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CONSENT FORM

SWOG 0000A: Prevention of Alzheimer's Disease Vitamin E and Selenium Trial (PREADVISE), Secondary Consent Form – Medical Evaluation for Possible Memory Problems.

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Patient's Initials

S0000A: "Prevention of Alzheimer's Disease With Vitamin E and Selenium Trial (PREADVISE)," Secondary Consent Form – Medical Evaluation for Possible Memory Problems

This is a clinical trial (a type of research study). Clinical trials include only people who choose to take part. Please take your time to make your decision. Discuss it with your family and friends.

You are being asked to take part in this research study because you are taking part in PREADVISE. PREADVISE is a study that looks at the use of vitamin E and selenium for preventing Alzheimer's disease and other memory diseases.

WHY IS THIS STUDY BEING DONE?

As part of PREADVISE, you have been having regular memory checkups. At this time, these memory checkups suggest that you may be having memory changes. Therefore, you are being asked to have a medical workup. Your doctor or a specialist that you can choose with help from the SELECT and PREADVISE doctors can do this workup to see if the memory change suggested by the checkup is related to a medical condition. The results of this testing will be used for medical diagnosis as well as for the PREADVISE research project.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participating in this study is your choice. If you volunteer to take part in this study, we think you will be one of about 150 to 200 men who may need this testing during their participation in PREADVISE.

WHAT IS INVOLVED IN THE STUDY?

The medical evaluation for possible causes of memory problems will take place in your doctor's office. This will take about an hour of your time. Your doctor also will order a brain scan (computerized tomography (CT) or magnetic resonance imaging (MRI)) that may take up to 30 minutes. The total amount of time you will be asked to spend for this medical workup is about one to two hours.

This medical examination will involve a review by your doctor of your medical history, medicines, a physical and neurological exam, and blood and urine tests. If you agree to this part of the study, your medical test results will also be sent to the PREADVISE doctors for their review of possible causes of memory change.

If the information from this medical examination or doctor visit does not suggest a medical cause for memory changes, your memory will continue to be screened using the 5-minute check at the next yearly SELECT study visit. If a diagnosis of a dementia results from this medical examination, you will be asked to continue to take both the screening and 45-minute memory and thinking tests each year that you stay in PREADVISE and SELECT.

WHAT ARE THE RISKS OF THE STUDY?

Medical evaluations for possible causes of memory changes present practically no risk. The potential risks or discomforts are small. You may experience tiredness or fatigue from the evaluation. A Magnetic Resonance Imaging (MRI scan) may cause possible anxiety due to the loud banging made by the machine and the confined space of the testing area. People with pacemakers, aneurysm clips, artificial heart valves, ear implants, or metal/foreign objects in their eyes are not permitted to undergo an MRI, but may have a Computed Tomography (CT scan). A CT scan involves exposure to a small amount of radiation. The amount of exposure is less then 1,000 millirems. (An individual living in a city receives about 100 millirems per year). Risks associated with the drawing of blood include soreness, bruising, infection, bleeding, pain, and lightheadedness or fainting. In total, less than three tablespoons of blood will be taken, and your body will quickly make up for this loss. There is also a risk that the medical exams will not be able to find a cause for your memory and thinking changes. However, if the cause is Alzheimer's Disease, medical diagnosis is correct 95 out of 100 times (95%) with this type of exam.

For more information about risks and side effects, ask the researcher or contact your physician.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There is no guarantee that you will get any personal benefit from participating in this part in this study. However, it may be possible that the early diagnosis of medical conditions that cause memory change can lead to effective early treatment for your condition.

WHAT OTHER OPTIONS ARE THERE?

If you choose not to take part in PREADVISE, but remain in SELECT, you have these other options:

You may choose not to have memory checkups at all. You can have memory checkups by your family doctor. All of the checkups on this study may be available at this center or at other locations. Please talk to your regular doctor about these and other options.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Only your doctor and the PREADVISE and SELECT doctors will see the results of your medical examination. Your personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as: the National Cancer Institute, the Sanders-Brown Center on Aging at the University of Kentucky, the Food and Drug Administration, the National Institute on Aging; the makers of vitamin E, selenium and placebo pills for the study and the Southwest Oncology Group.

If we publish the information we learn from this study in a medical journal, you will not be identified by name or in any other way.

WHAT ARE THE COSTS?

Taking part in the medical examination for causes of memory change will lead to added costs to you or your insurance. Added costs may result from blood studies, urine studies, brain scans, and doctor examinations needed to determine a cause for your memory loss. For example, your doctor may suggest other medical tests if you have an abnormal blood test. Please ask your nurse or doctor about any expected added costs.

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

You will receive no payment for taking part in this study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about important new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

The persons in charge of this study are Drs. William Markesbery, Frederick Schmitt and Richard Kryscio of the Sanders-Brown Center on Aging at the University of Kentucky.

For questions about the study or a research-related injury, contact ***the Northwest Community Clinical Oncology Program, 253-403-1461.*** For questions about your rights as a research participant, call ***MultiCare Health System Institutional Review Board at 253-403-3844.*** The Institutional Review Board (IRB) is a group of people who review research studies to protect your rights.

