CONSENT FORM TO PARTICIPATE IN THE WOMEN'S HEALTH INITIATIVE EXTENSION STUDY

WHI Clinical Coordinating Center
Fred Hutchinson Cancer Research Center
Seattle, Washington
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1-800-218-8415

The purpose of this form is to ask you to continue participating in the Women's Health Initiative (WHI) Extension Study. About 5 years ago, you were one of the 115,000 women nationwide that agreed to continue in the WHI. Since then, you have provided the WHI Extension Study program with yearly updates on your health and well-being. This program has recently been renewed and it is our hope that you will continue to be a part of this study in the future.

Purpose of the WHI Extension Study

The main purpose of the WHI Extension Study is to continue to learn more about the health of postmenopausal women. We hope to learn more about risks for heart disease, stroke, blood clots, cancers, osteoporosis and fractures, as well as factors related to healthy aging and quality of life. Because you and so many other women have participated for many years, the WHI is expected to provide considerable insight into the factors that may lead to or prevent other health events and conditions that women experience at later ages.

What Will You Be Doing?

If you agree to continue in the WHI Extension Study, you will be asked to fill out health forms each year, similar to the forms you have completed in the past. If you have had health events for which we need additional information, we may ask you to sign a Release of Medical Information form. These activities will take about an hour of your time each year.

Benefits and Risks

You will not receive any personal benefit from participating. By continuing to take part in the Extension Study, you will help advance scientific knowledge about postmenopausal women's health. The only risk for this study is a small risk of loss of confidentiality.

Costs

You will not be paid for being in the study. The WHI will not pay for any health problems or conditions that might occur during this study. The study does not replace your usual medical care.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

Your study records will be kept confidential and will not be released for any reason without your written permission unless compelled by law. Information from this study may be published in scientific journals or presented at scientific meetings but your identity will not be revealed.

Only WHI staff at the Clinical Coordinating Center at the Fred Hutchinson Cancer Research Center in Seattle, Washington, and the specific WHI Regional Center or the affiliated institutions responsible for your follow-up will have access to your identifying information to maintain contact with you and update your study records. The WHI Regional Centers and their affiliates will be selected from the enclosed list of current clinical centers.

Some other people or organizations may need to look at your records for research, quality assurance, or data analysis. They include:

- Institutional Review Boards (IRB), including the Hutchinson Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- US National Institutes of Health and the Office for Human Research Protections.

These people or organizations are interested in study data, not your personal information. Personal information is information that can identify you, such as your name, date of birth, social security number, phone number, or other information. We will do our best to keep the personal information in your medical record confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law.

Alternatives

This is not a treatment study. Your alternative is not to participate.

Right to Withdraw

Your decision to continue in the study is voluntary. You may stop at any time, for any reason, without notice. If you decide to stop participating in the study, it will not affect your medical care or your medical insurance coverage.

Other Information

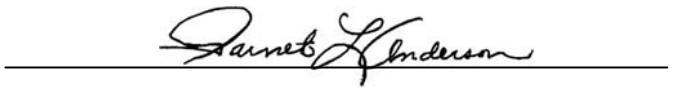
We ask for your permission to contact your spouse, close relative, or friend for updated information about your health in case you are unable to complete the health update forms. We may also try to obtain additional information about your health status through nationally available records, such as social security or Medicare. In the future you may be offered an opportunity to participate in other studies related to WHI. You may choose whether or not to participate in these studies. This decision will not affect your participation in WHI.

Voluntary Consent

If you have questions about any part of the study or your rights as a volunteer, a WHI staff person will answer them before you sign this consent form. You may call 1-800-218-8415 or any of the investigators listed at the beginning of this form. Also, if you are not satisfied with the manner in which this study is being conducted, or if you have any questions about your rights as a study participant, please call Karen Hansen in the Institutional Review Board Office of the Fred Hutchinson Cancer Research Center at 206-667-5900.

Investigator's Statement

The participant has been given a description of the WHI Extension Study. The participant was also provided a toll-free telephone number to call to discuss the procedures, including risks, and to ask any additional questions. A copy of the consent, signed and dated by the Principal Investigator, has been given to the participant.



Signature of Principal Investigator

May 1, 2010

Date

PARTICIPANT'S STATEMENT

I certify that I have read, or had read to me the description of the continuation of the WHI Extension Study. I understand this information and voluntarily consent to continue to participate. I understand that I may quit the study at any time. I have been given a toll-free number to call to ask questions about the study and my participation in it. I understand that if I have questions about the study in the future, I can call this same number and that any questions I have about my rights as a research subject will be answered by the person identified above or their representative. I acknowledge that I have received a signed copy of this consent form for my records.

____ _____ _____

Signature of Participant

Date