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

WHI Clinical Coordinating Center
The Fred Hutchinson Cancer Research Center
Seattle, Washington

[*Clinical Center*]

[*Principal Investigator*]

[*Other Investigators, as appropriate*]

[*24-Hour Contact*]

This form is to tell you about the Women's Health Initiative (WHI) Hormone Program Extension Study. You are invited to join the WHI Hormone Program Extension Study because you were a participant in either the WHI Estrogen plus Progestin Trial or the WHI Estrogen-Alone Trial. The WHI Hormone Program Extension Study will extend your participation in the WHI study through 2010. All participants in the WHI Hormone Clinical Trials—those who were in the active hormones and in the placebo groups—may join this research study. We expect thousands of Hormone Program participants across the United States to join and continue to contribute important information to women's health.

Purpose of the Hormone Program Extension Study

The main purpose of the WHI Hormone Program Extension Study is to continue to learn about the health of women after they have stopped the WHI Hormone Clinical Trials study pills. We hope to learn whether hormone-related health risks and benefits for heart disease, stroke, blood clots, breast cancer, colon cancer, other cancers, and osteoporotic fractures (broken bones), as well as quality of life, change after women have stopped taking the WHI study pills. We also hope to learn whether these changes are different for women who were originally assigned to take active hormone pills and those assigned to take placebo pills. This study will help us to find out if the risks and benefits related to hormone pills continue or disappear over time.

Reasons for the Hormone Program Extension Study

Results from the WHI Hormone Clinical Trials have given health care providers important information about the effects of hormones on diseases of aging in postmenopausal women. As more and more women are re-evaluating their use of hormone therapy, it is important to understand how stopping hormones changes these hormone-related effects on disease over time. This question has been asked by health care providers and the millions of women who were taking and continue to take estrogen pills, with or without progestins. The WHI Hormone Extension Program can find answers to the question by comparing the health changes in women who stopped taking hormone study pills with changes in women who stopped taking placebo pills.

What Will You Be Doing?

If you decide to join the WHI Hormone Program Extension study, you will be asked to fill out annual health forms during the next five years and to have annual mammograms during the first two years. You will not be asked to come into the WHI Clinical Center for these activities. The health forms will be similar to the medical history and hormone use updates you were asked to complete every 6 months while you were in the WHI Hormone Clinical Trial. However, for this Extension Study, you will only be asked to complete the forms once a year through 2010. The forms will be mailed to you, with a pre-paid mailing envelope, and you will be asked to return your completed form by mail. If the WHI staff has any questions after receiving your forms, they will contact you by telephone. We may also ask you to sign a Medical Release form to get more detailed information about health issues that you report on the form. During the first two years, the WHI staff will also remind you to have an annual mammogram and will ask your permission to obtain a copy of the mammogram report, just as when you were in the Hormone Clinical Trial.

The amount of time asked of you to participate in the Hormone Program Extension Study will be:

Activity	Total Time
• Completing health forms	About 30 minutes each year through 2010
• Releasing a copy of your annual mammogram report to the WHI staff	Less than 15 minutes each year during the first two years

Benefits and Risks

We cannot and do not guarantee or promise that you will receive any personal benefits from this study; however, there is also little risk. You may find that the yearly mammogram report requested by the WHI staff helps you remember to have this important breast cancer screening test that is recommended by many health care providers. By taking part in the Hormone Program Extension Study, you will help advance scientific knowledge about postmenopausal women's health. Specifically, you will help scientists learn about health changes after participants stop their study pills in the WHI Hormone Clinical Trial.

There are no risks to completing the health update forms for this study. The annual mammogram that you are asked to obtain during the first two years does use radiation, which may slightly increase the risk of developing breast cancer. Scientists of the WHI and the National Cancer Institute believe that this small risk is outweighed by the benefit of finding breast cancer early in women. Mammograms are recommended for all women in your age group every 1-2 years.

