Consent form for IRB-FY2016-363

MRI CONSENT FORM (non-paid subjects)

Introduction

You have been invited to take part in a research study to learn more about how people see and feel by measuring responses to visual and tactile stimuli using functional magnetic resonance imaging.

This study will be conducted by Jonathan Winawer of the Department of Psychology in the Faculty of Arts and Sciences at New York University, or by a designated member of his research staff working under the supervision of Professor Winawer.

You must be 18 years or older to participate in this study. If you are under the care of an epileptologist, you must have doctors’ consent in writing in order to participate.

Procedure

If you agree to be in this study, images of your brain, called scans, will be taken using a Magnetic Resonance Imaging (MRI) scanner. The MRI scanner is a machine that enables us to acquire images of the brain using the changing magnetic fields inside your body.

If you agree to take part in the study, you will be asked to do the following:

- Lie on a table that will be slid into the MRI scanner (so that your head and upper body are inside the magnet tube);
- Wear earplugs to reduce the noise made by the MRI scanner (the magnets can make very loud noises), or wear headphones to limit the noise from the MRI and allow you to hear audio and instructions for the tasks you are being asked to do or questions from the investigator or the MRI operator.
- Have foam pads placed around your head to help you hold your head still during the MRI scan, so that the scans will be clear;
- Lie still throughout your time in the MRI scanner;
- Allow three small electrodes to be placed on your body to record muscle movements. An electrode is a small sensor placed on the body that is connected by a wire to a monitor. It is used to detect muscle movements.
• Allow a special video camera to record your eye movements and blinking during the scan.
• Allow an electrode clip to be attached to one of your fingers on your non-dominant hand so that we may record your blood oxygen levels and heart rate responses during the scan.
• Allow an elastic belt to be placed around your abdomen to measure the depth of your breathing during the scan.
• Allow your physiological responses to be monitored – specifically so we may assess your skin conductance response, which is an indication of mild sweating that occurs as part of the body’s response to emotional events.
• Make responses with a button box to indicate judgments about visual, tactile, or auditory stimuli

Anatomical images (images that show us the structures in your brain) will be obtained during the first 15 minutes of the scan. After the anatomical images, functional images will be obtained for about an hour. Functional images are scans that show us how the brain works by illustrating what the brain is actively doing at a particular time. During this time, you will be asked to view various types of stimuli presented via a computer or feel stimuli presented by a vibrotactile stimulator. These stimuli will consist of words, photographs/drawings of common objects, scenes, people, geometric shapes, or textures. Some tasks may also include auditory stimuli (simple tones played a comfortable volume) or tactile stimuli (simple vibrations of the finger tips or arms). While viewing visual stimuli, you may also be presented with a small fixation marker (a dot or cross in the center of the display). While viewing these stimuli, you may be asked to potentially make simple decisions about these stimuli (e.g. “male or female face, or “animate or inanimate object?”). You may also be asked to make judgments about the fixation stimulus (e.g., press a button when the dot changes from red to green). In some conditions, you may be asked to make judgments about auditory stimuli (did the tone rise in pitch or fall in pitch) or tactile stimuli (which finger was vibrated).

Participation in this study may involve several practice sessions and MRI scanning sessions on different days, with at least 1 day between sessions. The entire study will consist of no more than 3 MRI scanning sessions, each lasting 1.5 hours. In addition there may be 1 practice session, where you will practice performing the same cognitive tasks with the same visual, auditory, and tactile stimuli that will be performed in the MRI scanning sessions, lasting 1 hour. The entire study should consist of a total of no more than 5.5 hours of your time, over a total period of up to 2 months.

During your MRI scanning session, occasional breaks of a few minutes will be provided. You will remain in the MRI scanner during breaks, but you may close your eyes and rest. You may rest for as long as you need to be ready to continue the session.

