UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS DOCUMENT

You may be eligible to take part in a research study – to be a subject in an experiment or to let us use information about you to help us learn more about important health care issues. This document gives you important information about the study. For example, it describes the purpose, risks, and possible benefits of participating in the study. Please take time to review this document carefully. After you have finished, you should discuss the information here, as well as any questions you have, with the researchers and your regular doctor. If you decide to take part in the study, you will be asked to sign this document. Do not sign this form unless you understand what the study is about and the risks and possible benefits of participating.

GENERAL INFORMATION ABOUT THE STUDY AND RESEARCHERS

1. Study title:

   Modeling the BOLD Response Accounting for Perfusion Effects: Simultaneous BOLD imaging and two-coil Arterial Spin Labeling

2. Names, degrees and affiliations of the researchers conducting the study:

   Hernandez, Luis, Ph.D.
   Vazquez, Alberto, M.S,
   Noll, Douglas, Ph.D.
   Lee, Gregory, B.S.

3. Study purpose:

   Functional MRI allows investigators to study how the brain works by detecting brain activity associated with a task. The goal of this research project is to advance the basic methods for functional MRI acquisition and processing. This project involves investigation into the basic physical and physiological mechanisms for functional MRI. Additionally, this project aims to improve the acquisition of blood flow images without the use of contrast agents, and to apply those methods toward functional imaging.

   The success of this project will produce a more accurate interpretation of functional images acquired using the BOLD effect, which is the basis of most functional MRI experiments. It will also produce an optimized method of measuring cerebral blood flow without any invasive procedures or external contrast agents. These techniques have broad research and clinical applications for functional imaging as well as stroke, brain trauma and other pathologies involving perfusion deficits.
INFORMATION ABOUT STUDY SUBJECTS

Participating in the study is completely voluntary. You do not have to participate. You may withdraw from the study at any time. You will not be penalized and will not lose any non-research benefits to which you otherwise may be entitled if you refuse to participate in the study or if you leave the study early. No aspect of your treatment (except the experimental procedures described below) or non-research benefits depends on your enrollment or continued participation in this or any other study.

4. Who is eligible to take part in the study?

Adults between the ages of 18 and 85 may participate in this study. Qualified subjects will be selected on a first-come, first-serve basis. 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.

5. Who may not take part in the study?

Subjects will be excluded if they have any history of neurological or psychiatric disorders, or any history of drug or alcohol abuse. In addition, according to 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.

Note: it is very important for you to give the researchers accurate and complete information about your medical history and condition.

6. How many people (subjects) are expected to take part in the study?

Up to 150 subjects will be recruited for this study

7. How long will I be asked to participate in the study – and how long will it take to complete the study?
The study will take between one and three hours

8. **If I want to withdraw from the study, what should I do?**

You can withdraw from this study at any time without loss of any non-study related benefits to which you would have been entitled before participating in the study. If you decide to withdraw, you may do so by notifying the study representative listed in the “Contact Information” section below.

### WHAT HAPPENS TO SUBJECTS IN THIS STUDY

9. **What experimental procedures or treatments will be done during the study?**

This functional MRI study 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 a knocking noise, but you will be able to talk with the operator or researcher through an intercom at various points during the study. 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 respond 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.

10. **What procedures or treatments done during the study might be recommended or performed by my doctor as part of my routine medical care, whether or not I participate in the study?**

    none

11. **Will my regular medical care be interrupted or changed in any way if I decide to participate in the study? If so, how?**

    no

12. **What information will I receive about the study?**

    During the study, the researchers will try to inform you of significant new findings that may impact your willingness to continue participating.
There is a risk that the magnetic resonance image may reveal something that is already in your brain, such as a tumor. Such a finding might require additional studies, and maybe even treatment, neither of which would be covered by the investigators. The scanning procedures used for this study will not be read by a specialist trained to make medical diagnoses from the scan. Furthermore, the type of scans we will use are not very sensitive to many neurological abnormalities. Therefore, it is also possible that any abnormality that you currently have will not be revealed by the images obtained for this experiment.

RISKS AND POTENTIAL BENEFITS OF THE STUDY

13. **What risks will I face by participating in the study?**

The known or expected risks for people participating in the study include:

- There is a potential risk of the main magnetic field forcefully attracting ferromagnetic/metallic objects towards the magnet.

- The scanner makes very loud noises that can result in hearing damage if exposed for a long time without proper hearing protection.

- Radio Frequency electromagnetic fields can induce heating if applied too long or with too much intensity.

- Fast imaging sequences, such as the those employed in this study, have the potential to induce peripheral nerve stimulation (PNS). PNS can be described as a light touching sensation on the skin surface and 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.

- If applied for too long or too intensely, radio waves such as the ones that MRI scanners use can raise the temperature of the tissue.

