

MARQUETTE GENERAL HEALTH SYSTEM
Regional Medical Center

CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY

TITLE: S0000B, "Prevention of Cataract and Age-Related Macular Degeneration With Vitamin E and Selenium - SELECT Eye Endpoints (SEE), Phase III Ancillary to S0000 - SELECT"

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You are being asked to take part in this research study (SELECT Eye Endpoints – SEE) because you are taking part in SELECT and because you have reported that you were diagnosed with age-related acute macular degeneration (AMD) or a cataract. We are asking you to release medical records about your eye diagnosis.

WHY IS THIS STUDY BEING DONE?

The purpose of SELECT, in which you are taking part, is to see if there is a difference in finding prostate cancer between a group of healthy men who received selenium alone, vitamin E alone, selenium and vitamin E and placebo.

Age-related acute macular degeneration (AMD) and cataract are two leading causes of visual impairment in older Americans. AMD is a disease that affects your central vision, and is the leading cause of visual problems and blindness with about 25% of people over 65 years showing some AMD. Cataract is a clouding of the eye's lens that causes loss of vision. More than 50% of adults in the U.S. aged 75 years and older suffer from visually significant cataract. Some evidence suggests that the vitamins being studied in SELECT might prevent these eye problems. This study will look at this question in a large group of men already assigned to take one, both or neither of these vitamins (men in the SELECT study).

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Taking part in this study is your choice. While all men in SELECT (about 32,400 men) will submit baseline information about cataracts and AMD, approximately 2,150 men may be asked to submit additional medical information about cataract and 820 men may be asked to submit additional medical information about AMD for this study.

WHAT IS INVOLVED IN THE STUDY?

Information about your health including prior diagnoses of cataract and AMD is being collected as part of the SELECT study. Because you have been diagnosed to have an eye

condition, we are asking you to release medical records related to your eye diagnosis (and contact information for your treating eye doctor) to Harvard Medical School (Dr. William Christen).

Dr. Christen will review your records and may contact your eye doctor to get additional details about your eye diagnosis.

HOW LONG WILL I BE IN THE STUDY?

Your decision to release medical records and information to contact your eye doctor for each applicable eye diagnosis will be the extent of your participation in this study.

WHAT ARE THE RISKS OF THE STUDY?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

For more information about risks and side effects, ask your physician.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There is no guarantee that you will get any personal benefit from taking part in this study. The findings of this study may help in our understanding of cataract or AMD and may help other people with these diseases in the future.

WHAT OTHER OPTIONS ARE THERE?

If you choose not to take part in S0000B, (SEE) but remain in SELECT, you have these other options:

You are encouraged to have eye checkups by your eye doctor and to follow the treatment recommended by your eye doctor. Remember that if you choose to take vitamin supplements for your eyes, the supplements must not contain vitamin E or selenium if you are in SELECT. 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. 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, Harvard Medical School, the Food and Drug Administration, the National Eye Institute; 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?

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 decline taking part in SEE without any effect on your participation in SELECT.

A Data and Safety Monitoring Committee, 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 Christen and Robert Glynn of the Harvard Medical School.

For questions about the study, contact the your physician _____
At 906-225-3922.

For questions about your rights as a research participant, contact the patient advocate at 906-225-4543.

WHERE CAN I GET MORE INFORMATION?

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 site...
www.cancer.gov

Visit the National Eye Institutes Web sites...
www.nei.nih.gov/

Or Prevent Blindness America®..
www.preventblindness.org/eye_problems

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

COSTS AND PAYMENTS:

You understand that the SWOG Group and Marquette General Hospital furnish no funds providing medical treatment for, or financial compensation to, human subjects in the event the investigational therapy results in loss or injury. You will be responsible for the cost of emergency medical treatment provided by this institution and/or by your physician. You are also aware that the SWOG Group and Marquette General Hospital will not take financial responsibility for non-acute medical problems.

Institutional Funding:

Funds are provided from the study sponsor to Marquette General Hospital on a per patient basis to help with the institution's costs of participating in this study.

WHOM DO I CALL IF I HAVE PROBLEMS OR QUESTIONS?

In the event that physical injury occurs as a result of this research, facilities for treatment of injury will be available; however, you will not automatically be provided with reimbursement for medical care or other compensation. For more information concerning the research and research-related risks or injuries, you can notify Dr. _____, or his/her associates, who may be reached by phoning the office at (906) 225-3922. During the evenings, weekends, or holidays you may phone Marquette General Hospital at (906) 228-9440, and request to speak with the oncology physician on call. You can also call the Patient Advocate at Marquette General Hospital at (906) 228-9440, if you have any questions, comments, or concerns about the study or your rights as a research subject.

CONFIDENTIALITY:

We will keep any information we learn from this study confidential and disclose it only with your permission, except as required by law. 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. If we publish the information we learn from this study in a medical journal, you will not be identified by name.

RIGHT TO WITHDRAW:

Whether or not you take part in this study will not affect your future relations with your doctors or Marquette General Hospital. If you decide to take part, you are free to stop whenever you want to. You understand that you have the right to refuse to participate in this research study if you so desire without any fear of prejudice to additional treatment for yourself. In addition, you understand that you may refuse to continue on this study, at any time after the start of therapy, without fear of prejudice to additional treatment you may need. You recognize that you have received a copy of this consent form, and your signature indicates that you have volunteered to participate in the study having read the information provided to you.

VOLUNTARY CONSENT:

You certify that you have read the preceding or it has been read to you and that you understand its contents. Any questions you have pertaining to the research or research related injuries have been and will be answered by Dr. _____ or his/her associates, who may be reached by phoning the office at (906) 225-3922. During evenings, weekends, or holidays you may phone Marquette General Hospital at (906) 228-9440, and request to speak with the medical oncologist on call. Any questions you have concerning your rights as a research subject will be answered by the Patient Advocate at Marquette General Hospital, who may be reached by phoning (906) 228-9440. You will be given a copy of this consent form.

Your signature below means that you have freely agreed to participate in this investigational study.

Patient's Signature

Date

Signature of person conducting
Informed consent discussion

Date

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this research study have been explained to the patient indicated, and that any questions about this information have been answered.

Investigator's Signature

Date

Your signature below means that you do not wish to participate in this investigational study.

Patient's Signature

Date

Signature of person conducting
Informed consent discussion

Date

Investigator's Signature

Date

IRB approved consent form 9/12/07