Costs

The procedures that are a part of this study will cost only your time and travel to obtain an annual screening mammogram during the first two years. You will bill your insurance company, Medicare, or Medicaid for the cost for these screening mammograms as usual. If you do not have sources to pay for these screening mammograms during the first two years, the study will pay these costs. However, additional diagnostic studies will not be covered by the study. The WHI has not set aside funds to pay for any health conditions that you may develop, and will not pay for

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. If you have questions about your costs, financial responsibilities, and/or medical insurance coverage for this activity, please contact [*CC financial office or other budgetary person and institutional department*] at [*phone number*].

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. 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.

ACCESS TO YOUR INFORMATION

You have the right to limit the use and sharing of your health information, and you have the right to see your medical records and know who else is seeing them. Everyone involved in this study respects your privacy. Any and all information about you obtained for this research study will be kept confidential and will not be released for any reason without your written permission unless compelled by law. In addition:

- staff are trained to protect your privacy and sign an agreement to do so;
- paper records are stored in locked files;
- computer records are password protected;
- your name or other personal information will not be included with any data shared with anyone who is not part of the WHI Study Research Staff.

USE AND DISCLOSURE OF YOUR MEDICAL INFORMATION

By signing this consent form, you are authorizing the use and disclosure of your health information collected in connection with your participation in this research study. Your information will only be used as we have described in this consent form and any applicable laws. If you decide to stop participating in the study, you may revoke your authorization, except to the extent that the law allows us to continue using your information.

What Information Will Be Used or Disclosed?

Health information related to this study may include, but is not limited to: demographic information, the results of physical exams, blood tests and related records, x-rays, and other diagnostic and medical procedures. This information may be used or disclosed in connection with this research study. We may request from your physician a copy of your medical record related to your diagnosis and treatment of cancer or other diseases if we have obtained from you a signed Medical Release form.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The [*CC*] WHI Research Staff
- The [*CC*] Administrative Panel on Human Subjects in Medical Research or Institutional Review Board (IRB) and any other unit of the [*CC*], as necessary
- The WHI Clinical Coordinating Center Staff at the Fred Hutchinson Cancer Research Center in Seattle, Washington
- The Institutional Review Board at the Fred Hutchinson Cancer Research Center

Who May Receive / Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration (FDA)

Your information may be redisclosed if the recipients described above are not required by law to protect the privacy of the information.

Expiration
Your authorization for the use and disclosure of your health information will continue indefinitely.

Right to Withdraw

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

Other Information

Your joining is important to the success of this study. You may join the WHI Hormone Program Extension Study whether or not you were in the active hormone or placebo group of the WHI Hormone Clinical Trials. You may also join even if you have started taking hormones prescribed by your health care provider. Unless many volunteers like you agree to join, this study will not be successful in meeting its goal of finding out the long-term health risks and benefits of recent hormone use. 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 to join this study.

If your mammogram suggests a possible health problem, we will ask you to go back to your doctor or clinic to evaluate the need for further tests. Copies of reports and hospital records of your doctor's follow-up may be requested by the WHI and become part of your WHI study record.

At the beginning of this study, the WHI staff will 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. 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. If you choose not to join the Hormone Program Extension Study, it will not affect your personal medical care or your medical insurance coverage. The study does not replace your usual 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 answer them before you sign this consent 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 [*IRB Official's Name*] in the Institutional Review Board Office of [*Clinical Center's Institution*] 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 not clear to you.

Investigator's Statement

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

_____ _____

Signature of Principal Investigator or Designee Date

PARTICIPANT'S STATEMENT

I certify that I have read, or had read to me the description of the WHI Hormone Program Extension Study. I understand this information and voluntarily consent to join. I understand that I may quit the study at any time. I have had a chance to ask questions about the study and my participation and about the need for access to my medical records. They have been answered to my satisfaction. I understand that future questions I may have about the research will be answered by one of the investigators listed above and that any questions I have about my rights as a research subject will be answered by the person identified above. I acknowledge that I will receive a signed copy of this consent form for my records.

_____ _____

Signature of Participant Date

_____ _____

Signature of Witness Date