

Consent to take part in a research study:
THE WOMEN'S HEALTH INITIATIVE Long Life Study

WHI Clinical Coordinating Center
The Fred Hutchinson Cancer Research Center
Seattle, Washington
Principal Investigators: Garnet Anderson, PhD & Andrea LaCroix, PhD
1-800-550-0025 (message line)

We invite you to join the Women's Health Initiative (WHI) Long Life Study. We expect about 8,000 WHI participants across the United States to join the Long Life Study. What we learn from this study will build on your past participation in the WHI to learn even more about health, aging, and the health effects of physical activity. Whether you decide to take part or not, you will still be enrolled in the WHI Extension Study.

1. What will happen in the WHI Long Life Study?

We plan to update some of the information that you provided when you first joined WHI in the 1990s.

So you don't have to drive to a clinic, a research assistant (a woman) will make an appointment to come to your home to collect the study data. If you prefer, the appointment can take place somewhere other than at your home, such as a doctor's office or a family member's home.

Here is the data we want to collect in this study:

- **Measurements:** We will check your blood pressure, pulse, height, weight, waist circumference, grip strength, balance, and your ability to walk about 12 feet and stand up and sit down from a chair.
- **Fasting blood draw:** We will draw about 2 tablespoons of blood with a small needle from a vein in your arm.

To be fasting, we will ask you to have nothing to eat and only water to drink for the *12 hours* before your appointment. After the blood draw, we will provide a light snack before collecting the rest of the study data.

2. What if I live in a skilled nursing care center?

We are sorry, but we are not able to include residents of a skilled nursing care center. If you expect your residence for the next 3 months to be in a nursing center, please check 'Yes' for question 3 ('Do you live in a skilled Nursing Center?') on page 5 of this form, and return the form to us in the reply envelope.

3. Who will come to my home, or other location, to collect my study data?

The WHI is working with a national health care examination company called EMSI (Examination Management Services, Inc.). The EMSI research assistants are well-trained by both EMSI and WHI, and they are experienced in drawing blood and taking the study measurements. For your comfort, EMSI does a background check on all of its research assistants before they are hired. EMSI will keep your WHI ID number and contact information confidential.

Within a few weeks of our receipt of your signed consent form, an EMSI clinical services scheduler will call you to schedule your appointment. The day before your appointment, your EMSI research assistant will call you to confirm. The EMSI research assistant will show you identification when she comes to your door. For more information about EMSI, please see the website: <http://www.emsinet.com>.

4. What will you do with my blood?

Soon after it is collected, we will send one tube of your blood to a hospital lab for a complete blood count (CBC). We will store the rest of your blood sample, and the genetic material in your blood (DNA and RNA), for future research testing. We will give you the results of your CBC, but we will not give you the results of the future research testing on your blood.

5. How long will I be in the study?

The research assistant's study visit to your home will take a little more than one hour. During and after the Long Life Study, you will still be enrolled in the WHI Extension Study.

6. Does taking part in this study have any risks?

The blood draw may briefly hurt, and possibly cause you to feel faint, lightheaded, or nauseated. There may be a bruise at the needle site, and there is a very slight chance of infection.

It is possible, even with careful monitoring by the research assistant, that you could fall during the balance and walking measurements.

As in all research studies, there is a slight chance that your personal/private information could be accidentally released.

7. Are there any benefits to taking part in this study? Will I be paid?

Before she leaves, the research assistant will give you a card with your blood pressure, pulse, height, and weight. If your blood pressure or pulse is outside of the normal range, the card will advise you to contact your doctor.

Within a few weeks of your appointment, we will mail you the results of your CBC. If the CBC results are outside of the normal range, we will advise you to contact your doctor.

NOTE: The WHI does not offer any diagnosis or treatment for illnesses. WHI will not pay for any follow-up medical care that your doctor may recommend.

8. What happens if I get hurt because I took part in the study?

Should you fall or have a serious health problem while the research assistant is at your home, she will call 911 and stay with you until help arrives. The cost for your treatment of any study-related injuries will be billed to you or your medical or hospital insurance.

9. How will the study find out about the health effects of physical activity?

An important part of the Long Life Study is a separately funded **Physical Activity Study**. At the end of your Long Life Study appointment, the research assistant will leave you with a packet of physical activity materials that includes: (1) a cover letter/ instruction sheet and sleep log, (2) a physical activity monitor, (3) a physical activity questionnaire, (4) a calendar with monthly forms for reporting falls, and (5) postage-paid envelopes.

