CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY
GROUP A

Researcher's Name(s): Jennifer O'Connor, MS, RN, CFCN, CNE
Deidre Wipke-Tevis, PhD, RN

Project Number: 2011705

Project Title: Foot Self-care in Older Adults without Diabetes

INTRODUCTION

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

You are being asked to participate in a clinical trial. When you are invited to participate in research, you have the right to be informed about the study procedures so that you can decide whether you want to consent to participation. This form may contain words that you do not know. Please ask the researcher to explain any words or information that you do not understand.

You have the right to know what you will be asked to do so that you can decide whether or not to be in the study. Your participation is voluntary. You do not have to be in the study if you do not want to. You may refuse to be in the study and nothing will happen. If you do not want to continue to be in the study, you may stop at any time without penalty or loss of benefits to which you are otherwise entitled.

You are being asked to take part in this study because you are an older adult without diabetes.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to explore foot self-care in older adults without diabetes. This research is being done because previous research has only focused on foot self-care in older adults with diabetes. The results will provide baseline information for future studies to develop and test ways to prevent foot problems in older adults without diabetes.

HOW MANY PEOPLE WILL BE IN THE STUDY?

About 32 people will take part in this study in two senior centers in the Tulsa area.

WHAT AM I BEING ASKED TO DO?

You will be asked questions about your demographic information (e.g. age, race/ethnicity, income, education level, living arrangements), ability to remember things, medical history, and any medications that you take. Your height and weight will be measured. Your ability to see and reach your feet will be

checked. You will complete 4 simple surveys about foot self-care and foot pain. You will remove your shoes and socks and the researcher will examine your feet.

You will attend 4 one-hour foot self care classes at the senior center. The classes will be once a week for four weeks. During these classes, you will learn about foot self-care and foot problems experienced by older adults. You will learn the correct way to care for your feet. You will be provided a personal foot care kit to practice foot self-care skills in class and at home.

You will fill out the same 4 surveys and have your feet examined again at 3 additional visits. You will also be asked some questions about your experiences and opinions about the classes and surveys during the second visit. Your responses will be recorded for accuracy.

HOW LONG WILL I BE IN THE STUDY?

Your participation will require a total of 4 assessment visits and 4 class sessions. Assessment Visits 2 through 4 will occur one month, four months, and eight months after the first visit. Each assessment visit will take approximately 60 to 90 minutes to complete. The class sessions will take 60 minutes each.

You can stop participating at any time without penalty.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You will receive no direct benefits from participation in this study, but you will receive education and training in foot problems and foot self-care.

WHAT ARE THE RISKS OF BEING IN THE STUDY?

There is a slight risk of minor injury or temporary discomfort from performing foot self-care: you may nick the skin, trim toenails too short, or develop an ingrown toenail.

There is a slight risk that you may experience some psychological discomfort from completing the surveys related to foot self-care.. If any of the questions make you uncomfortable, you do not have to answer the questions or participate in the discussion.

The greatest risk of this study is loss of confidentiality. The investigator will make every effort to protect the confidentiality of your personal information.

WHAT ARE THE COSTS OF BEING IN THE STUDY?

There is no cost to you to participate.

WHAT OTHER OPTIONS ARE THERE?

You have the option of not participating in this study and will not be penalized for your decision.

CONFIDENTIALITY

Information produced by this study will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the study in a form that could identify you without your written consent, except as required by law.

Intervention sessions will be audio recorded to make sure that each intervention session follows the prescribed plan and that each intervention group receives the same information and activities. The audio recordings will not be made available to anyone other than the research team and transcriptionist without your consent. In the event the audio tapes are needed by outside entities, you must give special written permission and will be given the opportunity to listen to the audiotape before giving your permission for their use if you so request.

WILL I BE COMPENSATED FOR PARTICIPATING IN THE STUDY?

You will be compensated $60 for the duration of the study: $10 for Visit 1, $20 for Visit 2, $25 for Visit 3, and $35 for Visit 4. If you attend all four visits in the study, you also will be given a bonus of $10.

WHAT IF I AM INJURED?

If you indeed experience injury from foot self-care, you will be provided a non-stick bandage and antibiotic ointment as needed. If further care is required, you will be referred to your primary care physician or local urgent care center.

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also provides, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri. In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary. You do not have to participate in this study.

You will also be informed of any new information discovered during the course of this study that might influence your health, welfare, or willingness to be in this study.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to continue participation in this study.

If you should develop any foot problems severe enough to require the attention of a physician, you will be removed from the study and referred to either your primary care physician or local urgent care.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time

WHOM DO I CONTACT IF I HAVE QUESTIONS, CONCERNS, OR COMPLAINTS?

Please contact Jennifer O'Connor MS, RN, CFCN, CNE if you have questions about the research.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Institutional Review Board (which is a group of people who review the research studies to protect participants' rights) at (573) 882-3181 or irb@missouri.edu.

You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact Jennifer O'Connor at 918-633-4520 or Deidre Wipke-Tevis at 573-884-8441.

A copy of this signed Consent form will be given to you before you participate in the research.

SIGNATURES

I have read this consent form and my questions have been answered. My signature below means that I do want to be in the study. I know that I can remove myself from the study at any time without any problems.

Subject	Date
Legal Guardian/Advocate/Witness (if required)*	Date
Additional Signature (if required) (identify relationship to subject)*	Date