

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Title of Project: Neural networks underlying the integration of knowledge and perception: MRI studies

Principal Investigators: Timothy Vickery, Ph.D

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you agree to participate.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn more about human perception. We are interested in how knowledge and context influences the way sensory information is processed and in turn neural functions underlying perceptual experiences of the world and the body. To examine these questions, we will examine your behavior during tasks as well as your neural activity, as measured using MRI, during tasks.

You are being asked to take part in this study because we are interested in how normal adult humans learn about the world and the body. You must be between the ages of 18 and 40, have normal or corrected to normal vision, normal hearing, are not pregnant, have no history of psychological or neurological conditions, are not currently taking psychoactive drugs, and have no non-removable metal in or on your body.

WHAT WILL YOU BE ASKED TO DO?

The experiment will take place at the Center for Biomedical and Brain Imaging. You will first be asked to complete instructions. You will be interviewed and asked to fill out forms. Before the actual experiment, you may be seated in front of a computer to complete practice. Next, we will complete a series of brain scans while you either rest or do tasks. You will be asked to perform a variety of tasks, including see visual stimuli and making simple choices using the keyboard and mouse; receiving tactile stimuli on your hand or arm and reporting if and where you felt stimuli and/or other body states. You will lie on your back inside the MRI machine while images of your brain are collected. A projector or monitor will be viewed via a mirror. You will hold one or two button boxes in order to make responses. You will also be fitted with a belt that measures respiration and a finger sleeve that measures heart rate. The experiment will take no more than 120 minutes to complete in one session, with no more than 90 minutes taking place in the MRI machine. You will be given frequent breaks (approximately every 10 minutes) to rest in between tasks.

What is involved in the study?

This study involves measuring the anatomy and activity of your brain using magnetic resonance imaging (MRI). You will be required to lie completely still on the bed that will slide into the bore of the MRI scanner. Functional MRI (fMRI) is an MRI scan of your head/brain that measures the activity of your brain while you do specific tasks. An MRI head coil will surround your head (a head coil is an apparatus that is

used to measure signals emitted from your brain). Your head will be supported with foam pads to make you more comfortable and to help you to keep your head still. Pillows and other cushions may be used (e.g., under your knees) to make you more comfortable. Several scans will be taken and you will need to remain still on the table for about 10 minutes at a time. You will be given periodic breaks, in which you will be able to relax but you will be asked to remain on the scanner bed for the duration of the session, which should last about 90 minutes.

We may monitor your eye positions using a camera mounted at the bore of the magnet. This eye recording is non-invasive and will require only short calibration and validation procedures occasionally during the experiment. These procedures involve simply moving your eyes to targets marked on the stimulus display screen.

You may additionally be asked to wear devices, such as a small clip on your finger to measure your heart rate, and/or a belt around your torso (over the clothing) to measure your breathing rate. You will be able to communicate with us via a built-in intercom. You will also be provided with an emergency bulb that you can squeeze at any time to let us know you want to come out of the MRI scanner. If at any time you feel uncomfortable or unwilling to continue, no matter what the reason, you can request to immediately stop the study, and the operator will remove you from the scanner. All scans are conducted by a certified MRI Technologist or other experienced personnel with relevant safety training.

During scans, you will need to leave your belongings in the control room. The control room is secure and accessible only to the researchers.

This is not a clinical evaluation

The images of your brain collected in this study are not intended to reveal illness, in part because this research protocol is not designed for clinical diagnosis. Your images will not be routinely examined by a clinical radiologist. The personnel at the MRI Center are not qualified to medically evaluate your images. However, if, in the course of collecting images, we have any concerns, we may show your scans to a clinical radiologist, who may suggest that you obtain further diagnostic tests. Do not rely on this research MRI to detect or screen for abnormalities.

At the investigator's discretion, you may view your images and receive digital copies of them. These images will show the inside of your body and you should be aware of the potential distress or discomfort that may occur by viewing these type of images.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

MRI is an imaging technique that uses radio waves and magnetic fields to produce images of internal structures in your body. While it is commonly used in hospitals, the MRI scanning used in this study is not part of a medical evaluation. Unlike X-rays, the MRI does not use any ionizing radiation, and it does not use radioactivity, so there is no radiation related risks from having an MRI scan done on you. Below there is a description of MRI related risks and what is being done to reduce any possible risks associated with them:

Metal: The MRI scanner produces a constant strong magnetic field, which may cause any metal implants, clips, or implanted medical devices within your body to shift position or malfunction. You will not be allowed to participate in this study if you have any implanted metal, clips or devices. You will be screened to make sure that it is safe for you to enter a strong magnetic field. Please provide us with as much information as you can, for example if you had surgery in the past, so that we may decide whether it is safe for you to be a participant. Metallic objects brought into the MRI environment can become hazardous projectiles and can also interfere with the data quality. To minimize this risk, metal earrings, other piercings, necklaces and any other metal in contact with your body must be removed prior to the study. You must also remove all items from your pockets, including coins, electronics (including cell phones and hearing aids) and wallets. You must remove belts with metal buckles, and you may be asked to change into a gown that we will provide if your clothing contains significant metal, including metal underwire bras.

