

**WASHINGTON STATE UNIVERSITY**  
Extension Food and Nutrition / College of Pharmacy  
**Research Study Consent Form**

**Study Title: On the Road to Living Well with Diabetes**

**Researchers:**

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**Sponsor:** Cooperative State Research, Education, and Extension Service (CSREES)

You are being asked to take part in a research study carried out by Sue Butkus PhD RD. This form explains the research study and your part in it if you decide to join the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything you don't understand. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. This study has been approved for human subject participation by the Washington State University Institutional Review Board.

**What is this study about?**

This research study is being done to learn how community education can help people manage diabetes and prevent the complications of diabetes. The purpose of this educational study is to help you learn about the five diabetes tests that can be used to check diabetes. When people with diabetes regularly get these five medical tests, they are more able to catch the early warning signs of problems and then take action to prevent or reduce the complications of diabetes.

You are being asked to take part because you have indicated you are living with diabetes.

Taking part in the study will take about two hours a week for six weeks, with a follow up session three months after the initial visit.

You cannot take part in this study if you are under 18 years of age.

**What will I be asked to do if I am in this study?**

If you take part in the study, you will be asked to

- Participate in a 1 1/2 to 2 hour educational program that will explain about the five diabetes tests people need to get from their doctor.
- Agree to have a free finger-stick blood-screening test when you enroll in the program and again three months later. This blood screening test is a hemoglobin A1c test which measures how well your diabetes has been controlled in the last three months.

WSU IRB # 4134-017  
Approved: 7/21/2009  
Valid until: 7/20/2010

- Agree to have your blood pressure measured.
- It will take about 10 minutes to get the results of the finger-stick and blood pressure tests.
- You will receive the results of your finger stick and blood pressure during the first educational program.
- Answer some questions about your knowledge and attitudes about diabetes when you enroll at the first meeting and again after three months. You are free not to answer any questions you may find objectionable. All your answers will be confidential. Your name will not be given to anyone and cannot be linked back to you. The questions will take about 15 minutes to complete.

### **Are there any benefits to me if I am in this study?**

The potential benefits to you for taking part in this study are:

- Information about the five diabetes tests.
- A list of resources so you know who helps people with diabetes in your area.
- The results of the finger-stick blood tests and blood pressure readings when you enroll and again at three months.

If you take part in this study, you may help others in the future, when people are able to manage diabetes they can prevent or reduce the complications of diabetes.

### **Are there any risks to me if I am in this study?**

The potential risks from taking part in this study are:

- This finger stick test may be a little uncomfortable, but it is very quick and very little blood is drawn, only a drop or two.
- As the blood pressure “cuff” or band tightens around the arm, this test may temporarily cause discomfort for a minute. Very occasionally, people are bruised by the test.
- Qualified staff will conduct tests. All necessary safety precautions will be taken when the tests are done. You may refuse if there is any discomfort.

### **Will my information be kept private?**

The data for this study will be kept confidential to the extent allowed by federal and state law. No published results will identify you, and your name will not be associated with the findings.

All of your study records will be assigned the same identification number.

All records will be kept in a locked location. The record for the identification numbers will be kept in a secure location, separate from the study records.

Under certain circumstances, information that describes you may be released for internal and external reviews of this project, but this will not have your name on it.

The researchers and research staff listed above and WSU Institutional Review Board

(IRB) will be the only people having access to your records. The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous. The data for this study will be kept for three years after the completion of the study as required by WSU.

**Are there any costs or payments for being in this study?**

There will be no costs to you for taking part in this study.

**Who can I talk to if I have questions?**

If you have questions about this study or the information in this form, please contact the researcher Sue Butkus PhD RD WSU Puyallup REC, 2606 West Pioneer, Puyallup, WA 98371-4989, butkus@wsu.edu, (253) 445-4553. If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board at (509) 335-3668, or e-mail irb@wsu.edu, or regular mail at: Albrook 205, PO Box 643005, Pullman, WA 99164-3005.

**What are my rights as a research study volunteer?**

Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. You may choose not to answer specific questions or to stop participating at any time.

**What does my signature on this consent form mean?**

Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.

**Statement of Consent**

I give my voluntary consent to take part in this study. I will be given a copy of this consent document for my records.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Participant

**Statement of Person Obtaining Informed Consent**

I have carefully explained to the person taking part in the study what he or she can expect.

I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of participation.

I also certify that he or she:

- Speaks the language used to explain this research
- Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her
- Does not have any problems that could make it hard to understand what it means to take part in this research.

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

\_\_\_\_\_  
Role in the Research Study