HIC#: 2000033277

ADULT CONSENT FORM
YALE UNIVERSITY

TITLE OF RESEARCH: ***Sensorimotor Computations***

PRINCIPAL INVESTIGATOR: ***Samuel McDougle, PhD***

PRINCIPAL INVESTIGATOR'S DEPARTMENT: ***Psychology***
FUNDING SOURCE: ***NIH***

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to study skill learning correlates in the brain
- Study activities will include: button presses on a computer keyboard or short wrist movements while undergoing functional neuroimaging.
- Your involvement will require 120 minutes.
- There may be some risks from participating in this study, including boredom and fatigue and the risks of functional scanning (see below).
- The study may have no benefits to you. However, the study will help us increase our understanding of human neural processes.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with Yale.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Invitation to Participate and Description of Project

You are invited to participate in a research study in the Action, Computation, and Thinking Laboratory, directed by Professor Samuel McDougle, in the Department of Psychology at Yale University. This study uses functional magnetic resonance imaging (fMRI) to investigate how your brain perceives the world and acts on it. The research deals with how people acquire and produce certain skills and how visual and auditory information are used to guide actions. We plan to have around 40 total participants in this specific experiment.

Before deciding whether to participate, it is important for you to be informed about the risks and benefits of participating. The remainder of this document provides these and other details of the study — its purpose, the procedures that would be performed, any risks of the procedures and how they would be mitigated, and possible

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benefits of participating. Once you have a clear understanding of the study, you will be asked whether you wish to participate. If so, you will be asked to sign this form.

Description of Procedures

This study examines how the brain supports different aspects of cognition, including perception and action. To observe the brain in action, we employ fMRI. You may be familiar with standard MRI, which is widely used to collect anatomical images, including of the brain. fMRI is a newer variant that uses the same apparatus to investigate brain *function* —that is, what parts of the brain are active over time. This is a dramatic advance over previous methods for measuring brain function in humans, which involved intravenous injection or inhalation of foreign substances and exposure to ionizing radiation. In contrast, fMRI does not require any invasive procedures and is a safe technology for infants, children, and adults that has been used for more than 25 years.

If you consent to participate in this study, you will begin with a short screening procedure. The instructions for the cognitive task will be explained to you in detail by a researcher before you get into the scanner. You will have the chance to ask questions.

In some cases, your participation may include 1-2 behavioral sessions outside of the scanner, lasting up to 1 hour each. These sessions may occur either at the same location as the scanner in the Brain Imagine Center at Dunham Hall, the Yale BrainWorks at 100 College Street, or the behavior lab at the 12th floor in 100 College Street. They will be used to pilot experimental designs, to train you on the cognitive tasks, or to measure behavioral performance before the scan.

During the scanning session, you will be provided with hearing protection, and will lie on the scanner bed, which will then be slowly moved into the bore of the MRI machine. We will then collect several images of your brain while you perform one or more tasks (e.g., viewing/hearing/feeling stimuli, shapes, tones, touches to your fingers). These will be used to identify the location and time course of brain activity. You may be asked to provide some response to the things that you see, including button presses or moving a small joystick. Scanning sessions will last up to 2 hours, including preparation time. You will be given the opportunity to take breaks between blocks to minimize fatigue.

Risks and Inconveniences

Magnetic resonance imaging (MRI) uses magnetic fields and radio waves to take pictures of the body. MRI is very safe, with no known long-term ill-effects. Hundreds of millions of people have safely had MRI scans. MRI uses a strong magnet, which can pull strongly on some metals. These metals must not be brought into the scan room. They could be pulled towards the magnet and cause serious injuries if they hit you. People entering the scan room must remove all metal from their body, clothing and pockets. This includes jewelry, hearing aids, watches, cell phones, keys, coins, and wallets.

We will ask you to fill out an MRI safety form to check if you have anything in your body which might be dangerous in the MRI. **It is very important that you fill out this form accurately and ask if you are unsure about anything**. Some metal objects could also heat up during the MRI, burning you. Electrical devices such as pacemakers could go wrong or stop working.

