Emory University
Consent to be a Research Subject

Title:

Principal Investigator:

Funding Source:

If you are the legal guardian of a child who is being asked to participate, the term “you” used in this consent refers to your child.

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.

Before making your decision:
- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview
The purpose of this study is to...

Procedures
Head Scanning: To be scanned, you will be asked to remove all jewelry and other metal-containing objects (including credit cards). You will enter a large room where a powerful magnet is located. You will be asked to lie down on a narrow table and then you will be put into a small tunnel approximately 6 feet long and 2 feet in diameter. You will then be asked to lie as still as possible during the scan for approximately XX minutes. You will have headphones and a microphone through which you will be able to communicate with the members of our team running the experiment. A small mirror will be positioned above your head so you will be able to see out of the end of the scanner. During scanning, you will hear a loud banging noise while the MRI machine takes pictures of your brain. This is normal. You will be given earplugs to make you more comfortable.

Computer Task: While you lie in the scanner, a computer display will be placed at one end of the tunnel. You will be able to see this through the mirror in front of your face. In some cases, we will need you to respond to things you see on the screen, and for this you will be given a small box with buttons that will be put under your hand when you are placed into the scanner. [Study specific details here]

Psychophysiological Assessment (optional): Some of your body’s responses may be measured while you perform the computer task, including heart rate, temperature, breathing, and changes in sweating. This requires wires or belts to be...
attached with stickers or Velcro to your fingers, hand, arm, chest, or leg. The wires and belts are not harmful and should give you a minimum of discomfort.

**Self-Report Questionnaire (optional):** You may be asked to answer some questions about how you felt while doing the computer task inside the scanner. You may also be asked to fill out personality questionnaires and surveys about activities you engage in.

**Risks and Discomforts**

There are minimal risks involved with this procedure, although it may at times be unpleasant.

The MRI machine is as loud as riding in a loud train—you will be given earplugs and headphones to lessen the noise.

You may experience some muscle discomfort while lying in the scanner. You may also become too hot or too cold, in which case you may ask for an adjustment of room temperature or a blanket. Some people become nervous or claustrophobic (anxious or afraid of closed spaces) in the scanner. If this happens to you, you may ask to be withdrawn immediately. You may also experience a sense of dizziness in the magnet. This is due to the strong magnetic field, and if it disturbs you, you may ask to be withdrawn.

Because the magnetic field will affect any metallic object, you should not participate if you have any type of metallic implant in your body, including pacemakers, aneurysm clips, shrapnel, metal fragments, orthopedic pins, screws, or plates, metallic IUD’s, or piercings that you cannot remove. If you have any of these, there is a risk that the magnetic field could cause them to move or heat up. It is important that you inform the study personnel if you have any implants.

Because FERN is not a hospital facility, there is no physician or emergency personnel on site.

This type of brain scan is not designed to detect problems of the brain. A radiologist will not be reading the scan. The study team will review the scan. If we determine that data from the scan suggest something that may be important clinically, we will share them with you so that you can discuss them with your own doctor.

[Because of the investigative nature of this study and the unknown effects of the magnetic field on the fetus, you should not participate if there is the possibility that you are pregnant.]

[Measuring your heart rate, temperature, respiration, and changes in sweating should not have any risks. Sometimes there is some discomfort when we remove the stickers holding the recording wires in place, but this is small. The wires are grounded and are only measuring your body’s responses, so there is no danger of electric shock.]

Due to the investigative nature of this study there may be other risks that are currently unknown.

**New Information**

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

**Benefits**

This study is not designed to benefit you directly. **This study is designed to learn more about...** The study results may be used to help others in the future.

**Compensation**

You will get $____ for each completed study visit. If you do not finish the study, you will be paid for the visits you have completed. You will receive $____ total, if you complete all study visits.
Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, and the Emory Office of Research Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

We will do everything we can to keep others from learning about your participation in the research. To further help protect your privacy, the investigators have obtained a Confidentiality Certificate.

What the Certificate of Confidentiality protects:
The National Institutes of Health has given this study a Certificate of Confidentiality. Emory would rely on it to not give out study information that identifies you. For example, if Emory received a subpoena for study records that identify you, we would say no. The Certificate gives Emory legal backup to say no. It covers information about you that could harm your image or finances. It also covers information about you that could harm your chances at a job or getting insurance.

What the Certificate of Confidentiality does not protect:
The Certificate does not prevent you or someone other than you from making disclosing your information. The Certificate also does not prevent Emory from releasing information about you:

- Information to state public health offices about certain infectious diseases
- Information to law officials if child abuse has taken place
- Information Emory gives to prevent immediate harm to you or others
- Information Emory gives to the study sponsor as part of the research

Voluntary Participation and Withdrawal from the Study

You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer.

The researchers and funder also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were objected to any future changes that may be made in the study plan;
- [reasons specific to this study – delete if none]
- or for any other reason.

Contact Information

Contact [researcher contact person] at [tel numbers]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
• if you have questions, concerns or complaints about the research.
• You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.
**Consent**

Please, print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

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<tr>
<th>Name of Subject</th>
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<tbody>
<tr>
<td>Signature of Subject</td>
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<tr>
<td>Signature of Person Conducting Informed Consent Discussion</td>
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<tr>
<td>Signature of Legally Authorized Representative</td>
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<tr>
<td>Authority of Legally Authorized Representative or Relationship to Subject</td>
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<tr>
<td>Signature of Assent for 17 year old Subject</td>
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