

This model informed consent form has been reviewed by the DCPC/NCI and is the official consent document for this study. Local IRB changes to this document are allowed. (Sections of this document which are in bold type should always be tried to be used in their entirety.) Editorial changes to these sections may be made as long as they do not change information or intent. If the institutional IRB insists on making deletions or more substantive modifications to the risks or alternatives sections, they should be justified in writing by the investigator and approved by the IRB. Under these circumstances, the revised language, justification and a copy of the IRB minutes must be forwarded to the Southwest Oncology Group Operations Office for approval before a participant may be registered to this study.

CONSENT FORM AND INFORMATION ABOUT

SWOG-9217, Chemoprevention of Prostate Cancer with Finasteride (Proscar), Phase III

TO BE CONDUCTED AT

- I. **You are invited to take part in this research study because you are a male of age 55 or older who has never been diagnosed with prostate cancer. You are being asked to participate in this research to determine if the medication, finasteride, can prevent prostate cancer.**

Prostate cancer is the most common cancer in older men, but only approximately one man in ten in your age group will develop prostate cancer during their life. The goal of this study is to determine if men using finasteride have a lower risk of developing prostate cancer.

We also want to find out what the quality of life for participants is according to the type of treatment they receive. It is very important to have your view about how you have been feeling during your treatment. This is especially important because you are healthy and this treatment is being used for possible prevention of cancer rather than as a treatment for a disease. By completing a questionnaire on a regularly scheduled basis, you will help describe the effect of this treatment on your quality of life.

We would also like to store your blood and tissue for possible use in future research studies. None of these would be of benefit to you, but could help us learn about other ways to prevent cancer. For this purpose, an extra 14 cc (about 3 teaspoons) will be drawn for future research purposes. (4/14/95)

Some research may require no identification of blood or tissue, so there would be no risk to you. We will keep a file that will allow identification of samples. If further projects are planned that require use of identifiable samples, you will be contacted and your consent would be necessary to do such research. (If you do not want to be contacted for future studies you can check a box at the end of this form.) (4/14/95)

As part of the ongoing scientific and biotechnological activities of the Southwest Oncology Group and its agents, these blood samples and any tissue specimens will be preserved and used for research and development purposes. As a result of these biotechnological activities, an economic benefit may be derived directly or indirectly by the Southwest Oncology Group, individual researchers, and others engaged in these activities. By signing this consent form, you authorize the preservation and use of these blood samples and any tissue specimens taken from you. (4/14/95)

For the individual participants in this study, it is not known if the risks will outweigh the benefits. The major potential benefit for the participants receiving finasteride is the prevention of prostate cancer if the study shows finasteride may or will have that effect. (2/5/96) Other potential benefits include shrinking of an enlarged prostate gland with resultant increase in urinary flow rate.

- II. If you decide to take part in this study, you will first undergo a digital rectal examination (in which the doctor feels the surface of your prostate with a gloved finger, feeling for irregularities which may be suspicious for cancer). You will also have a blood test (Prostate Specific Antigen or PSA) done which can be elevated in men with prostate cancer. If both of these tests are normal, your treatment will be decided by a process called randomization (similar to flipping a coin). Of the 18,000 men to be enrolled on this study, 9,000 will receive finasteride and 9,000 will receive a placebo (a tablet containing no medication). At some point during their participation in the study, every participant will receive placebo tablets for a period of time. You will receive your treatment as an outpatient. Your treatment (finasteride or placebo tablet) will be taken orally (by mouth) every day. You will not be informed which tablet you have been receiving until the end of the study, except in the case of a medical emergency.

While you are on this study, you will be seen initially at three months. At that time, you will be asked about any side effects you may be having from the tablet. If you are not experiencing difficulties, are taking the tablets on a regular basis, and desire to continue the study you will receive additional tablets. You will then return every six months. Once each year, your clinician will perform an examination of the prostate (digital rectal examination) as well as a blood test (prostate specific antigen) to look for evidence of prostate cancer. If the digital examination of the prostate suggests the presence of prostate cancer, your physician may recommend a prostate biopsy. (2/5/96)

During follow-up, if your prostate specific antigen (PSA) blood test becomes elevated, prostate cancer may be the cause. Your physician may recommend a prostate biopsy. Because the study drug, finasteride, directly affects the PSA level, the group receiving the study drug will have a different PSA level that prompts the recommendation for biopsy than that in participants who are not receiving finasteride. (12/30/96) For this reason, your blood test will be performed at a central laboratory and the results will be reported to your physician as "elevated" or "normal". By doing so, it will generally make your risk of needing a prostate biopsy equal, regardless of which treatment you receive.

