Title of research study: Pre-Treatment Counseling and Education for Urological Malignancy Patients

Investigator: Alan W. Shindel, MD, MAS

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have been identified as a man planning definitive management of prostate cancer with radiation therapy or surgical prostatectomy

What should I know about a research study?

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document**.**

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you may talk to the Principal Investigator or the Research Coordinator at (916-734-6498). In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/IRBAdmin.You may talk to an IRB staff member at (916) 703-9151, IRBAdmin@ucdmc.ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

For IRB Use

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	Approved
548665	12/16/2013

Why is this research being done?

We are interested in evaluating the benefit of expanded pre-treatment counseling and education for men planning to undergo management of prostate cancer with radiation therapy or surgical prostatectomy.

How long will the research last?

We expect that you will be in this research study for approximately 15 months (to include 12 months post-treatment follow-up).

How many people will be studied?

We expect about 150 people here will be in this research study, 75 people in Arm A and 75 in Arm B.

What happens if I say yes, I want to be in this research?

Expanded pre-treatment counseling and education consist of approximately 20 minutes of one on one time with Dr. Alan Shindel. During this appointment Dr. Shindel will discuss post-treatment quality of life expectations regarding urinary, sexual and bowel function. Post-treatment quality of life expectations are also addressed in detail in the book, " Promoting Wellness for Prostate Cancer Patients, a Guide for Men and Their Families," that all study patients will receive.

There are two Arms in this study. Arm A will meet with Dr. Shindel for pre-treatment counseling as described above in addition to completing a standard pre-treatment assessment under the direction of their treating physician. Arm B will receive a standard pre-treatment assessment under the direction of their treating physician. You may choose which arm you wish to take part in until one of the arms are filled; however, Dr. Shindel may not be available at the time of your pre-treatment meeting; in some cases an extra appointment will be required to participate in arm A.

At your first visit, once you have signed the consent form and have met all study requirements the following procedures will take place;

- Receive the book, "Promoting Wellness for Prostate Cancer Patients, a Guide for Men and Their Families."
- Complete two (2) surveys and one (1) questionnaire, which will take about 15 minutes to complete.
- Expanded pre-treatment counseling and education with Dr. Shindel for approximately 20 minutes (Arm A only)
- Complete Standard pre-treatment assessment and counseling

One of the study team members will meet with you at to complete two surveys and one questionnaire at approximately 3, 6 and 12 moths post radiation therapy or surgical prostatectomy. These post radiation and surgical prostatectomy visit coincide with when you see either Dr. Shindel or your oncologist. These

surveys and questionnaire are given to guide our clinical care and assess change in your situation over time.

Arm A patients will follow-up with Dr. Shindel at routine intervals after their treatment is complete.

Arm B patients will follow-up with the treating doctor; men in this arm may also be referred to Dr. Shindel at their request and the discretion of the treating doctor.

At the conclusion of each follow-up appointment you will be given a questionnaire about the quality of care you have received and if your post-treatment expectations are being meet.

Patients that have already received treatment for prostate cancer

If you have received treatment for prostate cancer, surgical prostatectomy or radiation therapy, prior to consenting, you are still eligible to participate in this study. Since you have already received treatment, the study arm will be dictated by the pre-treatment counseling you had received. If you consent, pre-treatment information will be gathered from you medical records to include weather or not you met with Dr. Shindel prior to treatment.

Going forward, at your regularly scheduled standard of care follow-up visits, one of the study team members will give you the two surveys and a questionnaire to complete. These surveys and questionnaire are given to guide our clinical care and assess change in your situation over time.

At the conclusion of each follow-up appointment you will be given a questionnaire about the quality of care you have received and if your post-treatment expectations are being meet.

No drugs or biological agents will be given to you. There will be no blood draws as part of this study; however, you may have blood draws or radiology tests as part of standard of care.

What happens if I do not want to be in this research?

You may decide not to take part in the research it will not be held against you.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. All data that has been collected up until the time you decided to withdraw consent will still be used but no further data will be collect.

Is there any way being in this study could be bad for me?

There are no physical risks from participating in this research study. There is a potential risk to privacy. The research team takes your privacy seriously. Only members of the research team will have access to the information you provide. The data collected will be de-identified and password-protected.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a better understanding of the treatment you will choose and accurate expectations for recovery and quality of life post treatment.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

During the course of the study, if the research team uncovers abuse, neglect, or reportable diseases, this information will have to be disclosed to appropriate authorities.

If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/compliance/pdf/notice.pdf) and in an attached document.

Can I be removed from the research without my OK?

The person in charge of the research study can remove you from the research study without your approval if you do not receive radiation therapy or surgical prostatectomy treatment for prostate cancer.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

You or your health plan will be billed for the costs of routine medical care you receive during the study. You will be expected to pay for the usual deductibles and co-payments, and for all routine care. The only portion of this study that is not standard of care is the Quality of Care Questionnaire for which you will not be billed. All other procedures are considered standard of care.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

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

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Are there other research opportunities?

If you are interested in being contacted for future research, please provide your phone number and/or email. This is completely optional.

_____(initials) Yes, I am willing to be contacted for future research opportunities. My phone number and/or email is: _____.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

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