Neural Basis of Sensory and Motor Learning: Functional Connections

NCT05124301

Informed Consent Form

June 18, 2024

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Neural basis of sensory and motor learning: Functional connections

IRB Protocol 13138

National Institutes of Health

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to understand how the areas of the brain work together to update your senses. We hope this information may be useful one day to improve rehabilitation techniques in patients with brain lesions.

You were selected as a possible participant because you contacted the investigator in response to an advertisement.

The study is being conducted by Dr. Hannah Block, Department of Kinesiology, Indiana University Bloomington. It is funded by the National Institutes of Health.

WHAT WILL HAPPEN DURING THE STUDY?

The study involves two visits to the Indiana University Imaging Research Facility (IRF) at 1101 E 10th St Bloomington, IN, 47405. The first visit is a familiarization session that takes 40-60 minutes. The second is the main session and takes up to 2.5 hours.

Familiarization session. You will be asked to fill out a screening form. You will be introduced to the reaching task, which involves sitting in front of a touchscreen and pointing at targets you see in a mirror. You will also lie in the mock MRI scanner so you can see what it is like. In the mock scanner you will learn to press buttons in response to movements of your index finger, which will be taped to a wooden stick. If you are comfortable performing these procedures, we will schedule the main session.

Main session. You will be asked to fill out a more detailed screening form to make sure you are eligible for MRI. If you pass the screening criteria, you will perform the reaching task several times outside the scanner, with MRI scans in between. We will escort you back and forth between the reaching task table and the MRI scanner several times. These are in adjoining rooms. For the MRI scans, you will be placed in the MRI machine and made comfortable. We will tell you each time what you need to do or not do during the scan. Sometimes you will be asked to lay quietly for up to 12 minutes. Other times you will do the button-pressing task from the familiarization session, with your index finger taped to a wooden stick, for up to 6 minutes.

It is very important to remain still during the MRI scans, especially your head. If at any time you feel uncomfortable, you can squeeze a red ball and the MRI technician will stop the scan immediately and remove you from the MRI machine. If you require the use of eyeglasses, we will provide a magnet compatible pair.

More about MRI: MRI uses a strong magnetic field and radio waves to obtain images of body organs and tissues. There is no radiation exposure involved. The MRI scanner is a cylinder surrounded by a strong magnetic field. During the scan you will be required to lay still on a bed that slides in and out of the cylinder. When the scanner takes pictures, you will hear loud knocking and clicking noises. You will wear ear protection to decrease the noise. You will be able to communicate with the experimenter throughout the entire experiment by talking in a normal voice. In addition, you will hold a red ball in your hand and you can squeeze it at any time to be removed from the scanner. Also, at any sign of discomfort we will end the session.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

There are no known significant risks associated with these procedures at this time. The only potential risk connected to the reaching task is fatigue or boredom. You may be uncomfortable completing the MRI screening checklist. For instance, there are questions about methods of birth control and the existence of tattoos and piercings.

The magnetic field and radio waves of MRI are considered too weak to do any biological damage. There are no long-term risks or consequences of MRI scans. In extremely rare cases (about one in a million), the radiofrequency energy used in MRI has produced burns (most of them minor). If you feel any heat or burning sensation you should notify the staff immediately and we will safely terminate the procedure. The Food and Drug Administration has recently made recommendations for exposure to MRI during studies. The MRI machine that will be used in this study satisfies these safety guidelines. If you wish to retain a copy of these guidelines, please ask the experimenter.

This MRI scan is not a medical test. It is designed to address research questions and it is not a complete scan for any clinical purpose. If there is an abnormality, the scan, the MRI technician, or the researcher may not detect it. If the technician or researcher suspects a possible abnormality, the scan will be sent without any participant identifiers to a neuroradiologist for further review. If the neuroradiologist recommends further action, you will be notified.

The procedures themselves are painless and not uncomfortable, except that you must lie still. The MRI machine is confining, and some people may feel claustrophobic when lying in the machine. Such individuals would be removed immediately.

fMRI may be harmful to an unborn child. If you are of childbearing potential (that is, if you are a woman with sexual partner(s) and do not use an adequate birth control method), you must be excluded. Adequate birth control methods (e.g., oral, implanted, or barrier methods) should be used by all participants and/or their sexual partner to prevent pregnancy while participating in this study. If you become pregnant while participating in this study, you should notify your physician. If you use an IUD for birth control you must be excluded.

While there is no evidence of increased risk with multiple scans, the risks associated with multiple scans are not known. The IUB imaging center is adopting an arbitrary maximum of 40 hours of scanning time per individual per year and the time involved in the present study is well below that limit.

There is also a risk of loss of confidentiality.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

If you are injured as a result of participating in this study, you will be responsible for seeking medical care and for the expenses associated with any care received. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health

care coverage. No money or funds are set aside to pay for these types of injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled by signing this Informed Consent form.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?
We don't expect you to receive any benefit from taking part in this study, but we hope to learn things which will help scientists in the future.

WILL I BE PAID FOR PARTICIPATION?
You will receive payment for taking part in this study. After completing the final session, you will receive gift cards worth $10/hour for the familiarization session and $25/hour for the main session. This will usually total around $75. If you withdraw before completing your sessions, you will not receive partial payment. However, if we exclude you from further participation after the familiarization session (this could happen, for example, if you are unable to do the tasks), you will be paid for that session at a rate of $10/hour.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?
The following individuals and organizations may receive or use your identifiable information:

1. The researchers and research staff conducting the study
2. The Institutional Review Boards (IRB) or its designees that review this study
3. Indiana University
4. Data safety monitoring boards and others authorized to monitor the conduct of the study
5. State or Federal agencies with research oversight responsibilities, including but not limited to:
    - Office for Human Research Protections (OHRP)
    - National Institutes of Health (NIH)

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HOW WILL MY INFORMATION BE PROTECTED?
Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies.
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information, documents, or specimens that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not

stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research when allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions or problems related to the study, please contact the researcher, Dr. Hannah Block, at 812-855-5390.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?
After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Indiana University.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw during an experimental session, simply tell the researcher. If you decide to withdraw in between sessions, you may notify whichever researcher you have been in contact with by phone or e-mail.

Your participation may be terminated by the investigator without regard to your consent if you are unable to perform the tasks.

PARTICIPANT'S CONSENT
In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

_____ **Participant's Printed Name** **Date**	_____ **Printed Name of Person Obtaining Consent** **Date**
_____ **Participant's Signature**	_____ **Signature of Person Obtaining Consent**