

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

**Study Title: RTOG 0415: A Phase III Randomized Study of Hypofractionated 3D-CRT/IMRT Versus Conventionally Fractionated 3D-CRT/IMRT in Patients with Favorable-Risk Prostate Cancer**

This is a clinical trial, a type of research study. Your study doctor(s), 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 and their associate, Judith Luce, M.D. from San Francisco General Hospital (SFGH) 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 participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have prostate cancer and your doctor has recommended external beam radiation therapy.

**Why is this study being done?**

One of the standard treatment options for your stage and type of prostate cancer is external beam radiation therapy. More recent radiation therapy planning methods with three-dimensional therapy or intensity modulated radiation therapy (IMRT) allows safer delivery of higher than standard daily doses of radiation. The purpose of this study is to compare the effects (good and bad) on you and your cancer of the standard dose of radiation therapy (41 treatments over 8 weeks) with a higher daily dose (experimental) of radiation (28 treatments over 5 and a half weeks over a shorter period of time) to see if the effects of the treatments are similar.

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

About 1067 people will take part in this study nationwide. About 50 people will participate in this study at UCSF and SFGH.

**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.

- History and physical exam, including a digital rectal exam (DRE) and an assessment of your ability to carry out activities of daily living (which will include questions such as whether you are able to feed, bathe, and dress yourself)
- A biopsy of your prostate to determine your Gleason score (a value that helps determine the stage of your prostate cancer)

- A blood test to determine your PSA (a value that helps determine the stage of your prostate cancer). About 2 teaspoons of blood will be drawn from a vein or, if you have one, a catheter. The study doctor may also test your testosterone and alkaline phosphatase levels.

### **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.

- History and physical exam, including assessment of your ability to carry out activities of daily living (*Weekly during radiation treatment*)

**You will need this assessment to see how the study is affecting your body.**

- Assessment of any side effects you may be experiencing from the treatment (*Weekly during radiation treatment*)

**You will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in either group.**

### **If you are in group 1 (often called “Arm A”)...**

You will receive the standard daily dose of three-dimensional radiation or IMRT. You will receive radiation therapy once daily, 5 days a week, Monday through Friday, for a total of 41 treatments. Each radiation treatment will take 15-30 minutes.

### **If you are in group 2 (often called “Arm B”)...**

You will receive a higher daily dose of three-dimensional radiation or IMRT. You will receive radiation therapy once daily, 5 days a week, Monday through Friday, for a total of 28 treatments. Each radiation treatment will take 15-30 minutes.

### **When you are finished receiving radiation...**

You will need these tests and procedures:

- History and physical exam, including a digital rectal exam (DRE) and an assessment of your ability to carry out activities of daily living (*Every 3 months for the first 2 years following the start of radiation, every 6 months for the next 3 years, and then annually*)
- Assessment of any side effects you may be experiencing from the treatment (*Every 3 months for the first 2 years following the start of radiation, every 6 months for the next 3 years, and then annually*)
- If your disease progresses, your study doctor may request a needle biopsy of your prostate to microscopically evaluate response to treatment

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

You will receive radiation treatments for either 5 and a half or 8 weeks. After you are finished receiving radiation, the study doctor will ask you to visit the office for follow-up exams every 3 months for the first 2 years following the start of radiation, then every 6 months for the next 3 years. After that, the study doctors would like to keep track of your medical condition indefinitely by seeing you for follow-up exams every year.

### **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 radiation can be evaluated by him/her. 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 decide to take you off 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 radiation. In some cases, side effects can be serious, long lasting, or may never go away. In addition, some of the side effects may be life threatening and, in rare instances, may cause 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 radiation include those which are:**

#### **Likely**

- Tanning, redness, or darkening of skin in treatment area
- Rash, itching or peeling of skin
- Temporary hair loss in the treatment area
- Temporary fatigue, nausea or diarrhea
- Abdominal cramps
- Bladder irritation with a stinging sensation
- Frequency or urgency of urination
- Rectal irritation with more frequent bowel movements
- Mild rectal bleeding that does not require treatment

#### **Less Likely**

- Urinary obstruction requiring the placement of a temporary urinary catheter

#### **Rare but serious**

- Injury to the bladder, urethra, bowel, or other tissues in the pelvis or abdomen

- Intestinal or urinary obstruction
- Inability to achieve an erection (inability of the penis to become hard)
- Rectal bleeding that requires medication or surgery to stop

### **Reproductive risks:**

You should not father a baby while on this study because the radiation can affect an unborn baby. It is important you understand that you need to use birth control while on the 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.

### **Unknown Risks:**

The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

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 is not known whether the higher daily dose of three-dimensional radiation therapy or IMRT is equivalent to the standard daily dose. We do know that the information from this study will help researchers learn more about these different doses as a treatment for prostate cancer. This information could help future patients with prostate cancer.

