INITIAL CONSENT TO TAKE PART IN THE WOMEN'S HEALTH INITIATIVE (WHI)

WHI Coordinating Center
Fred Hutchinson Cancer Research Center
Seattle, Washington

[Clinical Center]

[Principal Investigator]

[24-Hour Contact]

Consent to Participate in First Screening Clinic Visit

This form is to tell you about the activities that will occur during your first WHI clinic visit.

Reason for the Study

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 commonly 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.

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 160,000 women from approximately 40 centers in the United States will take part in this study. The WHI will investigate the possibility of improving the health of women age 50 to 79. Women will be followed in the study for 8-12 years. (How long you are in the study will depend on when you join. Women who enter the study in 1993 will be followed for up to 12 years, while women who join later will be followed for less time.)

Study Parts

There are two major parts to the WHI: a Clinical Trial and an Observational Study. The Clinical Trial will try to find out if there is a benefit to taking hormone replacement therapy, or to changing one's diet to a low-fat, high fruit and vegetable, and high grain eating pattern, or to taking daily calcium and vitamin D. By joining this part of the study, you may help to answer the question of whether these various changes will improve health. You may choose to take part in 1, 2, or 3 parts of the Clinical Trial.

The Observational Study part of the WHI will include women who do not join the Clinical Trial, but who are examined and followed for 8-12 years to provide more information about women's health, and to learn more about causes of disease in older women.

What Will You Be Doing?

Activities of the First Clinic Visit

The results of your first clinic visit will help to determine if you are able to join in the WHI. All of the activities are to see if you will be able to join either the Hormone Replacement part or the Dietary part of the study, or both. The WHI staff will be able to give you an idea of whether you might be able to join toward the end of the visit.

At this 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 your personal qualities and 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 1 hour prior to the test, you will not be able to smoke.

In addition, Clinic Staff may:

- Measure your physical ability in 3 ways:
  1) You will be asked to squeeze 2 handles together in one hand, to measure the strength of your hand.

  2) You will be asked to stand up out of a chair several times from a sitting position to measure the strength of your legs.

3) You will be asked to walk a distance of 18 feet and a clinic staff member will measure how long it takes you to walk that far. This will measure your walking ability.

Osteoporosis Substudy Clinical Centers only:

- You will be asked to provide a urine sample (about 1 tablespoon) which will be stored for laboratory tests at a later date.
- Your bone density will be measured in your hip, spine and in your whole body. The test is painless and takes about 30 minutes.

This first clinic visit should take approximately 2–4 hours to complete.

Abnormal findings of the following clinic tests will be reported to you, your doctor or your clinic: e.g., high 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. This stored blood will be used whether you are in the Clinical Trial or the Observational Study. These blood tests will not replace your usual medical care, and results will not be available for your medical care (for example, your cholesterol level 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.

Benefits and Risks

By taking part in this study, you will help increase scientific knowledge about the prevention of breast cancer, colon and rectum cancer, heart disease, and bone fractures (breaks) in women. Also, we will learn ways to prevent disease and promote the health of women from all backgrounds and lifestyles.

Pulse; Blood pressure; and height, weight, hip, waist and physical strength measures

There should be minimal risks with these tests.

Blood draw

There is a small risk with 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 1% of the natural background radiation a person receives living in a typical American community for one year. It is less than one half the radiation from a round-trip airline flight from the east to the west coast.

Urine Sample

The urine sample involves no risk.

Alternate Treatments

This clinic visit is only to find out if you are eligible to be in these studies.

Costs

The tests, procedures, medications 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. The Food and Drug Administration may be allowed to examine your study records for safety reasons. 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. Even if you decide to stop taking part in the study, you will still be asked to come for clinic visits so we can know what happens to you until the end of the study. 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 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 many volunteers like you agree to join, this study will not be possible. If, as a result, we learn that a low fat diet reduces the risk of breast cancer, colon or rectum cancer, or coronary heart disease, or that hormone replacement therapy reduces the risk of heart disease or broken bones, many women may benefit. We also expect to discover risks which may be associated with these treatments.

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. There may be reasonable exceptions to this rule. We therefore ask you to discuss with clinic staff any plans you may have to join other studies before doing so.

If any study test suggests that a health problem needs further follow-up, 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 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 any part of the study will not directly affect your personal medical care or your medical insurance coverage. The study does not replace your usual medical care.

An independent committee of experts in medical research will be reviewing study results regularly to see if there are clear benefits or harmful side effects. You will be informed if definite benefits or harmful results are found during the study.

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 study 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. I have had an opportunity to carefully review the Initial Informed Consent form, watch the Initial Informed Consent videotape, and ask questions about them.

_____ _____

Signature of Participant Date

_____ _____

Signature of Witness Date