

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Gary H Glover

Protocol Title: Development of Magnetic Resonance Imaging Techniques at 7.0T

IRB USE ONLY

Approval Date: November 20, 2012

Expiration Date: November 20, 2013

Name of Subject: _____

**DEVELOPMENT OF MAGNETIC RESONANCE IMAGING TECHNIQUES AT 7.0T
NO PAYMENT
Informed Consent Form**

Principal Investigator: Gary H. Glover, Ph.D.

Are you participating in any other research studies: ____ yes ____ no

Introduction:

You are invited to participate in a research study that is being performed to test new technology of magnetic resonance imaging (MRI). This includes a 7.0T MR system, new imaging software and radiofrequency coils. A magnetic resonance imager uses a strong magnet and radiofrequency magnetic fields to make images of the inside of the body. We expect to learn the best use of this new technology in finding and defining suspected disease or normal anatomy and function. The results of this examination may be compared with other diagnostic imaging techniques such as x-ray computed tomography and ultrasound in order to determine which method is best. Ultimately, this type of comparison will be used to design the most efficient and specific way to diagnose a particular problem in a cost effective manner. It is anticipated that 500 subjects will participate in this project. If you wish to participate in this study, you must sign this form. We anticipate that 500 subjects will enroll in this project at Stanford University.

Procedure:

You were selected as a possible volunteer for this study based on your completed pre-MR examination screening form that indicates you have no conditions that would preclude a magnetic resonance imaging procedure. If you decide to participate, Dr. Glover or a designated representative will describe the procedure to you.

The procedure is very much like an x-ray computed tomography scan where you will be asked to lie on a long narrow couch for up to two hours while the machine gathers information. This will be stipulated prior to the MR examination. During this time, you will not be exposed to x-rays but rather a magnetic field and radiofrequency magnetic fields. You will hear repetitive tapping noises and you will be required to wear earplugs or headphones to reduce the noise. This research exam may take longer than the usual MRI exam. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling.

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Subject's Rights

You will be told if any new information which may affect your condition or influence your willingness to continue participation in this study. You can discontinue the exam at any time. Your participation in this research project is voluntary. If you decide to participate, you are free to withdraw your consent, including your authorization regarding the use and disclosure of your health information, and to discontinue participation any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify Dr. Gary Glover at (650) 723-7577.

Alternative

The alternative is not to participate.

Risks:

The MR machine used in this research study is more powerful than one that you would normally find in most hospitals and clinics, allowing us to further understand how the brain and other organ systems in the body function. Tesla is the unit that is used to measure the strength of a magnet. The FDA has categorized MRI up to 8.0 Tesla as not a significant health risk. No serious ill effects have been reported at any facility operating at magnetic field strengths up to 8.0Tesla and there is no evidence that any harmful or adverse effects can be expected.

There are no known significant risks with this procedure since the magnetic fields and radiofrequency magnetic fields, at the strengths used, are felt to be without harm. There are conservative Federal guidelines for radiofrequency magnetic field exposure and our examinations fall within those guidelines. We feel these are safe levels and less hazardous than a comparable x-ray computed tomography examination.

Exceptions include if a person has one of the following: a cardiac pacemaker ; a certain type of metallic clip (i.e., an aneurysm clip in the brain); some types of prostheses; a biomedical implant or device in or on their body; has worked with metal or had a piece of metal removed from their eye(s); or has shrapnel, bullets, or buckshot in their body. Also, because the effects of the MR examination on a fetus are unknown, if you are pregnant or are trying to get pregnant, you cannot participate in this study.

As metallic objects may experience a strong attraction to the magnet, it is very important that you notify the researcher of any metal objects, devices or implants that are in or on your body before entering the magnet room. This includes biomedical devices such as pacemakers, aneurysm clips, prostheses, and other metallic objects embedded in the body such as bullets, buckshot, shrapnel, and any metal fragments from working around metal.

All other metallic objects must also be removed from your person prior to entering the magnet room or approaching the magnet to prevent them from becoming a projectile or being pulled by the magnet. This includes keys, jewelry, pocket knives, money clips, paper clips, safety pins, hair pins, and barrettes. In addition, objects such as watches, pagers, cell phones, credit cards, and hearing aids could be damaged in the presence of the magnetic field. A locker will be provided for you to secure all your items and valuables.

