Consent to Participate in a Research Study

Daily Activity and Health in the Lives of Adult Women

(DAHLiA Women)

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 a member of the Kentucky Women's Health Registry between the ages of 50 and 75, living near Lexington, 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 health and biological changes that may be important for 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 genes.

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

Because of the nature of the study, 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 the Center for Clinical and Translational Science (CCTS) at the University of Kentucky Medical Center and at your home.

You will need to come to the CCTS in UK Hospital ONE time during the study. That visit will take up to 4 hours.

After that visit and at every three months afterward for 2 years, you will be asked to fill out daily questionnaires on the internet and collect saliva in the morning and evening for 7 days. Each day's assessment may take up to 30 minutes. Someone from the study will bring you the materials for these visits and collect them when you are finished at your home or at UK, whichever you prefer.

The total amount of time you will be asked to volunteer for this study is 40 hours over the next 2 years.

WHAT WILL YOU BE ASKED TO DO?

You will come to UK for one visit that will last up to 4 hours. During that visit, you will be asked about your medical history and have a physical examination to make sure you are appropriate for this study. You will have your heart rhythm measured and your blood drawn.

Next we will measure your pain level from pressure. We will mark 3 spots on your left leg; 3 spots on your left arm, six spots on your neck and 7 spots on your low back. The test will be performed only at 3 spots on your arm and leg, 4 spots on your neck and back. The extra spots are to help us mark the same marks on everyone. A pressure device will be pressed against your skin and the pressure will gradually increase. You will push a button when the pressure becomes painful. The button will stop the pressure immediately. You can stop the experiment at any time if the pain is too severe. To familiarize you with these tests, 2 practice trials will be performed on your right arm. We will finish the study session with a cold water bath (4◦C) for your left foot for up to 2 minutes. We will then repeat the pressure pain test on your left arm.

You will then have a treadmill test to determine your level of physical fitness. The test will begin with you walking on the treadmill at a speed of 2.25 miles/hour and of 0% grade (incline). The treadmill speed will be increased by 0.37 miles/hour at the onset of each successive stage. The test will continue until a steady heart rate between 120 and 150 beats/min is reached. We will monitor your oxygen level, heart rate, blood pressure and a rating of perceived exertion during the final minute of each stage throughout the test. Finally, you will have a scan that determines your body composition using a DEXA machine often used to measure bone density.

After that visit and at every 3 months thereafter for 2 years, you will be asked to collect a small saliva sample every morning and evening and to complete an on-line diary for 7 days. The diary will ask about things like your goals for that day, your physical activity, your health symptoms, and your psychological well-being. A research assistant will also ask you some additional questions and give you a short cognitive test that lasts less than 5 minutes. Your research assistant will stick your finger with a lancet to collect a drop of blood on filter paper.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Blood Drawing and Fingerstick			
Soreness, bruising, pain, bleeding	Common	Not serious	Will go away on their own
Fainting or infection	Uncommon	Not serious	Fainting can require laying down for a short time; Infection may require treatment with antibiotics
Pain Testing			
Fainting	Uncommon	Not serious	Fainting can require laying down for a short time
Bruising or pain after pain sensitivity testing	Uncommon	Not serious	Will go away on its own
Exercise Testing			
Generalized muscular fatigue	Common	Not serious	Will go away on its own
Joint pain, cramps, dizziness	Uncommon	Not serious	Joint pain can be treated with over the counter pain relievers; cramps and dizziness will go away on their own
Cardiorespiratory distress, and even death	Rare	Serious	Cardiorespiratory distress can be medically treated and all participants will be carefully monitored during testing to avoid complications
EKG Patches for Heart Rate Variability and During Exercise Testing			
Redness of the skin	Redness can be common; allergic reaction is uncommon, but you should inform study personnel if you have an adhesive allergy	Not serious	Will go away on its own
Allergic reaction to adhesive	Uncommon	Not serious	Will usually go away on its own, but may require treatment

This research study involves exposure to a very small amount of radiation from the DEXA scan. The radiation dose from a typical DEXA scan produces approximately 1/300th of the natural background radiation dose we receive each year. This radiation dose would not be considered a risk of producing any harmful effects.

There is always a chance that any medical procedure can harm you, and the procedures in this study are no different. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

Because this is a long study, you may be inconvenienced related to the time involved. Answering questionnaires could cause mental stress or distress. In addition to donating blood and saliva for measurement of proteins, you will be donating DNA for genetic analysis. Breach of confidentiality associated with donation of genetic material could impact insurability, employability, reproduction plans, family relationships, immigration status, paternity suits, and stigmatization. Mental distress because of unknown results of genetic testing could occur.

