Consent to Participate in a Research Study

Self-Regulation, Stress, and Brain Health

Thought, Stress, and Immunity Study Members

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

You are being invited to take part in a research study about how patterns of thought and stress influence brain function and structure in older adults. You are being invited to take part in this research study because you are a member of the Thought, Stress, and Immunity (TSI) Study. If you volunteer to take part in this study, you will be one of about 80 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Suzanne C. Segerstrom, Ph.D, of the University of Kentucky Department of Psychology. 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 determine the influence of thought patterns and stress on brain imaging markers of brain structure and function.

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

There are no reasons why you should not take part in this study, unless you do not want to.

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

The research procedures will be conducted at the University of Kentucky's Magnetic Resonance Imaging and Spectroscopy Center (MRISC). You will need to come to MRISC, located in the basement of the Davis-Mills Building. The visit will take approximately 45 minutes for initial screening and practice, the scan will last up to 60 minutes, and post-scan computerized tasks will last approximately 30 minutes. You will be asked to repeat the scanning procedure about once every two years for 4 to 5 years, that is, two or three times including your initial scan. The total amount of time you will be asked to volunteer for this study is 7 hours over the next 5 years.

WHAT WILL YOU BE ASKED TO DO?

When you arrive for the study, and after you give consent for participation, you will be asked to fill out a few forms to screen for MRI eligibility. You will be given instructions for the computerized task that will be performed during the MRI scan and given an opportunity to practice this task on a computer in the screening room. The computerized task involves matching simple shapes and objects (such as letters and faces) to previously presented shapes and objects. After practicing the task you will be provided procedural details for the scan session (need to remain still, stay awake, etc.) and brought to the MRI

scanner by the experimenter where you will be asked to remove jewelry, hair accessories, belts, wallets, credit cards, and loose change. You can place these items into a locker for the duration of the scan. You will then be screened a final time for metal on your body with a hand-held metal detector wand and placed in the MRI scanner by the experimenter and MRI technician. You will be asked to remain awake at rest for several scan sequences and asked to perform the task that was practiced before the scan during other scan sequences. The experimenter and MRI technician will communicate with you over the intercom system throughout the scan session and alert you to which scan sequences are resting and which involve performing the task.

Following the scan session, you will be asked to complete a few computerized tasks in the practice room. These computerized tasks involve memorizing letters and solving simple math problems as well as completing visual patterns in a multiple choice format.

Some of your results from the Thought, Stress, and Immunity Study will be linked to data from this study.

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

You should not participate in this fMRI study if: (1) you have metal pins, plates, or clips in your body or have orthodontics that are not removable, (2) you have surgical implants such as pacemakers or cochlear implants, (3) you have permanent makeup or a tattoo with metallic components, (4) you are claustrophobic (afraid of small spaces), (5) you are pregnant, or suspect that you might be pregnant, (6) there is a chance that you have metal fragments in your body (from welding, bullets, BBs, or shrapnel), (7) you have ever suffered a major head injury, (8) you have ever been diagnosed with a neurological disorder (e.g. stroke, seizures), (9) you are currently on any medications that affect the central nervous system (e.g. depression, schizophrenia, panic disorder), (10) you have recently been diagnosed with a learning disability, (11) you are currently under the influence of alcohol or other recreational drugs, (12) you are currently not 18 years or older.

If you are pregnant, or suspect that you may be pregnant, you cannot participate in this study because the risk of exposing an unborn child to strong magnetic fields is not yet known.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks of participating in the MRI scan session are outlined in the table below. In addition to the risks listed below, you may experience a previously undocumented risk or side effect.

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Boredom, restlessness, dry or tired eye	It is expected to occur	Not serious	Application of eye drops before entering the MRI
Claustrophobia	It occasionally occurs	Can be treated	Yes, the volunteer will be removed from the scanner
Loud noise	It is expected to occur	Not serious	Yes, the volunteer will wear ear protection throughout the scan

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study. Your participation will help researchers better understand the relationship between patterns of thought and brain function and structure.

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 are a member of the TSI study and decide not to take part in this study, your decision will have no effect on your participation in the TSI study.

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

If you selectively do not want to be part of the MRI scan session or the computerized tasks that follow the scan you can participate in a subset of these studies (e.g. only the scan sessionor computerized tasks).

WHAT WILL IT COST YOU TO PARTICIPATE?

You may have to pay for the cost of getting to the study site. Parking will be provided for you.

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

You will receive $50 for taking part in the MRI scan session.

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 your records will be identified only by a code number.

We will keep private all research records that identify you to the extent allowed by law. However, 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. Also, we may be required to show information which identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as the University of Kentucky or the National Institute on Aging.

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.

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 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.

This research is being funded by the University of Kentucky Office for the Vice President of Research and the National Institute on Aging.

WHAT HAPPENS IF I GET HURT OR SICK DURING THE STUDY

If you believe you are hurt or if you get sick because of something that is done during the study, you should call Dr. Suzanne Segerstrom at 859-257-4549 immediately. 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 is your responsibility. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Usually, medical costs that result from 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.

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, Dr. Suzanne Segerstrom at 1-859-257-4549. 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.

_____ _____
Signature of person agreeing to take part in the study Date

_____
Printed name of person agreeing to take part in the study

_____ _____
Name of (authorized) person obtaining informed consent Date

_____
Signature of Investigator