

Consent to Participate in a Research Study

Daily Activity and Health in the Lives of Adult Women II

(DAHLiA Women II)

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about how women's daily activities and experiences affect their health. You are being invited to take part in this research study because you are experiencing chronic pain, between the ages of 50 and 75, and an Internet user. If you volunteer to take part in this study, you will be one of about 350 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Suzanne Segerstrom, PhD of University of Kentucky, Department of Psychology. There will be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to link daily life – especially the amount and quality of different activities – to aspects of psychological and physical health.

By doing this study, we hope to learn that some kinds of activity may help women to improve their mental and physical health. We also hope to be able to tell what kinds of activity are most helpful for different kinds of women, based on qualities such as their personality, level of fitness, and degree of pain.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

Because this study follows on DAHLiA I, people in DAHLiA II are asked to meet the same criteria to participate. You should not take part if you have any of the following:

- You are severely overweight (your BMI is greater than 40).
- You have taken or received oral, inhaled, or injected corticosteroids (e.g., prednisone) within the past 3 months.
- You have a pacemaker.
- You have a serious mental disorder such as depression.
- You have a serious medical condition such as autoimmune disease.
- You have a heart condition, such as a recent heart attack, angina, or severe arrhythmias, or severe high blood pressure (> 200/100).
- You have any condition that prevents the ability to exercise on a treadmill.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at your home, over the internet.

You will be asked to fill out daily questionnaires on the internet for 14 days. Each day's assessment may take up to 30 minutes.

The total amount of time you will be asked to volunteer for this study is 7 hours over 2 weeks.

WHAT WILL YOU BE ASKED TO DO?

You will be asked to complete an on-line diary for 14 days. The diary will ask about things like your goals for that day, your physical activity, your health symptoms, and your psychological well-being. At the beginning and end of the 2 weeks, your diary will contain some additional questions.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Because this is a long study, you may be inconvenienced related to the time involved. Answering questionnaires could cause mental stress or distress.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. All study information will be stored on a secure computer behind the University of Kentucky firewall. Any short-term storage on paper forms will be in locked cabinets in a locked room. Any portable storage devices for electronic information will be encrypted for security purposes and no information will be stored long-term on a portable device.

You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or

to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else.

Officials of the National Institutes of Health or the University of Kentucky may look at or copy pertinent portions of records that identify you.

Please be aware, while we make every effort to safeguard your Internet data once received on our servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to us.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

As thanks for your participation, you will receive \$10 for each diary completed between 8 pm and 2 am every evening.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Suzanne Segerstrom, PhD, at 859-257-4549 or segerstrom@uky.edu. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data collected from you may be shared with other investigators in the future. If that is the case the data will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with

human subjects, to make sure the study complies with these before approval of a research study is issued.

The National Institutes of Health are providing financial support and/or material for this study.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer at: (859) 323-1184.

You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

Signature of research subject or *research
subject's legal representative

Date

Printed name of research subject

Name of [authorized] person obtaining informed consent

Date

Signature of Investigator