

**Consent to Participate in a Research Study**  
**THOUGHT, STRESS, AND IMMUNITY IN OLDER ADULTS**

**WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH?**

You are being invited to take part in a research study about how thought, emotion, and behavior patterns and stress could affect the health of older adults, particularly the functioning of their immune system. You are being invited to take part in this research study because you are a current participant in the Thought, Stress, and Immunity Study or, if you are a new participant, you are living near Lexington, KY; over 60 years old; and in generally good health. If you volunteer to take part in this study, you will be 1 of about 300 people to do so.

**WHO IS DOING THE STUDY?**

The person in charge of this study is Suzanne Segerstrom, Ph.D., of the Department of Psychology at the University of Kentucky. There may 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 relate differences between people in thought, behavior, and emotional styles to mental health, heart health, and certain aspects of how the immune system functions. By doing this study, we hope to understand what personal characteristics and styles make people either vulnerable or resilient in terms of their mental and physical health and ability to tolerate stress.

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

The research procedures will be conducted in your home and/or at the University of Kentucky. Every six months, you will be interviewed and take one or more short tests of thought function in your home or at the university, whichever is more convenient for you. The interviewer will also take your blood pressure and an EKG to measure your heart rhythm. Each visit will take no more than two hours.

Around the time of each interview, a phlebotomist (someone trained to draw blood) will draw your blood in your home or at the university, whichever is more convenient for you. Each of these visits will take less than 30 minutes.

The total amount of time you will be asked to volunteer for this study is approximately 5 hours every year that you participate in the study. The study is expected to last approximately 5 years, with the possibility that it might be extended.

### **WHAT WILL I BE ASKED TO DO?**

Every six months, you will be asked to complete mood and health questionnaires and take a few tests. Your waist circumference, EKG (heart rhythm), and blood pressure will be measured. These are important risk contributors to health and certain aspects of immune function. Your blood will be drawn around the time of each interview. The blood will be taken from a vein in the inside of your elbow. Each time, 40 ml of blood (around 2½ tablespoons, or 1½ ounces) will be drawn.

### **ARE THERE REASONS WHY I SHOULD NOT TAKE PART IN THE STUDY?**

You should not take part in this study if you are taking medicine which affects the nervous or immune systems, have any disease affecting or affected by the immune system, have had recent chemotherapy, radiation, or general anesthesia, smoke, or have thinking or memory problems. If you are continuing in the study, there are no reasons why you should not continue unless you decide not to.

### **WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

It is possible you could become upset during study participation, for example, while completing the questionnaires or interviews. If necessary, you may choose not to answer a particular question or questions if they make you upset.

The EKG measurement equipment may leave slight redness where it was attached to your skin, but this is temporary. There are risks associated with having blood drawn, which include soreness, bruising, pain, infection, and possible fainting or bleeding.

There is always a chance that any medical treatment can harm you, and the treatment in this study is no different. We will do everything we can to keep you from being harmed. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

### **WILL I BENEFIT FROM TAKING PART IN THIS STUDY?**

There is no guarantee that you will get any benefit from taking part in this study.

### **WHAT WILL IT COST ME TO PARTICIPATE?**

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment you receive during this study that you would normally receive. These are costs that are considered medically reasonable and necessary and would be part of the care you receive if you do not take part in this study.

The University of Kentucky is not allowed to bill your insurance company, Medicare, or Medicaid for the medical costs of the procedures done strictly for research. Therefore, the sponsor has agreed to pay all the costs of the blood tests.

## **WHO WILL SEE THE INFORMATION THAT I GIVE?**

We will keep all research records private 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 identified in these write-ups. We may publish the results of this study; however, we will keep your name and other identifying information private.

If you participated in the “DAHLiA” or “Does Aerobic Training Increase Motor Cortex Cerebral Blood Flow and Motor Performance in Healthy Older Adults?” studies, information from this study may be combined with the information you provided in those studies. Such information will include results of cognitive testing and brain scanning.

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. For example, your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key. 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 we believe you pose a danger to yourself or someone else.

Someone from the Food and Drug Administration, the University of Kentucky, and the Department of Health and Human Services, which is sponsoring this study through the National Institutes of Health, may look at or copy records that identify you.

If you have participated in the earlier study, “Stress and Immune Function in Older Adults” (2001-2006), your research records from that study will be combined with your records from this study.

In addition, your cognitive function, blood pressure, and EKG will be monitored by study personnel. You will be provided with your blood pressure reading at each visit. If we find anything of concern in your cognitive function or EKG, we will notify you so that you can follow up with your physician. If you wish the results of these tests to be released to your physician, you will sign a separate permission for us to release specific information only to that specific person.

## **CAN MY 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 this 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.

## **WHAT HAPPENS IF I GET HURT OR SICK DURING THE STUDY?**

If you are injured or get sick because of something that is done during the study, you should call Dr. Segerstrom immediately at (859) 257-4549 or (859) 257-2207. It is important for you to understand that the University of Kentucky will not 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. That cost will be your responsibility. Your health care insurer (Medicare, Medicaid, private insurer) may or may not cover these costs. Also, the University of Kentucky will not pay for any wages you may lose as a result of being harmed by this study.

Medical costs that result from such research-related harm cannot be included as regular medical costs. The University of Kentucky is not allowed to bill your insurance company, Medicare, or Medicaid for these costs without first getting permission. You should ask your insurer if you have any questions about your insurer's willingness to pay under these circumstances. Therefore, the costs related to your care and treatment because of something that is done during the study will be your responsibility.

## **WILL I RECEIVE ANY REWARDS FOR TAKING PART IN THE STUDY?**

You will receive a \$50 gift certificate following the completion of each of your biannual interviews.

## **WHAT IF I HAVE QUESTIONS?**

Before you decide whether to continue in the study, please ask any questions that might come to mind now. Later, if you have questions, you can contact the investigator, Dr. Segerstrom, at (859) 257-4549 or (859) 257-2207. 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 (866) 400-9428. You will get a copy of this consent form to take with you.

## WHAT ELSE DO I NEED TO KNOW?

The National Institutes of Health are providing financial support and/or material for this study. You will be told if any new information is learned which may affect your condition or influence your willingness to continue taking part in this study.

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Signature of person agreeing to take part in the study

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Date

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Printed name of person taking part in the study

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Signature of person providing information to subject

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Date

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Signature of Investigator