Risks

There are no known significant risks or side effects associated with MRI scans. The magnetic fields, at the strengths used, are felt to be without harm and our MRI scanning procedures fall within the Food and Drug Administration [FDA] guidelines for radiofrequency electromagnetic field exposure created by the MRI. It is thought that these are safe levels and less hazardous than a comparable x-ray computed tomography (CT) examination.
There is a risk if metal objects are near the MRI because they can be drawn into the MRI scanner and that could hurt someone in or near the machine. Metal objects might be in a body if a person has electrically, magnetically or mechanically activated implants (such as cardiac pacemakers), or clips on blood vessels in their brain, or other metallic objects in their body such as shrapnel, bullets, buckshot, or metal fragments. To protect against this risk, you will be carefully screened for previous exposure to metallic fragments or to implanted devices. You will also be asked to place all metallic and magnetic objects in your possession (e.g. keys, jewelry, credit cards) in a locker outside the MRI room.

The Center for Brain Imaging uses software that is not regulated by the FDA because it is intended for research purposes and not for diagnostic purposes.

Although there are no known risks of an MRI scan to the unborn fetus, we will not let you take part in the study if you are or might be pregnant. We will have you take a urine pregnancy test right before the scan to find out if you are pregnant. If the test shows that you are pregnant, we will cancel the scan. Results will only be reported to you as this is considered private health information.

If you would like to decline this pregnancy test, please initial here:

My initials indicate that I choose not to take a urine pregnancy test and will still be scanned.

Some people have reported mild discomfort during MRI scans, such as:

- Claustrophobia (fear of enclosed spaces). You will be asked to lie on a table that slides into a horizontal cylinder only slightly wider than your body in all directions and your head will be secured to help you stay still. If you are likely to be uncomfortable or afraid in enclosed spaces, you should let the researcher in charge of the scan know.

- Mild back discomfort. If you have ever had back surgery or have a history of chronic backache, please notify the researcher in charge of the scan so that the padding on the MRI table can be enhanced.

- Reaction to noise levels. The MRI scanner makes loud knocking or beeping sounds during scans; earplugs and/or headphones will be provided to help reduce this noise.

- Peripheral nerve stimulation. Because the magnet turns on and off during the scan, the possibility exists for peripheral nerve stimulation. If this happens, you may feel creeping or tingling sensations, typically along your arms or lower back.

- Dizziness and nausea that may occur while you are in the MRI.

- Drying of eye contact lenses. This rarely occurs, but you should notify the investigator that you have contact lenses in your eyes, and you should either moisten your eyes before entering the scanner or remove your contacts. MRI safe glasses are available for use if needed, with lenses that accommodate the most common prescriptions.

- Feeling some warmth from the radio frequency coils can occur. The MRI scanner is set so that this warmth will be not heat the body to more than one degree of normal body temperature.

You may notify the research staff at any time if you feel uncomfortable, no matter what the reason. Between each scan, you will be in contact with the research staff through a microphone mounted in the...
MRI scanner. However, while the scanner is on, the speaker will be turned off and the research staff will not be able to hear you. Nonetheless, in the case of an emergency, you will have a handheld squeeze ball device to let the operator know if you wish to immediately stop scanning and be removed from the magnet. The MRI scan can be stopped at any time at your request; when you squeeze the squeeze ball, the research staff will be notified and stop the scan. If you think that you have experienced a research-related injury call Assistant Professor Jonathan Winawer (212 998 7922, jonathan.winawer@nyu.edu). Please be aware that emergency medical services are not available onsite.

Federal regulations require that all subjects be informed of the availability of medical treatment or financial compensation in the event of physical injury resulting from participation in the research. New York University cannot provide either medical treatment or financial compensation for any physical injury resulting from your participation in this project. You do not give up any legal rights to seek payment for personal injury by consenting to this research. Inquiries regarding this policy may be made to the Principal Investigator Jonathan Winawer (212 998 7922, jonathan.winawer@nyu.edu) or, alternatively, the NYU IRB at (212) 998-4808.

Benefits

Although you will receive no direct benefits, this research may help the investigator understand how visual and tactile stimuli are encoded in the human brain, and how this encoding supports perception.