We will ask that you wear the monitor, which is about one inch square and a half inch thick, on your waist for 7 days, and then mail it back to the study office with your completed physical activity questionnaire and sleep log in the postage-paid envelope.

The calendar has forms to report any falls you may have. All we will ask is that you check 'Yes' or 'No' for each day and return each month's form in a postage-paid envelope. If you report a fall by checking 'Yes' on one of the calendar forms, we will call you for a 15 minute interview about the details.

We will also invite about 200 of the 8,000 Long Life Study participants to come to a nearby WHI clinic for further physical activity monitoring tests. If you are eligible for this clinic visit, we will provide your contact information to the clinic. A study staff member will call you to ask about your interest in participating.

The Physical Activity Study will continue after the Long Life Study appointment while you wear the monitor for 7 days, complete your Physical Activity Questionnaire, and fill out one calendar form each month for a year.

At first, wearing the physical activity monitor may make you feel a little self-conscious, or it might feel a little uncomfortable. These feelings usually go away quickly. If you suffer an unexpected injury related to wearing the physical activity monitor, please notify the study office right away [Erin Hughes, 206-667-7341].

When you return the physical activity monitor to us, we will send you \$10 as a token of appreciation for your participation in this study.

You may opt out of the physical activity study if you wish and still take part in the rest of the Long Life Study. If you wish to opt out of the Physical Activity Study, check "No" to 'Participant's Statement #2' on page 5.

10. What are the costs of taking part in the study?

Other than your time, there are no costs to you for taking part in this study.

11. What will you do with my data?

Just as in WHI, your data will be combined with data from other participants to study the health of aging women. Also as in WHI, your genetic material, genetic data, blood, and study data may be shared with scientists in qualified and approved organizations – but only after your identifying information (e.g., name, address, and birth date) have been removed. These organizations may be non-profit (for example, a university), for-profit (for example, a drug company), or a secure genetic database. Any sharing with other organizations requires the approval of an Institutional Review Board whose job it is to make sure the research study protects the rights and welfare of people taking part in the study.

12. How will you protect my privacy and keep my personal information confidential?

As in WHI, your study records will be kept confidential to the extent permitted by law. There may be times when we are required by law to release study data. Also, some people or organizations may need to look at your research records for quality assurance or data analysis. They could include:

- Researchers involved with this study
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB
- US National Institutes of Health and the Office Human Research Protections

These people and organizations are interested in study data, not your personal information that can identify you (for example, your birth date). We will do our best to keep your personal information confidential, but we cannot guarantee it.

13. What are my rights if I take part in this study?

By signing this form, you do not give up any personal legal rights.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty for saying no or dropping out. Whatever you decide, your regular medical care will not change. You will still be a part of the WHI Extension Study.

14. Who can answer my questions about the study?

- **About this consent form:** Please leave a message for Dr. Garnet Anderson or Dr. Andrea LaCroix at 1-800-550-0025. Please also see the information on our Website: www.whi.org.
- **During the study, including concerns about EMSI:** Please leave a message for Erin Hughes at 1-800-550-0025, or call Erin directly at 1-206-667-7341.
- **About your rights as a study participant or other study-related concerns or complaints:** Please call Karen Hansen in the Fred Hutchinson Cancer Research Center's Institutional Review Office at 1-206-667-4867.

Participant's Statement

I have read (or someone has read to me) this consent form. I am aware that I am being asked to take part in a research study. If I had questions about the study, I asked them, and my questions were answered.

I understand that my study data, blood, and genetic material/genetic data from this study might be shared with qualified and approved organizations for research purposes only. I also understand that my genetic data might be added to a secure genetic database for use by many qualified researchers.

I voluntarily agree to participate in this study. I am not giving up any legal rights by signing this consent form. I will keep a copy of this signed document.

1. I agree to participate in the Long Life Study.

Yes **No** → Please return this form in the envelope provided.



2. I also agree to participate in the Physical Activity Study.

Yes **No**

**Printed name of study
participant**

Signature of study participant

Date and time

3. Do you live in a skilled nursing care center? **Yes** **No**

4. Current Address (next 3 months)

5. Current Phone Number: (____) ____ - _____