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

Study Title: Pioneering Advances in Care & Education (PACE)

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This is a research study about patient knowledge of treatment options and outcomes for men with early-stage prostate cancer. The study researchers, Peter R. Carroll M.D. M.P.H., Matthew R. Cooperberg M.D. M.P.H., Jeffrey Belkora Ph.D., and June M. Chan Sc.D. from the University of California San Francisco (UCSF) Department of Urology and one of your prostate cancer doctors or their trained research associate who are collaborating with the researchers, will explain this study to you.

This study includes 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 or friends if you wish. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have early stage prostate cancer and have not yet decided on a management or treatment plan for your cancer at this time.

Why is this study being done?

The purpose of this study is to understand which patient education strategies are most highly associated with informed treatment or management decisions.

The U.S. Department of Defense, Department of the Army Military Medical Research is funding this study.

How many people will take part in this study?

About 160 men total will take part in this study. All 160 subjects will be enrolled at community-based urologist practices affiliated with a research network organized by the University of California, San Francisco.

What will happen if I take part in this research study?
If you agree, the following procedures will occur:

- First you will be asked to review the informed consent form and if you agree to participate you will be asked to sign this form and return it to the researchers.

- You will be asked to fill out a paper survey and mail it back, in a postage paid envelope. The survey asks questions about your knowledge of prostate cancer treatment options and about your feelings about the possible outcomes associated with your treatments. If any questions make you feel uncomfortable, you may skip those questions and not give an answer.
  - If you choose, you may be given the option to complete these surveys online.

- Information will be collected from your medical record for study purposes. Specifically, information about your age; race; prostate specific antigen (PSA) test; biopsy test results (i.e., Gleason grade and number of biopsy cores); prostate size; information from physical exam (such as your height and weight); cancer stage; and the date of your upcoming consultation visit with your urologist.

- Before you meet your doctor to discuss treatment options, you may be offered the opportunity to review patient education materials or receive counseling, depending on what is being offered at your clinic at the time you schedule your visit. The materials may include print or web-based information, and the counseling may include telephone calls or in-person interviews to help you prepare for your visit. If you receive counseling, you may be advised to review specific educational materials and formulate your questions in a written list for you and your medical care team. A clinic employee or study team member may offer to assist you with these tasks.

- If you are currently on medications prescribed by your primary care doctor or urologist for your prostate, do not change any medications without checking with your urologist.

- At the office visit with your urologist, both before and after your meeting with your doctor, you will be asked to fill out surveys that ask again about your knowledge of prostate cancer treatment options, and your feelings about the possible outcomes.

- After the visit with your urologist but before you start treatment, you will be sent a final set of surveys that ask about your overall health and satisfaction with your cancer treatment you selected. You will also be asked about your interest in completing surveys on diet and lifestyle.

- Twenty-four participants will be selected for a phone conversation by one of the research team members at UCSF to ask you questions about your study experience. The researcher will make a sound recording of your conversation. After the interview, someone will type into a computer a transcription of what's on the recording and will remove any mention of names. The sound recording will then be destroyed.

- At the end of this study you may be asked to participant in another long-term follow up study about prostate cancer outcomes named '*Cancer of the Prostate Strategic Urologic Research Endeavor* or *CaPSURE*'. In order to participate in *CaPSURE* you will need to sign a separate consent form to be followed in *CaPSURE*.

- **Study location:** All these procedures will be done at your home and/or your urologist's practice.

How long will I be in the study?

Participation in the study will take a total of about 1-2 hours over a period of one (1) month.

The main study period ends after you visit your doctor to discuss and decide about your management of prostate cancer and complete post treatment decision survey.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher 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?

Possible risks related to the patient education strategies include:

1. **Confusion regarding decision-making**. Although patient education materials and counseling are always intended to clarify the issues surrounding your decisions, it is

possible they could create confusion.

2. **Anxiety and uncertainty.**
   - Participants may feel some anxiety or discomfort in completing study surveys – but you may skip any questions that you do not feel comfortable in answering.
   - Participants may feel more anxious and uncertain after reviewing patient education materials or receiving educational counseling.
3. **Dissatisfaction.** Participants may not like the patient education materials or counseling.
4. **Loss of Privacy.** Although members of the study team are trained in how to protect patient privacy, interactions with study researchers and staff could spread patient information more widely and increase the risk of loss of privacy.
5. **Unknown Risks:** Some patient education strategies 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.
6. For more information about risks and side effects of participating in this study, please ask one of the researchers.

Are there benefits to taking part in the study?

There will be no direct benefit to your from participating in this study. However, the information that you provide may help health professionals better understand how patient education materials and decision support aid men with their treatment decisions for prostate cancer.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is 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.

- Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study: Representatives of the Sponsor the Department of Defense, Department of the Army Military Medical Research.

- Representatives of the University of California.
- Representatives and study staff with the study at your local community-based urology practice.

Will any research-related procedures be billed to me?

No. The sponsor has agreed to pay for all procedures associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

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

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 in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researcher(s) Peter R. Carroll M.D., M.P.H., Matthew R. Cooperberg M.D. M.P.H., Jeffrey Belkora Ph.D., and June M. Chan Sc.D. at 415-353-7348. If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copy of this consent form 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 be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

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

Print Your Name

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Date

Participant's Signature for Consent

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Date

Signature of Person Obtaining Consent

Site ID

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STUDY ID

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