The physician(s) involved with the medical care of the patient is available to answer **ANY** question(s) concerning the research/drug program. In case of a problem or an emergency, the physician should be contacted by telephone (see cover sheet).

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WHERE CAN I GET MORE INFORMATION?

PREADVISE: www.mc.uky.edu/preadvise
The Alzheimer's Association U.S.: www.alz.org
The Alzheimer's Association Canada: www.alzheimer.ca

You may call the NCI's Cancer Information Service at
1–800–4–CANCER (1–800–422–6237) or TTY: 1–800–332–8615

Visit the NCI's Web sites…
CancerTrials: comprehensive clinical trials information http://cancertrials.nci.nih.gov.
CancerNet™: accurate cancer information including PDQ http://cancernet.nci.nih.gov.

You will get a copy of this form. You may also request a copy of the protocol (full study plan).

SIGNATURE

You are deciding whether or not to take part in this study. If you sign, it means that you have decided to volunteer to take part in this study, and that you have read and understood all the information on this form.

My consent to participate in SELECT and PREADVISE has been provided in a separate document.

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Patient's name (printed or typed)

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Patient's Signature Date

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Physician name (printed or typed)

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Physician Signature Date

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Signature of person conducting the
Informed consent discussion

____
Date

IRB Approval Date: 4/9/03
Revised: 12/17/03

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Authorization to Use or Disclose (Release) Identifiable Health Information For Research

Participant's Name: ______________________________________

Birthdate: ____

1. What is the purpose of this form?

The **Southwest Oncology Group** is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your identifiable health information, you must sign and date this form to give them your permission.

2. What health information do the researchers want to use?

The researchers want to abstract and use the portions of your medical record that they will need for their research. If you enter a Southwest Oncology Group research study, information that will be used and/or released may include your complete medical record, and in particular, the following:

- information about other medical conditions that may affect your participation
- medical data, including laboratory test results (such as DRE, PSA and blood pressure results), information about other medications and vitamins you are taking, your weight and smoking status, ultrasound, biopsy and pathology results
- information on side effects (adverse events) you may experience, and how these were treated
- long-term information about your general health status including information of the diagnosis of any cancers or cardiovascular problems
- tissue, toenail and blood samples, associated data related to the analysis of the samples
- your views about how you have been feeling while you are in the study

You may request a blank copy of the SELECT data forms from the Northwest CCOP to learn what information will be shared.

3. Why do the researchers want my health information?

The Northwest CCOP will collect your health information and share it with the Southwest Oncology Group if you enter a Cooperative Group research study, or to evaluate your eligibility for a study. The Southwest Oncology Group researchers will use your information in their cancer research study. You are being asked to take part in a study known as **SWOG S0000A, Prevention of Alzheimer's Disease with Vitamin E and Selenium (PREADVISE), Secondary Consent Form – Medical Evaluation for Possible Memory Problems.** You are being asked to take part in this study to determine how useful Vitamin E and Selenium might be for preventing memory change with age (including Alzheimer's disease and other disease that can affect the brain.

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4. Who will be able to use my health information?

The Northwest CCOP will use your health information for research. As part of this research, they may give your information to the following Groups taking part in the research. The Northwest CCOP may also permit staff from these Groups to review your original records as required by law for audit purposes.

- the Southwest Oncology Group (SWOG)
- public health agencies and other government agencies (including non-U.S.) as authorized or required by law
- other people or organizations assisting with Southwest Oncology Group research efforts
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed above.

5. How will information about me be kept private?

The Southwest Oncology Group will keep all identifiable health information confidential to the extent possible, even though they and other federal research groups are not subject to the same federal privacy laws governing clinical centers. The Southwest Oncology Group will not release identifiable health information about you to others except as authorized by this form, or required by law. If your identifiable health information must be shared with other organizations, the privacy laws that govern those organizations would apply.

6. What happens if I do not sign this authorization form?

If you do not sign this authorization form, you will not be able to take part in the SELECT study.

7. If I sign this form, will I automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a separate research consent form.

8. What happens if I want to withdraw my authorization?

You can change your mind at any time and withdraw this authorization. This request for withdrawal must be made in writing. Beginning on the date you withdraw your authorization, no new identifiable health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your authorization, you will be removed from the SELECT study at that time.

To withdraw your authorization, please contact the person below. She will make sure your written request to withdraw your authorization is processed correctly.

Karyn Hart, RHIT, CCRP
Clinical Research Associate Supervisor
Northwest CCOP
1003 South 5th Street, 2nd Floor
Tacoma, WA 98405
(253) 403-1461

9. How long will this authorization last?

If you agree by signing this form that researchers can use your identifiable health information, this authorization has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding my identifiable health information?

You have the right to refuse to sign this authorization form. You have the right to review and/or copy records of your health information kept by the Northwest CCOP. You do not have the right to review and/or copy records kept by the Southwest Oncology Group or other researchers associated with the research study.

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Signatures

I agree that my identifiable health information may be used and disclosed for research purposes described in this form.

Signature of Patient or Patient's Legal Representative:

____ Date:___________________

Printed Name of Legal Representative (if any):_______________________________________

Representative's Authority to Act for Patient:____

Signature of Person Obtaining Authorization:____

Printed Name of Person Obtaining Authorization:_____________________________________

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