Biopsy of the prostate involves the placement of a sound-wave device into the rectum immediately next to the prostate gland. Using this sound-wave device to look at the prostate as well as a guide, several pieces of tissue are removed from the gland. This can be somewhat uncomfortable and can cause bleeding in the urine or rectum or blood-tinged ejaculate (body fluid released by the prostate during sexual intercourse). There is also a risk of temporary inability to urinate or infection. If prostate cancer is detected, you will stop the study drug and will be treated in accordance with your wishes based upon recommendations made by your physician. (2/5/96)

It may be possible during the conduct of this study that a prostate biopsy is required of a group of individuals participating in the study. This may be required due to differences in the PSA blood test in the two groups.

In addition, you will also be monitored for your risk of heart disease. If you have abnormal cholesterol levels based on the blood specimen obtained at enrollment or are otherwise at high risk for heart disease, you will be referred to a doctor for evaluation and possible treatment of this problem. The purpose of this monitoring is to allow the study investigators to adequately interpret heart disease related events which occur during this study. (2/5/96)

You will be expected to continue on the study for seven years. (4/14/95) At the end of the study, a prostate biopsy will be required. The tissue removed from your prostate at any time during the study will be sent to a laboratory for testing and storage.

It is anticipated that early prostate tumors may be found during this study which otherwise would not have been found. However, it is also possible that tumors which do not need treatment may be found. At this time it is difficult to tell the difference between these types of tumors and it is therefore possible that you may receive unnecessary treatment which involves a significant risk of side-effects. (2/5/96) The treatment that you will receive if prostate cancer is found during the study will be decided by you and your doctor.

There are circumstances under which your doctor might be required to discontinue your tablets whether you agree or not. These circumstances include: the side effects of the treatment are placing you at undue risk; new information about the drug becomes available and this information suggests the drugs will be ineffective or unsafe for you.

The tablets are provided free of charge, as are the analyses of the PSA blood tests and the biopsy at the end of the seven years. Blood will be drawn for a cholesterol screening test at the first visit. This test will be completed and results provided free of charge only after you are randomized for the study. All clinic charges associated with the physical exams, drawing blood, and the rectal exams must be paid for by you or your insurance company. If cancer or other prostate diseases are discovered during the regular exams, then you will be referred to a doctor for care. Costs for diagnosis and treatment of prostate problems, prostate cancer, or other medical conditions during the seven years of the study are also paid for by you or your health insurance, just as they would be if you were not part of this study. These examinations are not a substitute for regular health check-ups such as an annual physical examination by your own doctor.

Finasteride is an approved drug for otherwise healthy men with a condition called "benign prostatic hyperplasia". It has been tested in more than 3,000 men and serious side-effects have not been evident.

- III. **Side effects some people have had after receiving finasteride therapy are listed as follows according to how often these side effects have been reported: impotence (failure to have or maintain an erection) (fewer than 4 out of 100 men), decreased sex drive (fewer than 4 out of 100 men), and decrease in the amount of semen released during intercourse (fewer than 3 out of 100 men). A very small number of reports have been received listing a severe allergic reaction as a side-effect of finasteride. This reaction may cause swelling of the lips, skin rash and itching. Although allergic reactions to this drug have been mild, this type of reaction may also cause swelling of the air passages and difficulty breathing. Reports have also been received listing breast enlargement and tenderness as a side-effect. (12/30/96)**

Although finasteride has been associated with the side effects described above, other side effects may occur which were not seen before. The side effects are usually temporary and stop when the drug is stopped. In some cases side-effects went away even while continuing to take finasteride.

