

STANFORD UNIVERSITY Research Consent Form		IRB USE ONLY
Protocol Director: Robert Dougherty, Ph.D	Protocol ID: 20042	Approval Date: September 30, 2016 Expiration Date: September 30, 2017
Protocol Title: Development and Evaluation of Functional and Quantitative MRI Techniques for Cognitive and Neurobiological Imaging (CNI)		

Print your name here: _____

Are you participating in any other research studies? YES ___ NO ___

PURPOSE OF RESEARCH

You are invited to participate in a research study designed to support the development of new MR methods and experimental designs that will be used by the community of users at Stanford's Center for Cognitive and Neurobiological Imaging (CNI). This research project will involve the development of new magnetic resonance (MR) pulse sequences, behavioral assays, and image analysis software that will be shared within the CNI community with the ultimate goal of applying those methods to the ongoing mission of understanding the human brain. This work is being carried out by researchers from several schools (including Ed School, Graduate School of Business, School of Engineering, and Humanities and Sciences).

This work is being carried out in cooperation with General Electric (GE) Healthcare, and GE is providing equipment for this study.

Your participation in this study is entirely voluntary. We expect to enroll 25 participants per year for this study. While participating in this research study, you should not take part in any other research project without approval from the Protocol Directors of each study.

DURATION OF STUDY INVOLVEMENT

For all subjects a single scanning session may last 45 minutes to 2 hours. You may be asked to participate in more than one scanning session scheduled on separate days.

PROCEDURES

If you decide to participate, Dr. Dougherty or a member of the research team will describe the procedures to you prior to your scan session.

You will be asked to complete a screening form prepared by the CNI staff to ensure that you do not meet any of the exclusion criteria for the study.

Magnetic resonance imaging (MRI) machines use a strong magnet and radiofrequency magnetic fields to make images of the inside of the body. You will be asked to lie on a long narrow table for 45 minutes to 2 hours while the machine gathers data. During this time you will be exposed to a strong

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magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the MR scanner. We will provide earplugs or headphones that you will be required to wear. Your eye movements may also be measured while you view stimuli.

While in the MR scanner you may be asked to either passively attend or actively respond in one or more of the following experimental conditions:

1. Passive watching or listening to stimulus information (e.g., visually presented patterns, visually or aurally presented words, letters, sounds or numbers).
2. Watching or listening to stimuli and making a response (e.g., a finger or verbal response) about the type of stimuli seen or heard.
3. Lying still with no stimulation.

You may have an opportunity to practice a task that you will be performing in the scanner. Stimuli will be presented on a screen that you view through a mirror fitted above your eyes or on goggles that fit over your eyes. If you are required to make a response, you will be given a response box with typical computer input mechanisms such as buttons, a scroll wheel, a track ball, or a joystick. You will be given adequate instruction regarding its use prior to the scan.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research staff if you believe you might be pregnant.
- Complete your questionnaires and screening forms as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time. If you wish to withdraw from the study for any reason you may

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notify the experimenter who will end your session immediately. The research staff will brief you on this procedure so that you are familiar with it.

At the discretion of the Protocol Director subjects may be taken out of this study due to unanticipated circumstances. Some possible reasons for withdrawal are:

- Failure to follow instructions of the Protocol Director
- The investigator decides that continuation would be harmful to you
- Pregnancy
- The study is canceled
- You do not meet inclusion criteria

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the Study Staff or Protocol Director immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator. . You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days. If you would prefer not to participate in the MR scan due to the presence of tattoos on your body, please inform a research team member.

There is a small possibility that you will experience a harmless localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you can discontinue the exam at any time. Such instances are due to stimulation of nerves, known as peripheral nerve stimulation.

Some of the radio frequency imaging coils, imaging software and devices being used in your scan are not approved by the FDA but are similar to

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counterparts that have been approved by the FDA. There is a small risk of heating from the cables associated with these devices. Steps will be taken to reduce the likelihood of this occurring. Please report any heating sensation to the research staff immediately.

