

INFORMED CONSENT GUIDELINES

CONSENT TO TAKE PART IN THE WOMEN'S HEALTH INITIATIVE (WHI) DIETARY ASSESSMENT SUBSTUDY

**WHI Coordinating Center
Fred Hutchinson Cancer Research Center
Seattle, Washington**

[Clinical Center]

[Principal Investigator]

[24-Hour Contact]

Consent to Participate in WHI Dietary Assessment Substudy

This form is to tell you about the activities that will occur when you participate in the WHI Dietary Assessment Substudy.

Purpose of the Study

The Women's Health Initiative (WHI), funded by the National Institutes of Health (NIH), is a study of ways to prevent breast cancer, colon and rectum cancer, heart disease, and bone fractures (breaks). About 163,000 women from 40 centers in the United States will take part in this study. An important part of WHI is to study the effect diet may have on the health of women age 50 to 79.

This dietary substudy will collect information on different ways of measuring diet. There are many ways to measure a women's diet and no one is sure what is the best way. If we have more information about the different ways of assessing food intake, it will help us understand the results of the entire WHI study.

What Will You Be Doing?

Activities of the First Clinic Visit

At this visit, Clinic Staff will:

- Review the questionnaires you completed before or at the clinic visit.
- Record the names and dosages of vitamin supplements you are currently taking.
- Measure your height, weight, waist and hips; take your pulse and blood pressure.
- Schedule you for another clinic visit.

Activities between the First and Second Clinic Visit

WHI staff from the Clinical Coordinating Center in Seattle will mail you Food Questionnaire and a postage-paid return envelope. We will ask you to complete the Food Questionnaire immediately and mail it to Seattle in the envelope provided.

WHI staff in Seattle will call you four different times to ask you about the foods you ate on the previous day. These calls will be unscheduled (surprise calls). You do not need to keep track of the foods you eat, or change how you normally eat. Each call will last 20 to 30 minutes.

Activities of the Second Clinic Visit

At this visit, Clinic Staff will:

- Have you watch a video on how to keep a food record.
- Give you a food record to keep track of the foods you eat for four days.
- Schedule you for your third clinic visit.

Activities of the Third Clinic Visit

At this visit, Clinic Staff will review your food record with you. The Staff will make a copy of the food record for you to keep. You may receive a call from the WHI staff in Seattle asking for more information on the foods you ate on those four days.

Benefits and Risks

By taking part in this study, you will help increase scientific knowledge about ways to measure food intake in women. There should be no risks of participating in this study.

Costs

The visits that are a part of this study will cost only your time and travel. You will not be paid for being in the study.

Confidentiality

All of your study records will be kept strictly confidential as required by law. Your personal identity will not be revealed in any publication or release of results. Only WHI staff at the [name] Clinical Center and the Clinical Coordinating Center at the Fred Hutchinson Cancer Research Center in Seattle, Washington, will have access to your study number, name, social security number and address for the purpose of study wide mailings, as well as maintaining and updating your study records. After completing the study, we will remove all personal identifiers from study records, which will be kept indefinitely for analyses.

Right to Withdraw

Your decision to join in this study is voluntary. You may quit at any time, for any reason, without notice.

Voluntary Consent

If you have any questions about any part of the study or your rights as a volunteer, a WHI staff person will be on hand to answer them before you sign this consent form. Also, if you have any questions about your rights as a participant in this study, please call _____ in the Institutional Review Board Office of [Clinical Center] at [phone number]. If you have any questions at any time, you may call: [Clinical Center name and phone number] or any of the investigators listed at the beginning of this form. Before you sign this form, please ask any questions on any part of this study that is unclear to you.

Other Information

Your joining is important to the success of this study. Unless volunteers like you agree to join, this study will not be possible.

Investigator's Statement

I have provided an explanation of the above research program. The participant was given an opportunity to discuss these procedures, including possible alternatives, and to ask any additional questions. A signed copy of the consent form has been given to the participant.

Signature of Principal Investigator or Designee

Date

PARTICIPANT STATEMENT

I certify that I have read, or had read to me, and that I understand the WHI Dietary Assessment Substudy description and I voluntarily consent to join in this study. I understand that I may quit the study at any time. I have had a chance to ask questions. I understand that I may ask further questions at any time and that I will receive a copy of this signed consent form for my records.

Signature of Participant

Date

Signature of Witness

Date