- Other than those described above, there are no known biological risks due to exposure to the magnetic fields such as those that will be utilized in this study.

- As with any research study, though, there may be additional risks of participating that are unforeseeable or hard to predict.

14. **What will be done to reduce or monitor these risks?**

You and all investigators will be screened for metallic objects prior to entering the scan room to minimize the risk getting struck by a metallic object being pulled by the magnet.

You will be required wear foam earplugs or other hearing protection, as is routine for clinical patients, to prevent risk of hearing damage due to the inherently loud noise of MR scanning.
The protocols that will be applied to you will be carefully pre-tested prior to the study, to ensure that you are not exposed to excessive Radio Frequency electro-magnetic fields. Additionally, our scanner is fitted by an RF power monitor that automatically shuts down the transmitter if the power gets above FDA guidelines.

The minor risk of discomfort due to lying still for an hour will be minimized by custom pads and pillows to make you as comfortable as possible.

Female subjects: As a precaution, all female subjects who are or may be pregnant will be excluded from participation. As part of our screening, you will be asked questions about the date of your last menstrual cycle and whether contraceptives have been used if you have been sexually active in the past four weeks. You will be encouraged to undergo a free pregnancy test. You may elect to self-administered a urine pregnancy test or undergo a blood serum pregnancy test. The urine pregnancy test is not as accurate as a blood serum test, but the blood serum test requires that blood be drawn from your arm. There will be no cost to you for either test. You will be able to communicate with the scan operator via an intercom and may trigger an audible alarm at any time. If, at any point, you experience any discomfort, please inform the investigator and the study will be stopped.

15. What happens if I am hurt or become sick as a result of the study?

This study has been designed to minimize expected risks to you and other participants. However, as is the case with all medical care, you may experience problems or side effects even when precautions are taken to avoid them. If complications occur, the researchers or University of Michigan will help arrange for medical treatment, including, if necessary, emergency treatment. This study does not, however, pay for these related medical or other costs. Therefore, the costs may be billed to your insurer or you may have to pay for them if your health insurance does not cover them. You do not waive any right to seek additional compensation in the event of a personal injury by signing this form.

*Please note: it is important that you tell both the researchers and your regular doctor about any injuries or side effects you experience while participating in the study.*

16. Can I expect any benefit from participating in the study?

We cannot promise that you personally will receive any benefits from being in this study. Except for monetary compensation for your time, you will receive no direct benefits from taking part in this study.

17. If I participate in this study, can I also participate in other studies?

There is no added danger from this study if you decide to participate in other studies as well.

**ENDING THE STUDY**

18. If I decide to leave the study early, what is likely to happen to me? Are there likely to be any dangers in doing so?
There is no danger associated with leaving the study early.

19. **What are some of the reasons why the researchers might take me out of the study even if I want to continue to participate?**

There are many reasons why the researchers may need to end your participation in the study. These include, but are not limited to:

- Continuing to participate could be harmful to your health or to others.
- Your eligibility to participate changes.
- Your condition changes and you need treatment that is not allowed while you continue to participate in the study.
- You fail or refuse to follow instructions from the researchers.
- The study is suspended or cancelled.

### FINANCIAL INFORMATION

20. **Who is sponsoring or funding the study?**

   **National Institute of Health (NIH):** An NIH grant covers many of the research costs such as salaries and costs of data storage and analysis.

21. **What, if any, costs are considered “study-related” and what, if any, costs are considered part of clinical care? Who will be billed for the study-related costs and who will be billed for clinical care?**

   All costs are considered study-related.

22. **Are subjects paid or given anything for being in the study?**

   You will be paid for your time and effort at a rate of $25 per hour, rounded up to the nearest half-hour. If you prematurely withdraw from this study, your payment will be prorated according to the length of time that you did participate.

   *This study could one day lead to a commercial product, from which the University of Michigan, sponsors of the project, and/or the researchers may benefit. Subjects will not be entitled to nor have any claim to any proceeds, profits or other benefits if this happens; nor will they have any claim or right of ownership to any inventions, improvements, or ideas developed during or as a result of the study.*

23. **Who has a financial interest in the study or in the study’s sponsors?**

   The researchers conducting the study:

   The University of Michigan:
CONFIDENTIALITY OF SUBJECT RECORDS

University of Michigan policies and certain federal and state laws require that personal health information be kept confidential but allow disclosures in specific situations. You are not required to sign this document, but if you do not, you will not be able to participate in this study.

24. Why would my health information be disclosed?

There are many reasons why your health information may be used or disclosed in the course of this study. For example, the researchers may need the information to verify that you are eligible to participate in the study, or to monitor the results, including side effects. Other university and government officials, safety monitors, and study sponsors may need the information to ensure that the study is conducted properly. Also, information may need to be disclosed to insurance companies or others responsible for your medical bills in order to secure payment.