Pregnancy: Exposure to MRI scanning might be harmful to an unborn child. Although there are no established guidelines at this time regarding MRI and pregnancy, you should be informed that there is a possibility of a yet undiscovered pregnancy related risk. If you know or suspect you may be pregnant or if you do not want to expose yourself to this risk, you will be excluded from participating in this study.

Inner ear damage: MRI scanning produces loud noises that can cause damage to the inner ear if appropriate hearing protection is not used. Earplugs and/or headphones will be provided to protect your ears.

Claustrophobia: When you are inside the MRI scanner, the “bore” of the scanner will surround your head and torso. We are interested in brain structure and activity, and your head will be centered inside a close-fitting scanning coil positioned in the bore of the scanner. If you feel anxious in confined, spaces you may not want to participate. If you are unsure, you can try our “mock” scanner to evaluate your comfort level with the enclosed space of the magnet bore. If you decide to participate and begin to feel claustrophobic, you will be able to tell us via the intercom or the squeeze ball and we will discontinue the study immediately.

Burns: In rare cases, contact with the MRI transmitting and receiving coil, conductive materials such as wires or other metallic objects, or skin-to-skin contact that forms conductive loops may result in excessive heating and burns during the experiment. The operators of the MRI scanner will take steps, such as using foam pads when necessary, to minimize this risk. Tattoos with metallic inks can also potentially cause burns. In addition, please let the MRI operator know immediately if you experience any heating or burning sensations during a scan. The scanning session will be stopped as soon as you tell the operator.

Nerve or muscle stimulation. While the scanner is operating, there is a small chance that the rapidly changing magnetic fields could cause a slight tingling sensation or a muscle twitch, usually felt in the upper arms or torso. While these sensations may be startling, they are not dangerous or a health risk, and they have no lasting consequences. The sensations should stop when the scan ends. Because these sensations may nevertheless be distracting or even possibly uncomfortable, please squeeze the signal bulb to alert the scanner operator if you feel tingling or muscle twitching, and we will immediately stop the scan. You will then have the opportunity to choose to withdraw from the study or to continue.

Other Risks. Besides the risks listed above, there are no other known risks from the magnetic field or radio waves at this time. Although functional MRI scanning has been used for more than 20 years, long-term effects are unknown.

WHAT ARE THE POTENTIAL BENEFITS?

You will not benefit directly from taking part in this research. However, the knowledge gained from this study may contribute to our understanding of human cognitive function.

HOW WILL CONFIDENTIALITY BE MAINTAINED? WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

All information obtained during the study will be held in strict confidence to the fullest extent possible by law. In no case will your personal information be shared with any other individuals or groups without your expressed written consent. Your images will be stored on secured computer servers and will be archived indefinitely. The experimental data acquired in this study may, in an anonymized form that cannot be connected to you, be used for teaching purposes, be presented at meetings, published, shared with other scientific researchers or used in future studies. Your name or other identifying information will not be used in any publication or teaching materials without your specific permission. Your research records may be viewed by the University of Delaware Institutional Review Board, which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. Records relating to this research will be kept for at least three years after the research study has been completed.

Your behavioral data and images will be de-identified and linked to a non-identifying alphanumeric code. The link between that code and your identity will be stored in a secure, password-protected document, along with the time and date of your participation, your name, and contact info (telephone and email). This document will only be accessible only to approved researchers on this protocol. The linking information will only be used in case of the need to contact you regarding any incidental findings on your brain images, or in the case that that your scans are used as part of a future study (with your consent). The linking information will never be shared with researchers who are not approved as part of this protocol.

WILL THERE BE ANY COSTS TO YOU FOR PARTICIPATING IN THIS RESEARCH?

There are no costs associated with participating in the study.

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATION?

You will receive a minimum of \$5 per half hour of participation on completion. The amount will be prorated according to the time spent participating if you decide to withdraw from the study for any reason. If you were required to park in a municipal lot for a fee, we will pay for your parking fee for the duration of your time participating in the study.

USE OF DATA COLLECTED FROM YOU IN FUTURE RESEARCH:

The research data we will be collecting from you during your participation in this study may be useful in other research studies in the future. Your choice about future use of your data will have no impact on your participation in this research study. Do we have your permission to use in future studies data collected from you? Please write your initials next to your preferred choice.

_____ **YES**_____ **NO****DO YOU HAVE TO TAKE PART IN THIS STUDY?**

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your decision to stop participation, or not to participate, will not influence current or future relationships with the University of Delaware.

As a student, if you decide not to take part in this research, your choice will have no effect on your academic status or your grade in the class.

If, at any time, you decide to end your participation in this research study, please inform our research team by telling the investigator(s). If you do not complete all procedures listed in this form, you will only receive compensation for the tasks you finish.

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact Principal Investigator Dr. Timothy Vickery at 302-831-1511, or e-mail him at tvickery@psych.udel.edu.

If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at hsrb-research@udel.edu or (302) 831-2137.

Your signature on this form means that: 1) you are at least 18 years old; 2) you have read and understand the information given in this form; 3) you have asked any questions you have about the research and the questions have been answered to your satisfaction; and 4) you accept the terms in the form and volunteer to participate in the study. You will be given a copy of this form to keep.

Printed Name of Participant_____
Signature of Participant_____
Date

Person Obtaining Consent

(PRINTED NAME)

Person Obtaining Consent

(SIGNATURE)

Date