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.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Elizabeth Salt, ARNP at 218-2852 immediately. For 24-hr coverage of medical issues related to the study, you should call the UK paging operator at 859-323-5321 and ask for the Rheumatology consult service. Elizabeth Salt, in consultation with Kristine Lohr, MD, will determine what type of treatment, if any, that is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research related harm will be your responsibility or may be paid by Medicare or Medicaid if you are covered by Medicare, or Medicaid (if you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.

A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be substantial.

You do not give up your legal rights by signing this form.

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

As thanks for your participation, you will receive $50 after completion of the first visit at UK and $25 for each “visit” thereafter. In addition, if you complete the diary between 8 pm and 2 am every evening, you will receive an additional $25 at each visit.

If, during your first visit at UK, we determine that you are not eligible for the study after all, you will receive $25 for your time and effort.

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. 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.

POTENTIAL FUTURE USE

Blood Specimen

Dr. Segerstrom would like to keep some of the blood collected during the main study participation but is not used for other tests for that study. No additional blood or tissue will be taken. If you agree, the blood samples may be used in future research.

Researchers may also need health information about the people who provide specimens. We are also asking for your consent to place information from your medical record and/or research record in a database to be used for research. Your name and address will not be placed in the database.

Please read each sentence below and think about your choice. After reading each sentence, mark "yes" or "no." If you have questions, please talk to the investigator or staff. Remember, no matter what you decide to do about the storage, or banking, and future use of your blood samples, you may still take part in the main study. If you answer yes to either choice below you also give your authorization for your accompanying health information to be used and disclosed along with the blood.

1. Do you give permission for your blood samples to be kept by Dr. Segerstrom in a central location/specimen bank at the University of Kentucky until they are used up but no longer than 10 years for use in future research to learn more about how to enhance, detect, or treat to improve well-being?

   ☐ Yes ☐ No _____Initials

2. Do you give permission for your blood samples to be used for future research about other health problems?

   ☐ Yes ☐ No _____Initials

The sample(s) (blood, tissue or fluids) that you are giving will no longer belong to you and might be used in studies that lead to new products for research, diagnosis or treatment. These products might have some commercial value. There are no plans to provide financial compensation to you should this occur.

Genetics research and banking:

In addition to the main study, you are being asked to volunteer in a genetic sub-study to study your genes, or DNA (deoxyribonucleic acid). Genes are made up of DNA. Your DNA is like a huge database of chemical bases that carry the "blue prints" or instructions to tell each and every cell in your body what they should do. Genes can influence the likelihood that you will get certain diseases. Your participation in

this sub-study is optional. You can still be in the main study even if you do not wish to participate in this sub-study.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Please read each sentence below and think about your choice. After reading each sentence, mark "yes" or "no." If you have questions, please talk to the investigator or staff. Remember, no matter what you decide to do about the storage, or banking, and future use of your DNA samples, you may still take part in the main study.

You give your permission for your DNA to be stored in a central location/DNA bank at the University of Kentucky for future use by the study investigators. We plan to store (or bank) the DNA samples until they are used up but they will not be kept longer than ten years. You give authorization for your accompanying health information to be used and disclosed as marked below:

1. Do you give permission for your DNA samples to be kept by Dr. Segerstrom for use in future research to learn more about how to enhance, detect, or treat to improve well-being?

   ☐ Yes ☐ No _____Initials

2. Do you give permission for your DNA samples to be used for future research about other health problems?

   ☐ Yes ☐ No _____Initials

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data/ blood collected from you may be shared with other investigators in the future. If that is the case the data/blood 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.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic information, including age. We will also collect your personal contact information so that we may contact you over the 2-years of the study.
- The results of your laboratory tests on blood and saliva; the results of your exercise testing and DEXA scan; the results of your pain testing.

Your health information will be used for:

- To determine your eligibility for the study.
- To contact you during the study period.

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- University of Kentucky representatives.
- UK Hospital.
- The National Institute of Aging at the National Institutes of Health which is the agency funding this research.
- Personnel in the UK Center for Clinical and Translational Science (CCTS).
- Your primary physician will be contacted if researcher in the course of the project learns of a medical condition that needs immediate attention.

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**
- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans**

After signing the form, you can change your mind and NOT let the researcher(s) release or use your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Dr. Suzanne Segerstrom, University of Kentucky, 012B Kastle Hall, Lexington, KY, 40506-0044 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You may not be allowed to participate in the study.

The use and sharing of your information has no time limit.

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 or *research subject's legal representative — Representative's relationship to research subject

*(*If, applicable)* Please explain Representative's relationship to subject and include a description of Representative's authority to act on behalf of subject:

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_____

Name of [authorized] person obtaining informed consent/HIPAA authorization Date

_____

Signature of Investigator