You must also tell us if you are wearing anything that could contain metal. For example, some medication patches have a metal backing. Some clothing can contain metal fibers that could also heat up during the MRI. We will provide you clothes to change into if needed.

During the MRI scan, you may feel uncomfortable or worried. When the MRI scanner is making pictures, it makes loud tapping, buzzing, and beeping noises. Without protection, this could damage your hearing. We will give you with earplugs and/or headphones to reduce the sound to a safe level. While the scanner is making noises, we will not be able to hear you. We will give you a squeeze bulb for you to contact us.

The MRI scan is intended for research and not to find disease. The researchers are not qualified to medically interpret your scan. If we do see something that may be a concern, we will let you know. You can then decide if you want to discuss this with your doctor. The investigators and Yale University are not responsible for any treatment that you receive based on these findings. The pictures collected in this study are not a healthcare MRI exam and will not be made available for healthcare purposes.

Loss of confidentiality is a risk in any research study. To keep your personal information secure, all data will be collected using an ID number only so there will be no identifying information stored with the data.

Benefits

There are no direct benefits to you for participating in this study. You may, however, benefit from the knowledge that you are contributing to important research and may learn something about the brain and how brain research is conducted. More specifically, the results from this research will inform the scientific community and society at large about the brain mechanisms underlying perception and action. This could help design interventions to improve human sensorimotor behavior, such as during rehabilitation, which could advance potential treatments for neurological disorders.

Economic Considerations

You will be paid $30/hour (in *cash*) for participation in scanning sessions. A “session” includes all preparation time in addition to actual scan time. If a session is terminated early due to participant discomfort, scanner malfunction, or other unforeseeable event, you will nonetheless be paid for the session. You will additionally be paid $20/hour for the time spent participating in the study outside of the scanning sessions, including any cognitive tasks you complete before or after the day of the scanning session. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

Confidentiality

We understand that information about you in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to participate in this study, the researchers will obtain information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address, as well as images of your brain. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will retain the ability to

link you to your coded information, but this link will be kept secure and available only to select members of the research team.

We will not share any of your information with other researchers for future research studies, even if we remove all identifiers such as your name. This research is covered by a **Certificate of Confidentiality** from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

fMRI data will be stored on a secured Yale computer cluster that is managed by the Yale Center for Research Computing. Electronic consent forms and demographic information will be stored on the HIPAA-aligned Yale Qualtrics server. Other digital data from this study will be stored on password-protected computers with full-disk encryption and/or on a secured server. Paper records and other media will be stored in a locked cabinet in our lab space. Any identifiable information that is obtained in connection with this study will remain strictly confidential and only disclosed with your advance permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. De-identified data may be presented at research meetings, published in scientific journals, shared with research collaborators, and/or posted anonymously in data repositories as required by funding agencies and/or scientific journals.

In Case of Injury

If you are injured because of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. If you are injured before the study or during sessions outside of the scanner, seek treatment and contact the principal investigator as soon as you are able. If a medical emergency occurs during a scanning session, the researchers will follow established protocols. You do not give up any of your legal rights by signing this form.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not

be able to enroll in this research study and will not receive study procedures as a study participant if you do not provide consent.

If you do become a participant, you are free to stop and withdraw from this study at any time. To withdraw from the study, you can talk to a member of the research team at any time and tell them that you no longer wish to take part. The researchers may also withdraw you from participating in the research if necessary (e.g., you do not show up for your visit). Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. Lastly, any significant new findings developed during the course of the research will be provided to you freely. Please let us know if you would like such updates.

Questions

We have used some technical terms in this form. Please ask about anything you don't understand and take as long as you need to consider this research carefully before deciding whether to participate.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject: _____

Signature: _____

Date: _____

_____ _____

Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Professor Sam McDougle at samuel.mcdougle@yale.edu or (646) 369-0651. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688.