelvis
- Even though there may be no health risk, some radioactive seeds may travel to other parts of the body through a vein; however, the seeds release radiation only for a period of time

Rare but Serious

- Damage to the rectum requiring surgery or a colostomy (external bag to collect stool)

For more information about risks and side effects, ask your study doctor.

Reproductive Risks

Very small amounts of radiation from the radioactive seeds can reach other people. Talk to your study doctor if you are sexually active or are in close contact with small children and/or pregnant women. Exposure to radiation may be harmful to an unborn child. There is not enough medical information to know what the risks might be. You or your sexual partners must use one of the following birth control measures while you are in this study: condoms, diaphragm, birth control pills or injections, intrauterine device (IUD), surgical sterilization, abstinence. In addition, you should use condoms during the first month following seed implantation due to the possibility that the seeds can be released during ejaculation.

Unknown Risks

There may be as yet unknown risks associated with the study treatment. You will be informed of any new information as it becomes available.

Are there benefits to taking part in this study?

It is possible that this treatment will get rid of your prostate cancer. This could stop the cancer from spreading to other parts of your body. This may give you a healthier and longer life, but it is also possible this study may not make your health better.

We do know that the information from this study will help doctors learn more about prostate seed implants as a treatment for cancer that has come back in the prostate. 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:

- Surgical removal of the prostate (prostatectomy)
- Freezing the prostate (cryosurgery)
- Hormonal therapy
- Prostate seed implantation that is not as a part of this 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?

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 (RTOG)
- Local institutional research boards
- The National Cancer Institute (NCI) and other government agencies, such as the Food and Drug Administration (FDA), involved in keeping research safe for people

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.

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://www.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 doctors, Mack Roach III, M.D., I-Chow Joe Hsu, M.D., Alexander Gottschalk, M.D. and Joycelyn Speight, M.D., if you feel that you have been injured because of taking part in this study. You can tell the doctors in person or call him/her at (415) 353-7175.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, treatment will be available. The costs of the treatment may be covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

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.

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 doctors about any questions or concerns you have about this study. Contact your study doctors, Mack Roach III, M.D., I-Chow Joe Hsu, M.D., Alexander Gottschalk, M.D. and Joycelyn Speight, M.D. at (415) 353-7175.

For questions about your rights while taking part in this study, call the office of the **Committee on Human Research**, UCSF's Institutional Review Board (a group of people who review the research to protect your rights) at **415-476-1814**.

Consent Form for Use of Tissue for Research

About using tissue for research

You have had a biopsy (or surgery) to see if you have cancer. Your doctor has removed some tissue to do some tests. The results of these tests will be given to you by your doctor and will be used to plan your care.

We would like to keep some of the tissue that is left over 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. 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://www.cancerdiagnosis.nci.nih.gov/specimens/patient.pdf>.

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. 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.

For those patients whose tumors come back after receiving prostate seed implantation:

If your study doctor recommends it and if you give your permission, you may have another biopsy to confirm that your tumor has come back. We would like to have this tissue sent to a central study office, so that a central pathologist can confirm that your tumor has come back. In addition, we would like to keep some of the tissue that is left over 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.

Things to think about

The choice to let us keep the leftover tissue 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 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. Then any tissue that remains will no longer be used for research and will be returned to the institution that submitted it.

In the future, people who do research may need to know more about your health. Although the study doctor/institution may give them reports about your health, it will not give them 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 and will not be sold. The research done with your tissue may help to develop new products in the future. In some instances, there may have potential commercial value. There will be no additional charge, and you will not receive any payment or financial benefit from any products, tests, or discoveries.

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

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 research review board at IRB’s phone number.

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

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

Yes

No

2. 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

3. Someone may contact me in the future to ask me to take part in more research.

Yes

No

For patients whose tumors come back after receiving prostate seed implantation:

4. My tissue may be sent to a central pathologist to confirm that my tumor has come back.

Yes

No

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

Yes

No

6. 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).

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.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent

Date

Translator's Signature