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The 7.0T MR system at the Lucas Center being used to perform scans, including radiofrequency imaging coils and the imaging software, are not approved by the FDA.

There is a risk of heating from radiofrequency imaging coils, the cables of radiofrequency imaging coils, and/or the cables from monitoring devices such as those that record physiologic processes by way of an electrocardiogram, pulse oximeter (plethysmograph), and EEG (electroencephalography). This also includes cables and special accessories used in the bore of the magnet including button response boxes or to deliver stimuli. Please report any heating/burning sensation immediately. You may have the scan stopped at any time if this occurs.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and shouldn't be painful. However, you may have the scan stopped at any time if this occurs.

Dizziness and nausea will occur if you move quickly near the magnet or if the head is moved within the bore of the 7.0T magnet.

On very rare occasions, the individual may feel some eye discomfort. The scanning will be stopped if this occurs. These symptoms, if present, will subside shortly after leaving the magnet.

The procedure may involve risks that are currently unforeseeable.

Please take note that some subjects have experienced claustrophobia; you may discontinue the scan at anytime. If you think that you have experienced a research-related injury call Dr. Glover at (650) 723-7577.

Important Consideration:

While participating in this study, you should not take part in any other research project without approval from all of the investigators. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

Withdrawal from Study

At the discretion of the protocol director, subjects may be taken out of this study for reasons such as failure or inability to follow study instructions, cancellation of the study, other administrative reasons or other unanticipated circumstances.

If you decide to participate, you are free to withdraw your consent and to discontinue participation at anytime without prejudice.

Benefits:

You will be contributing to the development and testing of new noninvasive imaging technology (i.e., technology that does not rely on either surgery or on the use of drugs) which may help

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patients with various medical disorders. WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

Incidental Findings: The investigators for this project are not trained to perform radiological diagnosis, and the scans performed in this study are not optimized to find abnormalities. The investigators and Stanford are not responsible for failure to find existing abnormalities in your MRI scans. However, on occasion the investigator may notice a finding on a MRI scan that seems abnormal. When this occurs, a neuroradiologist will be consulted as to whether the finding merits 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 neuroradiologist, and Stanford are not responsible for any examination or treatment that you undertake based upon these findings. Because the images collected in this study do not comprise a proper clinical MRI series, these images will not be made available for diagnostic purposes.

Payment:

No payment will be provided for this study.

Cost:

There will be no additional cost to you for participation in this study.

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Confidentiality:

Your identity will be kept as confidential as possible as required by 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 may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

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.

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

Contact Information:

- **Appointment Contact:** If you need to change your appointment, please contact Anne Marie Sawyer at (650) 725-9697.
- **Questions, Concerns, or Complaints:** If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director. You may contact Dr. Gary Glover now or later at (650) 723-7577.
- **Emergency Contact:** If you feel you have been hurt by being a part of this study, or need immediate assistance please contact Dr. Gary Glover at (650) 723-7577.
- **Alternate Contact:** If you cannot reach the PD, please page the research team at (650) 723-8222, 15689.
- **Independent of the Research Team Contact:** If you are not satisfied with the manner in which this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a research study subject, please contact the Stanford Institutional Review Board (IRB) to speak to an informed individual who is independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. Or write the Stanford IRB, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401. In addition, please call the Stanford IRB at (650)-723-5244 or toll free at 1-866-680-2906 if you wish to speak to someone other than the research team or if you cannot reach the research team.

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Compensation:

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 but this study does not provide financial assistance for additional medical or other costs. Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

Experimental Subject's Bill of Rights:

Persons who participate in a medical experiment are entitled to certain rights. These rights include but are not limited to the subject'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;
- 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 are 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 anytime, and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form;
- and 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.

Conflict of Interest Disclosure:

Dr. Gary Glover serves as an unpaid consultant to GE Healthcare, a company whose equipment is being used in this study.

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YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

Signature

Date

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied - that the participant has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent

Date