GE Healthcare, the manufacturer of the MR scanner, will be supporting this research by providing some of the software for the MR scanner. This software provided by GE Healthcare has not been approved by the FDA and is considered to be investigational but from a safety standpoint, poses no significant risk to you.

Dizziness or nausea rarely may occur if you move your head rapidly within the magnet.

IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.

The scans performed in this study are for research purposes and are not optimized to find medical abnormalities. The investigators for this project are not trained to perform medical diagnosis. The investigators and Stanford are not responsible for failure to find existing abnormalities within these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact you and your primary care physician 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 physician, and Stanford are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

The effects of an MRI scan on a fetus are not known. Therefore, if you are, or could be pregnant we will not perform the scan.

The following are discomforts, inconveniences, and risks that you may experience during the study: (a) Travel to the testing site that is required for this study may inconvenience you; (b) The MRI environment is noisy and confining; either of these features may cause you discomfort (of course, you are free at any time to withdraw from the study and therefore to remove yourself from the uncomfortable environment); (c) Lying on one's back for a 2-hour period may cause you some discomfort; if this becomes significant for you, you may withdraw from the study and be removed from the MRI

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scanner; (d) The investigators will thoroughly screen you for any contraindications for scanning (e.g., implanted metal in your body, pacemakers, infusion pumps, etc.); if you pass this screening and there is nonetheless implanted metal, there is some risk that this may heat slightly during the scanning.

POTENTIAL BENEFITS

While there are no direct benefits to you for participating in this study, your participation will contribute to the understanding of human brain function. We cannot and do not guarantee or promise that you will receive any benefits from your participation in this study.

ALTERNATIVES

The alternative is not to participate.

CONFIDENTIALITY

Your identity will be kept as confidential as possible within the scope of the law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records, including neuroimaging data and the results of behavioral testing, may be shared with other researchers both within Stanford and at other institutions outside of Stanford. In this case you will be identified only by a unique code number and no personally identifying information will be shared. Information about the code will be kept in a secure location and access limited to research study personnel.

GE Healthcare scientists who are working at Stanford University in support of this research may have access to your private information. Your study data and images may be utilized by GE Healthcare to help develop new MRI products. Any of your study data shared with GE Healthcare through research reports or presentations will not contain any information that can identify you.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

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Patient information may be provided to Federal and other regulatory agencies as required. The FDA, for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

FINANCIAL CONSIDERATIONS

Payments and costs:

You will not be paid for your participation in this study. There is no cost to you for participating in this study.

Compensation for research-related injury:

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program.

You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns or Complaints:

If you have any questions, concerns, or complaints about this research study; its procedures, risks or benefits, you should contact the Protocol Director, Dr. Dougherty at 650-725-0051. You should also contact Dr. Dougherty at any time if you feel you have been harmed as a result of your participation in this study.

Independent Contact:

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board

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(IRB) to speak to someone independent of the research team at (650) 723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

Appointment Contact:

If you need to change your appointment, please contact a member of the research team at 650-725-0051.

SUBJECT'S RIGHTS

Your decision whether or not to participate will not prejudice your medical care. If you wish to participate in this study, you must sign this form. If you decide to participate, you are free to withdraw consent, including your authorization regarding the use and disclosure of your health information, and to discontinue participation at any time. If you decide to terminate your participation in this study, you should notify Dr. Dougherty at 650-725-0051. There are no anticipated consequences to withdrawal from the research study.

You have the right to refuse to answer any questions or participate in any aspect of the study. You will be told if any new information is learned which may affect your condition or influence your willingness to continue participation in this study. Your privacy will be maintained in all published and written data resulting from the study.

The extra copy of this consent form is for you to keep

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- Be informed of the nature and purpose of the experiment;
- Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- Be given a description of any attendant discomforts and risks reasonably to be expected;
- Be given an explanation of any benefits to the subject reasonably to be expected, if applicable;

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- Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- Be given an opportunity to ask questions concerning the experiment or the procedures involved;
- Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- Be given a copy of the signed and dated consent form
- Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

Signature of Adult Participant

Date

Print Name of Adult Participant

Person Obtaining Consent:
.

Signature of Person Obtaining Consent

Date

Print Name of Person Obtaining Consent