If you are sexually active and your sexual partner is capable of bearing children, we strongly recommend that you use an effective method of birth regulation to avoid fathering a child during the course of this study. If your sexual partner is currently pregnant we strongly recommend that you use a condom to avoid exposing your sexual partner to your semen during the pregnancy. The amount of finasteride that could be absorbed from semen by a woman is unknown. There is a possibility that finasteride can harm a developing male fetus.

Additionally, crushed finasteride tablets should not be handled by a woman who is or may become pregnant because of the possibility of absorbing the drug through the skin. Because you will not know whether or not you are receiving finasteride, you are asked to refrain from donating blood or blood products while you are taking the study drug. This precaution is also to prevent exposure to finasteride by a woman who is or may become pregnant.

There is no known treatment for preventing prostate cancer. (2/5/96)

- IV. No commitment is made to provide free medical care or compensation in the event of injury or illness resulting from participation in this study. Continuing medical care and/or hospitalization will not be provided free of charge but must be paid for in the same way your regular medical care is paid. We cannot pay you to take part in this study.

- V. We will keep any information we learn from this study confidential and disclose it only with your permission. By signing this form, however, you allow us to make your records available to the National Cancer Institute, the Food and Drug Administration, a qualified representative of the drug manufacturer, and the Southwest Oncology Group. When we publish the information we learn from this study in a medical journal, you will not be identified by name. Your medical records for this study will be sent by facsimile transmission (FAX machine) directly into a central computer. It is possible (although unlikely) that your records could be sent to the wrong machine in error.
- VI. Whether or not you take part in this study will not affect your future relations with your doctors (there will be no loss of benefit or change in attitude) or _____ (hospital name). If you decide to take part, you are free to stop whenever you want to.

VII. You have the right to refuse to participate in this research study (and receive any treatment recommended by your physician) if you so desire without any fear of penalty or loss of benefits. In addition, you may refuse to continue on this study, at any time after the start of therapy, without fear of prejudice to additional treatment. If you withdraw from the treatment part of this study, we would like to continue to follow you and, unless you object, collect information from your medical records. (4/14/95) By signing this form, you recognize that you have received a copy of it, and your signature indicates that you have volunteered to participate in the study after having read the information provided to you.

VIII. The doctor(s) involved with your care can answer any questions you may have about the drug program. In case of a problem or emergency, you can call the doctors listed below day or night.

Office Home

Dr.
Dr.
Dr.

You can also call the Institutional Review Board (# _____) if you have any questions, comments or concerns about the study or your rights as a research participant.

IX. We will give you a copy of this form to keep.

X. You are deciding whether or not to take part in this study. If you sign, it means that you have decided to volunteer. (4/14/95)

Date

Signature of Participant

Signature of Witness

Signature of Investigator

Time

I do not wish to be contacted for future studies on my stored blood fluid or tissue. (4/14/95)

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PARTICIPANT DATABASE PROJECT

TO BE CONDUCTED AT

The Prostate Cancer Prevention Trial (PCPT) is creating a centralized database of participant names and addresses. This database will be used to create address labels in order to send study-related materials and information directly to you from the Southwest Oncology Group Statistical Center and/or Operations Office. The centralized database will facilitate quicker mailing of these materials to you since they will not have to be routed through your study site.

Only the PCPT staff at [name of participant's Study Site], the Southwest Oncology Group Statistical Center in Seattle, Washington and the Southwest Oncology Group Operations Office in San Antonio, Texas will have access to your name and address exclusively for the purpose of study-wide mailings. Your address form will be sent by facsimile transmission (fax machine) directly into a central computer. It is possible (although unlikely) that your records could be sent to the wrong machine in error. Your address information will not be rented, sold or made available to any person and/or group outside the Prostate Cancer Prevention Trial.

You do not have to provide your name and address as part of your involvement with the PCPT. If you do not provide your name and address, study-related materials and information will continue to be distributed to you by your Study Site.

All of your study records will be kept confidential to the extent required by law. When we publish the information we learn from this study, you will not be identified by name.

Participant Statement

I have read this permission form and understand its purpose. I have contacted my PCPT Study Site to discuss any questions I have, or to discuss any parts of this permission I do not understand. I understand that I may ask further questions at any time. I understand that I may remove my name and address from the participant database at any time for any reason.

Signature of Participant

Date

Signature of Witness

Signature of Investigator

Time