

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Routine Functional Magnetic Resonance Imaging of the Brain

Company or agency sponsoring the study: University of Michigan

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

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

1.1 Key Study Information

Your child may be eligible to take part in a research study. This form contains important information that will help you decide whether your child should join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about your child's possible participation in this study. If you decide to consent to your child taking part in the study, you will be asked to sign this form before your child can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information. You should consider the reasons why your child might want to join a research study or why it is not the best decision for your child at this time.

Research studies have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision for your child to participate in this study, consider all of these matters carefully.

This research collects health-related information to better understand brain development. This research will involve an MRI brain scan, during which images of the brain will be collected. The goals are to identify which brain regions are involved during performance of tasks and to measure physical features of the brain.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to have your child join the study. For this study, some of these risks may include anxiety from being confined in the space of the MRI scanner, discomfort from the loud noises made by the scanner, or slight dizziness, light-headedness, or nausea during or immediately after the scanning session. Because of the strong electromagnetic fields, there is a risk that loose objects outside of your child's body could be accelerated by the magnetic field and strike your child. There is also a risk that the magnetic

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fields could disturb a metal fragment in your child's body, interfere with an implanted device, such as a pacemaker or neurostimulator, or cause metal (including foil-backed medication patches) on or in your child's body to heat up, causing him or her harm. Additionally, this study has the potential to cause "peripheral nerve stimulation" (PNS), a light touching sensation on the skin surface, lasting only for a few seconds. It may cause mild discomfort, but is not harmful to your child. There is a possibility that the MRI may reveal an abnormality that is already in your child's head or brain, such as a cyst or tumor. There is also a risk of a breach in confidentiality. More detailed information will be provided later in this document.

This study may not offer any benefit to your child now but may benefit others in the future from the knowledge gained in this study. More information will be provided later in this document.

We expect the amount of time your child will participate in the scanning session to be up to 4 hours, depending on the companion study requirements

You can decide not to have your child participate in this study. Not participating in this study will have no consequences upon your child's well-being at all.

Even if you decide to join the study now, your child is free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

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. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. Your child does not have to participate if he or she doesn't want to. Your child may also leave the study at any time. If your child leaves the study before it is finished, there will be no penalty to your child, and your child will not lose any benefits to which he or she is otherwise entitled.

3.1 Who can take part in this study?

Youth between the ages of 10 and 18 may participate in this study. Participants must be able to tolerate small, enclosed spaces without anxiety and should not have any metals or implanted devices within their body, e. g. aneurysm clips, pacemakers, artificial limbs.

In addition, according to magnetic resonance imaging (MRI) safety protocols, participants 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. Participants 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. Participants 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 your child has had so that we might know if there is a chance that any metal would be inside your child. Also, if your child's job (e. g. as a metal worker) or any other experience might have left metal fragments in his or her body, please inform us. The strong magnetic field could disturb a metal fragment in your child's body or interfere with an implanted device, such as a pacemaker, causing your child harm.

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

3.2 How many people are expected to take part in this study?

It is anticipated that at least 10,000 participants will participate; however, it is unknown how many participants will participate in research studies that involve fMRI.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

You and your child have agreed to participate in a companion study that is utilizing the functional magnetic resonance imaging (fMRI) laboratory. While at the fMRI lab, your child 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 child's body will take from 30 minutes to 3 hours, and your child will be asked to remain as still as possible during the entire period. Small hand and foot movements are allowed in between scans (your child will know they are being scanned because he or she will hear loud knocking noises), but it is essential that your child's head remains in the same position during the entire time he or she is in the scanner. Your child 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. Your child will also be able to trigger an audible alarm at any time. While your child is lying in the scanner, he or she will be asked to perform a task during which the scanner will be operated and brain images will be acquired. The task may be presented to your child 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). Your child may be asked to respond to stimuli with button presses that are recorded by computer. Your child 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 child's 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 child's participation at the fMRI lab will be complete after the MRI scanning session.

4.4 What will happen with my information and/or biospecimens used in this study?

With appropriate permissions, your child's collected information may also be shared with other researchers, here, around the world, and with companies.

Your child's identifiable private information will be stripped of identifiers and may be used for future research studies, education or training; or distributed to another researcher for future research studies, education or training without additional informed consent.