Incidental Findings

The investigators for this project are not trained to perform radiological diagnosis, and the MRI scans performed in this study are not designed to find abnormalities. The investigators and NYU are not responsible for failure to find existing abnormalities in your MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. Should this occur within twelve months of the scan a neuroradiologist would be consulted and the MRI scan will be sent to the NYU Medical Center. This MRI scan along with the consulting neuroradiologist's report will be part of your permanent medical record. If the neuroradiologist thinks that further investigation of the finding is called for, the investigator will contact you and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting neuroradiologist, and NYU are not responsible for any examination or treatment that you undertake based upon these findings. Because the images collected in this study do not comprise a proper clinical MRI study these images will not be made available for diagnostic purposes.

Cost and Compensation

You will not be paid for participation in this study. You are not required to participate in this study and your participation is entirely voluntary. There will be no cost to you associated with participation in this study.

If you earn (or if you are compensated) in excess of $600 from New York University, within any calendar year, for participation as a research subject, you will need to report the earnings/payments as income on your taxes, as NYU will be required to report the payments to the IRS as other income and will issue you a 1099 form.
Rights

Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. Nonparticipation or withdrawal will not affect your grades or academic standing.

Many forms of research involve some risk of injury. In addition, there may be risks associated with this study that we do not know about. In spite of all the care and precautions taken by the investigators, you might develop medical complications from participating in this study. If you should sustain any injury during the course of the research or experience any side effect from a study procedure, please contact the Principal Investigator Jonathan Winawer at the following telephone number 212-998-7922. If such complications arise, the researchers will assist you by referring you to appropriate medical practitioners, but this study does not provide financial assistance for additional medical or other costs. Also, NYU is not responsible for research and medical care either by NYU practitioners or those at other institutions. You do not give up any rights to seek payment for personal injury by signing this form.

If there is anything about the study or your participation that is unclear or that you do not understand, or if you have questions or wish to report a research-related problem, you may contact Jonathan Winawer at

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6 Washington Place, 9th floor
New York, NY 10003-6634
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For questions about your rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects (UCAIHS), 665 Broadway, Suite 804, New York University, (212) 998-4808 or ask.humansubjects@nyu.edu. Please reference the study number IRB-FY2016-363.

Confidentiality

Confidentiality of your research records will be strictly maintained. Information will be stored in the investigator’s file and will be identified by a code number. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information not containing identifiers may be used in future research or shared with other researchers without your additional consent.

The results of this study may be published in a book or journal or used for teaching purposes. However, your name or other identifiers which could identify you will not be used in any publication or teaching materials without your specific permission, which will be requested in writing. However, the MRI images of your brain may be shared anonymously (that is, without any way of identifying who the scan is of) for research or teaching purposes, or displayed at scientific conferences or in publications.
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena.

Exceptions include:

- A federal, state, or local law requires disclosure.
- Your explicit approval for the researchers to release your name and/or personally identifiable information.

Future Research

I authorize the principal investigator, Jonathan Winawer, and his co-investigators to contact me about future research on brain function within the NYU Center for Brain Imaging. If I agree, then a researcher affiliated with the NYU Center for Brain Imaging might contact me in the future and he or she will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

☐ I agree to be contacted by a researcher affiliated with the NYU Center for Brain Imaging about research studies conducted at the NYU Center for Brain Imaging.

OR

☐ I do not want to be contacted by a researcher affiliated with the NYU Center for Brain Imaging.

Signature of participant or legal representative  Date

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your participation in this study. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for another CBI research study. It does not mean that you must join in any additional study.

Agreement to Participate
YOUR SIGNATURE INDICATES THAT YOU HAVE READ THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, THAT YOU ARE 18 YEARS OF AGE OR OLDER, AND THAT A COPY OF THIS CONSENT DOCUMENT HAS BEEN GIVEN TO YOU TO KEEP.

Participant’s Signature ___________________________ Date ________________

Participant’s Printed Name ___________________________

I certify that I have presented the above information to the subject and secured his or her consent.

Experimenter’s Signature ___________________________ Date ________________