Phase I-II trial of hypofractionated conformal proton beam radiation therapy
for favorable-risk prostate cancer

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**NCT# 00831623

Informed Consent Document

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LOMA LINDA UNIVERSITY
MEDICAL CENTER

DEPARTMENT OF RADIATION MEDICINE
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INFORMATION AND CONSENT FORM

HUMAN RESEARCH AND INFORMED CONSENT: You are being provided information about a human research study. The doctors at Loma Linda University Medical Center, Department of Radiation Medicine, study the nature of disease and try to develop better methods of diagnosis and treatment. This is called clinical research. In order for you to decide whether you should be in this study, you should understand enough about its risks and benefits to make an informed decision. This process is known as informed consent. **Please read this consent form carefully; do not hesitate to ask questions about any of the information in it.**

PURPOSE OF THE RESEARCH STUDY: You are invited to take part in this study because you have been diagnosed with early stage prostate cancer and are considering proton therapy. The purpose of this study is to determine if a shorter, more intense treatment schedule will result in equivalent tumor control rates and no increased side effects as compared to our current institutional standard treatment of an equivalent dose given over a longer period of time.

DESCRIPTION OF THE RESEARCH PROCEDURES: If you take part in this study, you will receive proton radiation therapy treatments once a day, five days a week, for 4 weeks. As part of this study, prior to study entry you will receive the following Standard of Care tests and procedures:

- History and physical exam, including digital rectal exam
- Non-contrast CT 3-D planning scan
- PSA
- Baseline urinary status evaluation
- Review of biopsy specimens
- Your study doctors may order additional x-ray exams if needed

Following treatment:

- Clinic visits including history & physical exam with digital rectal exam & PSA blood test following treatment at 3 months and every 3 months for first 2 years, then every 6 months for years 3-5, then yearly thereafter
- Blood tests, CT scans, and X-rays as needed per your study doctors
- Follow-up visits will continue for the rest of your life according to the schedule determined by your study doctor and coordinated with your personal physician

Initials _____

Date _____

POTENTIAL RISKS: Cancer therapies often have side effects. The treatment used in this program may cause all, some, or none of the side effects listed. Known possible side effects are listed below, but there is always the possibility of previously unknown or unanticipated side effects occurring.

Risks and side effects related to the Proton Therapy include those which are:

Likely (early SE, temporary)	Less Likely (early SE, temporary)	Rare But Serious
• Diarrhea • Bladder irritation • Fatigue • Burning, reddening or tanning of skin	• Pubic hair loss • Abdominal cramps • Rectal bleeding • Nausea	• Permanent injury to bladder, urethra, and rectum resulting in bleeding, infection, or incontinence • Permanent impotence

All precautions will be taken throughout your therapy to minimize or prevent side effects from occurring. Many side effects can be controlled with medication, which your doctor will prescribe for you when indicated. Appropriate monitoring after completion of your treatment should include physical examinations, blood tests, and scans performed several times per year for the first 5 years, then annually to monitor the effects of treatment and your disease status. The Institutional Review Board of Loma Linda University has determined that participating in this study may expose you to a minimal additional risk beyond that of conventional proton radiation.

POSSIBLE BENEFITS OF THE RESEARCH: It is not possible to predict whether any personal benefit will result from your participation in this study. This research is being done to optimize prostate cancer treatments. This information may be scientifically useful and will hopefully benefit future patients.

VOLUNTARY NATURE OF PARTICIPATION: Participation in this study is voluntary. Your decision whether or not to participate or withdraw at any time from the study will not affect your ongoing medical care/relationship to your doctors and will not involve any penalty or loss of benefits to which you are otherwise entitled. You may get a second opinion about your decision to be in this study from another doctor at your own cost. Likewise, your study doctor may withdraw you from the study for any reason without your agreement or may stop the study entirely. For clinical trials involving experimental treatment: If you decide to withdraw from the study, you must notify the study doctor or study staff immediately at (909) 558-4243.

NEW INFORMATION ARISING DURING THE RESEARCH: During this research study, the investigators may learn new information regarding the risks and benefits of the study. If this occurs, they will tell you about this new information. New information may show that you should no longer participate in the research. If this occurs, the persons supervising the research will stop your participation in it.

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ALTERNATIVE PROCEDURES OR TREATMENTS: Alternatives which could be considered in your case include electing not to participate in this study, in which case you would receive the other standard treatments for prostate cancer, such as conventionally fractionated proton radiation to the prostate gland over a period of 9 weeks, or surgery, or no treatment.

CONFIDENTIALITY: The records relating to your participation in the study will be maintained with your medical records. However, authorized research investigators may review the records of this research. Other health care providers will have access to research-related information contained in your medical record with your written permission. Privacy and confidentiality of these records will be protected to the extent provided by law. The results of this research may be published. Published reports will not include your name or any other information that would identify you.

COSTS: You or your insurance company will be responsible for all costs incurred as part of your cancer treatment program, including physician's fees and diagnostic studies to evaluate your disease status, as well as hospital costs if such care is needed.

PAYMENT FOR PARTICIPATION: There will be no payment for participation in this study.

IMPARTIAL THIRD PARTY CONTACT: If you wish to contact an impartial party not associated with this study regarding any complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, 909-558-4647 for information or assistance.

PERSONS TO CONTACT: Study doctors include Jerry D. Slater, MD, principal investigator of this study, as well as attending physicians in the Department of Radiation Medicine. If you have questions regarding your participation in this study, you may speak with Dr. Slater or the study doctor who explained the study to you at (909) 558-4243.

RESEARCH RELATED INJURY: RESEARCH RELATED INJURY: Your study doctors will be monitoring your condition throughout the study, and precautions will be taken to minimize the risks to you from participating. If you are injured or become ill from taking part in this study:

- If the situation is a medical emergency **call 911** or go to the nearest emergency room. Then, notify the study doctor as soon as you can.
- For a non-emergency injury or illness, notify your study doctor as soon as you can.
- To contact Dr. Jerry Slater during regular business hours, dial (909) 558-4243. After hours, call (909) 558-4000 and ask for the Radiation Medicine doctor on call and identify yourself as a subject in this study.

Initials _____

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INFORMED CONSENT

I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I have received a copy of the California Experimental Subject's Bill of Rights and have had these rights explained to me. Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities. I may call Dr. Jerry Slater during routine office hours at (909) 558-4243 or during non-office hours at (909) 558-4000 and ask for the Radiation Oncologist on call if I have additional questions or concerns. I understand that if I am enrolled in an in-patient study, my primary care physician may be notified of my participation, for proper coordination of care. I hereby give voluntary consent to participate in this study.

I understand I will be given a copy of this consent form after signing it.

Signature of Subject Printed Name of Subject

Date

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with a copy of the California Experimental Subject's Bill of Rights, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered. For in-patient studies, I understand that it is my responsibility to notify the subject's primary care physician of study participation, as needed, for proper coordination of care. I will provide the subject or the legally authorized representative with a signed and dated copy of this consent form.

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Signature of Investigator(s) Printed Name(s) of Investigator(s)

Date