5. INFORMATION ABOUT STUDY 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 could access your child's fMRI research record. Only those directly involved in this study will have access to the research records. All records

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Instructions revised 11-12-2018

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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 your child as comfortable as possible. Your child will be able to talk to us throughout the study, and your child will be able let us know right away if he or she wants to stop the study and get out of the scanner. Your child will also be given the opportunity to experience what the MRI scanner is like via the use of a simulator or "mock scanner" which is a similar size and allows your child to see what it is like to be in the hole in the machine and hear the MRI scanner noises.

[2] The MRI scanner makes loud, vibrating noises. Your child 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 your child. 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 your child feels dizzy or light-headed, we will have him or her 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 child's body could be accelerated by the magnetic field and strike your child, causing him or her injury. There is also a risk that the magnetic fields could disturb a metal fragment in your child's body, interfere with an implanted device, such as a pacemaker or neurostimulator, or cause metal (including foil-backed medication patches) on or in your child's body to heat up, causing him or her 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 your child has no metal on his or her 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 your child has no metal inside his or her body that would cause him or her harm during the MRI scan.

[6] There is the potential that a magnetic resonance image may reveal an abnormality that is already in your child's head or brain, such as a cyst or tumor. Many such abnormalities are not clinically significant, but you or your child 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 child's scan images will not be routinely examined by a specialist trained to make medical diagnoses. Any abnormalities that your child may currently have may not be noticed in the images obtained in this experiment. If you or your child have any current health concerns, you should consult your child's doctor.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

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, your child 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 your child has during this study. You should also tell your child's 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 your child. It may also affect the results of the studies. You and your child 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?

Your child may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from 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 you or your child's willingness to stay in this study. If new information is provided to you after your child has 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 child's 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. ALTERNATIVES TO PARTICIPATING IN THE STUDY

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 child's well-being at all.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

Your child is free to leave the study at any time. If your child leaves the study before it is finished, there will be no penalty to your child. Your child will not lose any benefits to which he or she may otherwise be entitled. If you choose to tell the researchers why your child is leaving the study, you or your child's 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".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No, your child will not be harmed if he or she decides 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 child's best interest to stay in the study.
- Your child become ineligible to participate.
- Your child's condition changes and you need treatment that is not allowed while he or she is taking part in the study.
- Your child does 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?

There are no costs or billing for this study.

By signing this form, you do not give up your right to seek payment if your child is 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 child's 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?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You and your child will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your child's research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Once data collection is complete the records will be de-identified. The investigators will keep any confidential information that can link you to the data under lock and key or in secure computers.

9.2 What protected health information (PHI) 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 your child for this study, and is required in order for your child to take part in the study.

There are many reasons why information about your child 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 your child can take part in the study.
- The researchers may need the information to check your child's test results.

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Instructions revised 11-12-2018

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- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB 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 child's medical bills or other costs of your child's participation in the study.
- The researchers may need to use the information to create a databank of information about brain structure, function, or development.
- If your child receives any payments for taking part in this study, the University of Michigan accounting department may need your child's 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 your child 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 or your child are.

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

As a rule, the researchers will not continue to use or disclose information about your child, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about your child 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 child's information
- To provide limited information for research, education, or other activities. (This information would not include your child's name, social security number, or anything else that could let others know who your child is.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

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

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Instructions revised 11-12-2018
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- 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 : Barb Hibbard

2360 Bonisteel Ave.
Ann Arbor, MI 48109-2108
(734) 936 0558

You may also express a question or 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
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).*

12. SIGNATURES

Sig-A

Consent for my Child 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 child and the study team. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my child's 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 for my child changes, either I or my legal representative may be asked to re-consent prior to my child's continued participation in this study. I understand that my child will also be asked for his/her assent, but that I must also consent for him/her to participate.

Legally Authorized Representative or Parent Permission

Subject Name: _____

Parent/Legally Authorized Representative:

Printed Legal Name: _____

Signature: _____

Address: _____

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

Relationship to subject: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If "Other," explain: _____

Reason subject is unable to consent: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Sig-B

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.

Printed Legal Name: _____

Title: _____

Signature: _____

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