UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Routine Functional Magnetic Resonance Imaging of the Brain

1.2 Company or agency sponsoring the study: University of Michigan

1.3 Names, degrees, and affiliations of the researchers conducting the study:
Hernandez-Garcia, Luis, Ph.D., Department of Biomedical Engineering, University of Michigan
Noll, Douglas, Ph.D., Department of Biomedical Engineering, University of Michigan
Peltier, Scott, Ph.D., Department of Biomedical Engineering, University of Michigan
Jonides, John, Ph.D., Department of Psychology, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
Functional MRI allows investigators to study how the brain works by detecting brain activity associated with a task. The goals of this protocol are (1) to collect images of the brain during performance of a mental task in order to identify what brain regions are involved and (2) to measure the physical features of the brain.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?
Adults between the ages of 18 and 85 may participate in this study. Subjects must also be able to tolerate small, enclosed spaces without anxiety and should not have any metals or implanted devices within your body, e. g. aneurysm clips, pacemakers, artificial limbs.

In addition, according to magnetic resonance imaging (MRI) safety protocols, subjects will be excluded from any studies if they have any history of an implant of pacemakers or pacemaker wires, open heart surgery, artificial heart valve, brain aneurysm surgery, middle ear implant, hearing aid, braces or extensive dental work, cataract surgery or lens implant, implanted mechanical or electrical device, or artificial limb or joint. Subjects will also be excluded if have any history of foreign metallic object in the body such as bullets, BB's, pellets, shrapnel, or metalwork fragments. Subjects will be excluded if they are pregnant, claustrophobic, have uncontrollable shaking, or cannot lie still for one hour.

It is extremely important that you tell us about any and all surgeries you have had so that we might know if there is a chance that any metal would be inside you. Also, if your job (e. g. as a metal worker) or any other experience

might have left metal fragments in your body, please inform us. The strong magnetic field could disturb a metal fragment in your body or interfere with an implanted device, such as a pacemaker, causing you harm.

For women of child-bearing ages: You should not take part in this study if you are pregnant, are attempting to become pregnant, or suspect you might be pregnant. Although there are no known risks to a developing baby posed by MRI, we will provide a urine pregnancy test for you, at no cost to you, if you are uncertain about the possibility of your being pregnant.

3.2 How many people (subjects) are expected to take part in this study?
It is anticipated that at least 10,000 subjects will participate; however, it is unknown how many subjects will participate in research studies that involve fMRI.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
You have agreed to participate in a companion study that is utilizing the functional magnetic resonance imaging (fMRI) laboratory. While at the fMRI lab, you will be screened for MRI precautions and have a sequence of MRI scans performed.

Functional MRI involves lying on a table which then moves into a hollow machine (the magnet). The actual MRI examination of your body will take from 1 to 3 hours, and you will be asked to remain as still as possible during the entire period. Small hand and foot movements are allowed in between scans (you will know you are being scanned because you will hear loud knocking noises), but it is essential that your head remains in the same position during the entire time you are in the scanner. You will hear knocking noises and will be able to talk with the operator or researcher through an intercom at various points during the scanning session. You will also be able to trigger an audible alarm at any time. While you are lying in the scanner, you will be asked to perform a task during which the scanner will be operated and images will be acquired. The task may be presented to you visually on a screen in the scanner (checker boards, numbers, letters, objects, or words) or through headphones (tones or spoken words). The task might also involve sensory stimulation (puffs of air or brushing finger tips). You may be asked to response to stimuli with button presses that are recorded by computer. You will be given instructions prior to entering the scanner and will be informed when the task is about to begin.

We are also asking permission to store your fMRI image data obtained during the scanning session in a database for future research studies related to brain structure and function.

4.2 How much of my time will be needed to take part in this study?
The scanning session will take up to 4 hours, depending on the companion study requirements

4.3 When will my participation in the study be over?
Your participation at the fMRI lab will be complete after the MRI scanning session.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are:
There is a risk that personnel not involved with the fMRI lab access your fMRI research record. Only those directly involved in this study will have access to the research records. All records will be maintained in a locked cabinet in a room with limited access and/or in an electronic password protected file.

fMRI scanning:

[1] There is a minor risk of discomfort or anxiety from being in the confined space of the MRI scanner. We will provide pads and blankets to make you as comfortable as possible. You will be able to talk to us throughout the study, and you will be able let us know right away if you want to stop the study and get out of the scanner.
[2] The MRI scanner makes loud, vibrating noises. You will wear foam earplugs to reduce the loud noises made by the scanner and prevent any hearing damage.

[3] Some studies, like this one, have the potential to cause "peripheral nerve stimulation" (PNS). PNS is a light touching sensation on the skin surface, lasting only for a few seconds. It may cause mild discomfort, but is not harmful to you. The MRI machine is operated within FDA guidelines so the potential for inducing PNS is low.

[4] Sometimes, subjects report a temporary, slight dizziness, light-headedness or nausea during or immediately after the scanning session. If you feel dizzy or light-headed, we will have you get up slowly from the scanner.

[5] Because the strong electromagnetic fields can move metal objects and cause heating, there is a risk that loose objects (jewelry, keys) outside your body could be accelerated by the magnetic field and strike you, causing you injury. There is also a risk that the magnetic fields could disturb a metal fragment in your body, interfere with an implanted device, such as a pacemaker or neurostimulator, or cause metal (including foil-backed medication patches) on or in your body to heat up, causing you harm. We keep the environment around the MRI scanner completely free of loose metal objects that could be moved by the magnetic field, and we will make sure that you have no metal on your body that could be affected by the MRI scanner. We will also ask you questions and have you complete an MRI screening form to make sure that you have no metal inside your body that would cause you harm during the MRI scan.

[6] There is the potential that a magnetic resonance image may reveal an abnormality that is already in your head or brain, such as a cyst or tumor. Many such abnormalities are not clinically significant, but you may need or want to investigate them further. Such a finding might require additional studies, and maybe even treatment, which would not be paid for by the investigators, the sponsor, or the University of Michigan. However, you should also know that your scan images will not be routinely examined by a specialist trained to make medical diagnoses. Any abnormalities that you may currently have may not be noticed in the images obtained in this experiment. If you have any current health concerns, you should consult your doctor.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal or direct benefits from being in this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

Bear in mind that your images will NOT be read/interpreted by a radiologist or by the researchers and any imaging findings that may be incidentally detected will likely go unobserved.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
Not participating in this study will have no consequences upon your well-being at all.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No, you will not be harmed if you decide to end your scanning session before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
The companion study informed consent has details regarding payment for your participation in the study. Contact the companion study investigators with questions regarding payment for participation.

8.3 Who could profit or financially benefit from the study results?
No.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Luis Hernandez-Garcia, Ph.D.
FMRI Laboratory
2360 Bonisteel Ave.
Ann Arbor, MI 48109-2108
(734) 763 9254

Study Coordinator: Ruth Halsey
2360 Bonisteel Ave.
Ann Arbor, MI 48109-2108
(734) 936 0558

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- Other (specify):_____

12. SIGNATURES

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

For use only if required by sponsor:

Date of Birth (mm/dd/yy): _____

ID Number: _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____