CONSENT TO TAKE PART IN A RESEARCH STUDY:

THE WOMEN'S HEALTH INITIATIVE LONG LIFE PHYSICAL ACTIVITY CALIBRATION STUDY

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1-800-550-0025 (message line)
<<Local Sites to insert local site contact name, phone number and emergency phone number.>>

Now that you have completed your Long Life Study home visit, we would like to invite you to take part in the Women's Health Initiative (WHI) Long Life Physical Activity Calibration Study (Calibration Study). As mentioned when we talked to you on the phone about the Calibration Study, you are one of about 200 Long Life Study participants invited to join the next phase of this research.

1. Why is this study being done?

The purpose of the Calibration Study is to learn more about measuring the health effects of physical activity. We are especially interested in learning about what levels of physical activity help older women avoid heart disease. This study is especially important for older women because there is not much information available about physical activity guidelines for older women. We call this study the Calibration Study, which means we will take detailed measures to help us tell apart different levels of physical activity in older women such as being fairly still (sedentary), lightly active or moderately active. This in turn will help us learn how physical activity may influence health and heart disease in older women.

2. Who is eligible for this study?

Women are eligible for this study if they completed a Long Life Study home visit, consented to the physical activity part of the Long Life Study, and met the telephone screening questions about general health conditions, heart health, ability to walk continuously for 10 minutes, and physical ability to balance.

3. What will happen in this research study?

We will ask you to attend a clinic study visit that will last 2 hours.

This is what will happen during the clinic visit:

- We will measure your height and weight.
- We will ask you to complete a short survey asking about your physical activity.
- We will ask you to wear a small heart monitor on a strap around your rib cage, a small back pack with breathing mask that will measure how much oxygen you use, and small physical activity monitors (on your hips and wrist). You will wear these activity measurement items during the parts of the visit when you are doing activities or walking.
- We will ask you to do five activities for seven minutes each. The activities include sitting and watching a DVD, standing and washing a drying dishes, standing and folding towels, sitting and sorting cards, standing and dust mopping. You will wear the activity measurement items while doing these activities.
- We will ask you to walk a quarter mile within 15 minutes at your usual pace while wearing the activity measurement items. A quarter mile is about six (6) city blocks or slightly less than the length of four (4) football fields. The walking takes place indoors.
- We will ask you to walk on a treadmill at both a slow and moderate pace for up to 10 minutes without assistance while wearing the activity measurement items.
- We will ask you several times throughout the visit to rate how much effort you feel the activities are taking. The ratings are asked in a range from very very light effort up to very very hard effort. The activities are expected to range from very very light to somewhat hard (moderate).
- If at any time during the visit you feel uncomfortable, you may ask to stop the activities or ask to stop wearing the activity measurement items.

4. How long will I be in the study?

After you complete the clinic study visit, your participation in this study is over. You will still be enrolled in the WHI Extension Study and asked to complete annual questionnaires about your health status. You will also still be in the Long Life Study and complete your Falls/Injury postcards each month for the rest of the year.

5. What are the risks or possible discomforts from being in this study?

We designed this study to protect your safety while doing the activities described above. Study staff are trained to help prevent injuries. However, you could be injured doing the activities we ask you to do. The walk may cause shortness of breath or heart problems ranging in severity from discomfort to a serious health

event or very rarely, death. Study staff will watch you closely for signs and symptoms of discomfort. If you feel you should stop a test, you can just say, "Stop," and we will stop the test.

6. What are the possible benefits from being in this study?

If you agree to take part in this study, there may or may not be direct benefits to you. This study will help us better understand the health effects of physical activity in women. For example, we hope to learn whether the movements you do in your everyday life are related to heart disease risk factors or future heart attacks. We also hope to learn if everyday activity is related to staying independent and avoiding disability. As a result of participating in this study, you may learn about your own fitness level.

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

Should you fall or have a serious health problem while at the clinic for this study, the research assistant will call 911 and stay with you until help arrives. If you realize after you return home that you were injured from participating in this study, we want you to notify the clinic right away.

The cost for your treatment of any study-related injuries will be billed to you or your medical or hospital insurance.

8. What are the costs of taking part in the study? Will I be paid?

Other than your time and transportation costs to get to the clinic, there are no costs to you for taking part in this study.

You will receive <<up to $50, per site budget discretion>> to compensate you for time and travel costs. No other form of compensation will be provided.

9. What will you do with my data?

Just as for WHI and the Long Life Study, your clinic visit data will be combined with data from other participants to study the health of women who have reached the age of 72. Also, as for WHI, your study data may be shared with scientists in qualified and approved organizations – but only after removing your identifying information (e.g., name, address, birth date). These organizations may be non-profit (for example, a university) or for-profit (for example, a drug company). 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.

10. 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 may have as a participant in this study.

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.

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

As for 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 IRBs from <<insert local site name>> or the Fred Hutchinson Cancer Research Center
- 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.

12. Who can answer my questions about the study?

- **About this consent form:** The clinic staff member who presents the consent form to you will be able to answer your questions.
- **During the study:** Please call the study staff using the telephone numbers at the top of the consent form.
- **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 participate in a research study. I have had the opportunity to ask questions, and my questions were answered.

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

Printed name of study participant	**Signature of study participant**
	AM/PM
	Date and time

Investigator/Research Staff

I have explained the research to the participant who signed above. A signed copy of this consent form has been given to the participant.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

cc: Participant