### **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 could include the following options, either alone or in combination with each other:
  - External (non-three-dimensional) radiation therapy
  - Internal radiation (seed implants or brachytherapy)
  - Three-dimensional radiation therapy or IMRT similar to the therapy described in this study
  - Surgery
  - Hormone therapy
- Taking part in another study
- Getting no treatment (With this choice, your tumor could continue to grow and your disease could spread)

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?**

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 National Cancer Institute (NCI) and other government agencies involved in keeping research safe for people, like the Central Institutional Review Board (CIRB) and the Food and Drug Administration (FDA)
- The Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials [for CTSU participants only]
- A Data Monitoring Committee (DMC) that regularly meets to monitor safety and other data related to this study

### **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/insurance company to find out what they will pay for. Taking part in this study may or may not cost you or your insurance company more (or less) than the cost of getting regular cancer treatment.

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.

### **Will I be paid for taking part in this study?**

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

### **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., Joycelyn Speight, M.D., and Judith Luce, M.D., 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 (415) 353-7175, if you're a UCSF patient. If you're SFGH patient, then you can call your doctor at (415) 476-4082 x414.

**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 or the study sponsor, RTOG depending on a number of factors. The University and the study sponsor do 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 doctor about any questions or concerns you have about this study. Contact your study doctor(s) Mack Roach III, M.D., I-Chow Joe Hsu, M.D., Alexander Gottschalk, M.D., Joycelyn Speight, M.D. and Judith Luce, M.D. at (415) 353-7175 or (415) 476-4082 x414.

**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**.

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**Please note: This 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.**

**You can say "yes" or "no" to each of the following studies. 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 treatments are having. In the future, this information may help patients and doctors as they decide which treatments to use to treat cancer.

You will be asked to complete four questionnaires at the following time points: immediately before you enroll in the study, at 6, 12, and 24 months following the start of your radiation treatment, and at 5 years following the start of your radiation treatment. It takes about 25-30 minutes to fill out the questionnaires.

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 four questionnaires. You may change your mind about completing the questionnaires at any time, and you may choose to discontinue answering the questionnaires altogether at any time.

No matter what you decide to do, it will not affect your care or your participation in the main part of the study.

Just like in the main study, we will do our best to make sure that your personal information will be kept private. You will not be paid for taking part in this study.

**Please circle your answer**

I choose to take part in the Quality of Life study. I agree to fill out the four Quality of Life questionnaires.

Yes

No

**Consent Form for Cost Study**

It is important to look at many aspects of cancer treatments including cost. The information will help those who make reimbursement policy better understand the cost and effects of treatments. One way to analyze costs is to link treatment data to Medicare reimbursement of treatments and of any symptoms you may experience during and after treatment. For example, we would look at the reimbursement for the doctor's time to evaluate you and all your records and the time it takes for the doctor and radiation therapists to do radiation treatment planning and then to actually treat you with radiation therapy. We would also look at Medicare reimbursement for the treatment of any side effects of therapy like diarrhea or urinary frequency or other side effects that may occur.

In order to get your data from Medicare on reimbursement amounts your social security number is required; due to the need for this data, you will be asked to provide your social security number. Your social security number will not be used for any other purpose. We will do our best to make sure that your personal information is kept private; the chance that this information will be given to someone else is very small.

Linking the Medicare reimbursement costs with the treatment outcomes will provide a comparison of cost and effects for each treatment arm. No individual patient can ever be identified by combining all costs and treatment outcomes.

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 provide your social security number. You may refuse to take part in the cost part of the study but still participate in all other parts of the study. No matter what you decide to do, it will not affect your care or your participation in the main part of the study.

Just like in the main study, we will do our best to make sure that your personal information will be kept private. You will not be paid for taking part in this study.

Please circle your answer.

I choose to take part in the Cost study. I agree to provide my Social Security number, which will be used for no other purpose then for the study of costs and effects of this study.

Yes \_\_\_\_\_ Social Security Number \_\_\_\_\_ No \_\_\_\_\_

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

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

You have had a biopsy (or surgery) to see if you have cancer. Your doctor has removed some of your 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 from your biopsy 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.rtog.org/tissue %20for20%research\\_patient.pdf](http://www.rtog.org/tissue%20for20%research_patient.pdf)

In addition, you will have blood tests before you start treatment. We would like to keep about four tablespoons of blood for future research as well. If you agree, this blood will be kept and may be used in research to learn more about cancer and other diseases. One specific test will analyze whether your blood contains certain genes and if the side effects you had on radiation are related to these genes. We will then try to see if these genes can help us learn about why some people get worse side effects than others.

Your tissue and blood may be helpful for research. The research that may be done with your tissue and blood 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 and blood 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 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 and blood 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 blood. Then any tissue or blood that remains will no longer be used for research; remaining tissue will be returned to the institution that submitted it and remaining blood will be destroyed.



**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://www.cancer.gov/>**

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

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**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