

MEDICINE of THE HIGHEST ORDER

CONSENT FORM

Rochester Prevention Research Center: Development and evaluation of an Internet-based decision aid for men with newly diagnosed prostate cancer

Principal Investigator: James Dolan MD

Co-Investigators: Peter Veazie PhD, Hong Zhang MD PhD, Chunkit Fung MD, and Edward Messing MD

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

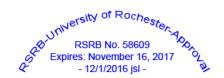
This form will explain this study to you. Please ask questions about anything that is not clear using the contact information below, either before you agree to participate or at any time after. You may review this consent form, and then think about and discuss the study with family or friends.

- ➤ Being in this study is voluntary it is your choice.
- If you join this study, you can change your mind and stop at any time.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you have recently been diagnosed with low or intermediate risk prostate cancer.

This study is being conducted by James Dolan MD, Peter Veazie PhD, Hong Zhang MD PhD, Chunkit Fung MD, and Edward Messing MD, from the University of Rochester Medical Center's Departments of Public Health Sciences, Radiation Oncology, Medical Oncology and Urology respectively.



Purpose of Study

The purpose of this study is to test a new tool called a decision dashboard that is designed to help patients understand the pros and cons of the different treatment options available for newly diagnosed low and intermediate prostate cancer.

Description of Study Procedures

If you decide to take part in this study, you will be asked to complete a questionnaire that will take about 15-30 minutes to complete. The survey will ask you questions about what you already know about prostate cancer treatment, questions about your background and education level, and about your prostate cancer diagnosis.

The information you provide will be reviewed by a study team member to confirm your eligibility to participate in the study. If you are found to be ineligible you will be notified of this by email and you will not have any further participation in the study.

If you are found to be eligible to participate, we will email you a link to a website containing an interactive decision dashboard, which has detailed information describing the options available for treating your cancer and a list of sources of trusted additional information about prostate cancer treatment.

We will also email you a letter to give to the doctor(s) who is (are) involved in treating your cancer informing them that you are enrolled in the study and giving them an email address and phone number in case they want to contact us for further information about the study.

After a treatment decision has been made by you with the help of your doctors, you will be asked to answer a series of questions about how the treatment decision was made and how helpful the information you received from us was in choosing a treatment.

You will also receive two follow-up surveys approximately 2-3 and 6-9 months after you notify us that you have made a treatment decision. These follow-up surveys will ask questions about your health status and how you feel about the treatment choice you made. You will complete the surveys on a computer by following a link sent to your email address.

Number of Subjects

Approximately 70 subjects will take part in this study.



Duration of the Study

Your participation in the study will last approximately 6 to 9 months. Each survey will take 30 minutes or less to complete.

Risks of Participation

There is a risk of invasion of privacy that could lead to potential embarrassment or jeopardy to financial standing, employability or reputation. We will minimize this risk by keeping all of your responses confidential.

We will not store any directly identifiable information about you with your survey responses. All of the information we collect will be stored in a secure manner and only study team members will have access to it. All identifying information will be destroyed at the earliest possible time following completion of the study.

Please note that the information you will receive if you decide to take part in the study is intended to provide a general overview of the differences among currently recommended prostate cancer treatment options based on current research and expert opinion. However, these research results may not be directly applicable to the treatment of your prostate cancer. For this reason you should not make any decisions about your cancer treatment without consulting your health care provider(s).

Benefits of Participation

You might not benefit from being in this research study.

New Study Findings

If we discover anything that might make you change your mind about continuing in the study, we will let you know.

Sponsor Support

The University of Rochester is receiving payment from the Centers for Disease Control and Prevention (CDC) for conducting this research study.

Costs

There will be no cost to you to participate in this study.

Payments

You will be entered into a lottery after completing a post-decision questionnaire and follow-up surveys 2-3 and 6-9 months after making a decision. Lottery winners will receive a \$50 Amazon.com gift card. The number of winners will be 5 % of the number of subjects enrolled in the study. Each time you submit one of the three required study questionnaires you will receive entry tickets: one ticket after the first questionnaire, three more when you submit the second



questionnaire, and five more when you submit the third and final questionnaire for a possible total of nine overall.

<u>Confidentiality of Records and Authorization to Use and Disclose</u> <u>Information for Research Purposes</u>

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we have to get your permission to use your personal health information. We will use your personal information such as your email address, name, and phone number to schedule and manage the completion of study-related surveys. Your answers to the survey questionnaires will be used to learn more about your decision process.

We will store all information electronically in password-protected files on a secure computer server. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

Your permission to use your health information for this study will not expire unless you tell us you want to cancel it. We will keep the information we collect about you until the end of study activities. Identifiable information about you will be destroyed as soon as possible.

A copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices will be emailed to you upon confirmation of your eligibility for the study.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: James Dolan MD at 585-276-5161 or

ProstateTrials@urmc.rochester.edu

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation



Taking part in this study is voluntary. You are free not to take part or to withdraw
at any time, for whatever reason. No matter what decision you make, there will
be no penalty or loss of benefit to which you are entitled. In the event that you do
withdraw from this study, the information you have already provided will be kept
in a confidential manner.

After reading the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study.

By clicking "Next" you agree to participate in the study and consent that you are willing to answer the questions in this survey and the three follow-up surveys described above and be entered into the study lottery.

NEXT