CONSENT FORM FOR THE OBSERVATIONAL STUDY PART OF THE WOMEN'S HEALTH INITIATIVE (WHI)

WHI Coordinating Center
Fred Hutchinson Cancer Research Center
Seattle, Washington

[Clinical Center]

[Principal Investigator]

[24-Hour Contact]

This form is to tell you about the Observational Study (OS) part of the Women's Health Initiative (WHI). If you are able, you may choose to be in this part of the study. We expect thousands of women across the U.S. to be in the WHI.

Many of the women who come for at least 1 clinic visit will not be able or willing to join the WHI Clinical Trial. As one of these women, you have an opportunity to join in a very important study to look at the relation between lifestyle factors and health, as well as quality of life. Women can be in this study by completing the study questionnaires, having a brief physical exam (at start of study and 3 years later), and providing a blood sample (also repeated at 3 years). This study will look at the role of several health habits (for example, physical activity and diet) and exam results (such as blood pressure and body weight), as well as factors measured in the blood sample. The study will then look at how these factors affect risks of heart disease, cancer, general health, and quality and length of life.

Purpose of the Observational Study Part of the WHI

The main purpose of the Observational Study part of the WHI is to learn more about women's health, and to learn more about the causes of disease in women age 50 to 79. The WHI Clinic Staff has determined that you are able to join this part of the WHI.

Reasons for the Observational Study Part of the WHI

There are several major diseases that women may get as they get older. Heart disease is the most common cause of death in women age 50 to 79. Breast cancer is the most commonly occurring major cancer in women. Cancers of the colon and rectum are the third most common major cancers in women. Hip fractures (breaks) occur in about 150 out of 1,000 women age 50 and over.

If we could prevent these diseases, women could expect to live longer and healthier lives.

What Will You Be Doing?

If you decide to join in this part of the study, you will be followed for about 8-12 years. During this follow-up period, you will be contacted by mail each year and asked to complete health update questionnaires and mail them back to the clinic. These questionnaires should take about 30 minutes to complete.

You will also receive a WHI newsletter each year, informing you of news about the study and general information about health for women your age.

You will be invited to return to the clinic in 3 years. Before that visit, you will be mailed questionnaires to complete and bring with you to the clinic visit. At that clinic visit, Clinic Staff will:

- Review the questionnaires you completed before or at the clinic visit.
- Record the names (and possibly dosages) of medications you are currently taking.
- Measure your pulse, blood pressure, height, weight and the distance around your hips and waist.
- Give you some questionnaires about yourself and your lifestyle to complete, either in the clinic or at home.
- Briefly interview you about female hormones you may have used.
- Draw about 3 tablespoons of blood for laboratory tests. For 12 hours prior to the blood test, you will not be able to exercise vigorously, eat, or drink anything except water and your regular medications. For one hour prior to the test, you will not be able to smoke.

Osteoporosis Substudy Clinical Centers only:

- You will be invited to return to the clinic every 3 years.
- At the 3rd, 6th and the 9th yearly visits, your bone density will be measured in your hip, spine and in your whole body. The test is painless and takes about 30 minutes.
- At each visit, you will also be asked to provide a urine sample (about 1 tablespoon) which will be stored for laboratory tests at a later date.

All of the activities of this 3rd Year Clinic Visit should take no more than 1½ hours to complete.

Abnormal findings of the following clinic tests will be reported to you, your doctor or your clinic: blood pressure or blood test for anemia done at your Clinical Center.

Some of the blood drawn will be stored for tests at a later date, including possible genetic studies. These blood tests will not replace your usual medical care and results will not be available for your medical care (for example, your cholesterol will not be reported to you or your doctor). Research studies require only looking at all lab results together, and individual results will not be available.

One percent (1 in 100) of women will be invited for a repeat Screening Visit 1 and 3rd year Clinic Visit to test the accuracy of certain measures.

Benefits and Risks

There may be no direct benefit to you for participating in this study. By taking part in this study, you will help to increase scientific knowledge about the prevention of breast cancer, colon and rectum cancer, heart disease, and fractures (broken bones) in women, and about women's experiences and lifestyles that affect their health as they get older.

Pulse; blood pressure; and height, weight, hip and waist measures

There should be minimal risks with these activities.

Blood draw

There is a small risk with the process of drawing blood. You may feel a little discomfort as the needle goes through the skin. There may be some bruising at the site where blood is drawn. Pressing hard on the spot for 1 or 2 minutes after the needle is removed will help to prevent a bruise. Very rarely, the arm may become infected. Occasionally a woman may feel lightheaded or even faint when her blood is drawn. If you feel faint, tell the person drawing your blood and she or he will have you lie down until the feeling goes away.

Osteoporosis Substudy Clinical Centers only

Bone Density Measurement

The bone density measurement involves a small amount of radiation. Small amounts of radiation may have potential harm, but the risk is difficult to measure and is probably very small. The total radiation from the bone density measurements is less than 4% of the natural background radiation a person receives living in a typical American community for one year. It is about the same radiation as 3 coast-to-coast airline flights from the east to the west coast.

Urine Sample

The urine sample involves no risk.

Alternate Treatments

This part of the study does not involve treatment.

Costs

The tests, procedures and visits that are a part of this study will cost only your time and travel. Any test or procedure that would normally be billed to your insurance company, Medicare, or Medicaid will be billed to those sources. If you do not have sources to pay for tests and procedures, the study will pay these costs.

The study and Clinical Center have not set aside funds to pay for any health conditions that you may develop, and will not pay for any health problems or conditions that might occur during the course of this study. These might be covered by your usual insurance, Medicare or Medicaid. You will not be paid back for any wages lost from taking part in this study. You will not be paid for being in the study.

Confidentiality

All of your study records will be kept confidential to the extent required by law. Your personal identity will not be revealed in any publication or release of results. If a health condition is detected during this examination, you will be told about it and the information will be given to your doctor or clinic. 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. Study records will be kept indefinitely for analysis and follow-up. This study is authorized by Privacy Act 42 United States Code 241.

Right to Withdraw

Your decision to join in this study is voluntary. You may quit at any time, for any reason, without notice. We hope you will take part for the entire time of the study because we will use all of this information to draw correct conclusions. If you decide to leave the study, we hope to be able to contact you yearly to see how you are doing. If you decide to leave the study, it will not affect your regular medical care.

Voluntary Consent

If you have any questions about any aspect 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. Additionally, if you have any questions about you 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 many volunteers like you agree to join, this study will not be possible.

We have tried to make joining the study as easy as possible for you. Please let us know if there are ways you think it would be easier for you and others to join this study.

In order for this study to be valid, you should not join other health studies where you would be assigned at random (like the flip of a coin) to receive a medication, special test, or special treatment.

If any study test suggests that a health problem needs further study, you will be sent back to your doctor or clinic, who will evaluate the need for further study. Copies of reports and hospital records of your doctor's follow-up may be requested by the WHI and become part of your study record at the [Clinical Center]. If you are unable to complete the follow-up forms, the WHI clinic staff may contact your spouse, close relative, or friend for updated information about your health. If you move, and we are not able to find you, we may try to locate you through nationally available records, such as social security. Whether or not you choose to join the Observational Study part of the WHI will not affect your personal medical care or your medical insurance coverage. The study does not replace your usual medical care.

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 description of the Observational Study part of the WHI. I voluntarily consent to join in this part of the study. I understand that I may quit the study at any time. I have had a chance to ask questions about the Observational Study part of the WHI. 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. I have had an opportunity to carefully review the Observational Study Informed Consent form and ask questions about it.

_____ _____

Signature of Participant Date

_____ _____

Signature of Witness Date