25. What information will be disclosed?

If you agree to participate in this study and sign your name on the last page, you will be giving the University of Michigan, including its Health System (hospitals, health centers, clinics and health care providers) and other providers involved in your care permission to disclose your medical information (doctors’ notes, lab results, x-rays, hospital charts, etc.) to the researchers.

However, your name and other information that would directly identify you will not be used in any publications or presentations resulting from this research study, unless you give us separate written permission.

26. How will the researchers protect my privacy?

We shall put the information collected about you during the study into a research record. We shall not enter in this record your name, registration number or anything else that might allow someone to find out that the information belongs to you. In other words, no one will be able to link the information on your research record to you. Study records that contain your name (safety screening, payment, and consent forms) will be secured by Dr. Hernandez in a locked cabinet.

27. Other than the research staff, who might see information about me collected during the study, or other related medical records?

- University of Michigan faculty, staff and contractors responsible for oversight of the research.
- Government officials who oversee research (such as the federal Office for Human Research Projections and the Food and Drug Administration).
- Safety monitoring boards that oversee the safety of this study.
- Research sponsors or funders and their representatives.
In addition, information including your name, address, social security number, date of birth, diagnosis and treatment may be sent to insurance companies or others who are billed for all or part of the procedures performed during the study.

28. **What happens to information about me after the study is over?**

Even after the study is complete or after you decide to withdraw from the study, information about you may be used or disclosed as follows:

- To preserve the integrity of the other information collected during the study.
- As part of a data set used for research, educational and other lawful activities that does not include your name, social security number, or other identifying information.
- To University faculty, staff and agents responsible for oversight of the research.
- As required by applicable federal or state law. For example, if you withdraw from the study at any time, a record of your withdrawal and the reasons you gave for withdrawing will be kept as part of the study record. In addition, government officials who are responsible for oversight and review of clinical trials may require certain disclosures.

It is important to understand that once your medical records have been disclosed as described above, they may no longer be protected directly by federal privacy regulations issued under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). However, as long as the information is held in any part of the University of Michigan Health System, it is protected by the Health System’s privacy policies. For more information about these policies, please ask your doctor for a copy of the University of Michigan’s Notice of Privacy Practices, or visit our website at [http://www.med.umich.edu/hipaa/npp.htm](http://www.med.umich.edu/hipaa/npp.htm).

**CONTACT INFORMATION**

For more information about the study or the study procedures or treatments, or to withdraw from the study, contact:

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

To report any illness or injury you experience during the study, contact the researchers listed above and your regular doctor.

For more information about your rights and responsibilities as a research subject, or to express a concern about the study, contact:

University of Michigan Medical School Institutional Review Board (IRBMED)
4558 Kresge I
200 Zina Pitcher Place
Ann Arbor, MI 48109-0570
Telephone: 734-763-4768
Fax: 734-763-9603
e-mail: irbmed@umich.edu

Alternatively, you may file an anonymous report by calling the University of Michigan Compliance Help Line at 1-888-296-2481. Privacy violations also may be reported to the Health System Privacy Officer at the same number.

*Please provide as much information as possible when you make a report, including the name of the researcher, the IRB Archive number (at the top of this form), and details about the complaint. This will help us do the necessary follow-up.*

**RECORD OF INFORMATION PROVIDED**

Your signature on the next page means that you have received copies of all of the following documents:

- [ ] This Informed Consent Document
- [ ] Other (specify): ________________________________
Research Subject:

I understand the information printed on this form and in the attached materials. I have been given copies of all of these. I have discussed this study, its risks and potential benefits, and alternatives to participation in the study with ________________________. My questions so far have been answered. I understand that if I have any additional questions or concerns about the study or my rights as a research subject, I may contact one of the people listed above. I also understand that I will receive a copy of this document at the time I sign it and later upon request.

Signature of Subject: ____________________________ Date: __________

Name (Print legal name): ____________________________

Address and Phone: ____________________________

Patient ID: ____________________________ Date of Birth: __________

If applicable: Name, Address, Telephone and Signature of Person Legally Authorized to Give Consent:

__________________________ ____________________________

Relationship to Subject:  □ Parent  □ Spouse  □ Child  □ Sibling  □ Legal Guardian  □ Other: ____________________________

Principal Investigator (or Designee):

I have given this research subject information on the study that I believe to a reasonable degree of medical certainty is accurate and sufficient for the subject to understand fully the nature, risks and benefits of the study, and the rights and responsibilities of a research subject. There has been no coercion or undue influence.

Name: ____________________________ Title: ____________________________

Signature: ____________________________ Date of Signature: ____________________________

Copies of This Document:

In addition to the copy you receive, copies of this document will be stored in a separate research file and entered into your regular University of Michigan medical record.

Witness Signature: ____________________________ Date: ____________________________