Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the parent or guardian granting permission for a child in this study.

Print child's name here: _____

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."
Are you participating in any other research studies? _____ Yes _____No

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

PURPOSE OF RESEARCH

You are invited to participate in a research study of new technology in magnetic resonance imaging (MRI). This includes new imaging software and radiofrequency antennae (RF coils). Like an MRI scanner, the modified machine uses a strong magnet and radiofrequency magnetic fields to make images of the inside of the body. We hope 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 MR imaging techniques to determine which method is best. Ultimately this type of comparison will be used to design the most efficient and specific way to obtain the type of imaging information we are after. You were selected as a possible participant in this study because you are a healthy adult or pediatric volunteer.

Your participation in this study is entirely voluntary.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent, *a*nd to discontinue participation at 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 H. Glover at 650 723-7577.

This research study is looking for one thousand healthy people within the United States, specifically Stanford University and the surrounding area.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately five years with up to four hours of active participation by each subject who undergoes the magnetic resonance imaging scan.

PROCEDURES

If you choose to participate, Dr. Glover (650) 723-7577) or a designated representative will describe all procedures to be followed. You were selected as a possible volunteer for this study based on your completed pre-screening form that indicates you have no conditions that would preclude a magnetic resonance imaging (MRI) procedure. This MRI machine uses a strong magnet and radiofrequency magnetic fields to make images of the body interior. You will be asked to lie on a long narrow couch for up to 2, 4 or 6 hours for normal volunteers while the machine gathers data.

During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields. You will not feel either. 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 to protect your hearing. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling. You may also be fitted for a bite bar in order to keep your head from moving during the scans.

You may be asked to perform cognitive tasks while lying in the scanner that include:

1. Watching words or pictures on a TV-like screen in the scanner, or listening to words or other sounds through earphones (for example, seeing pictures of geometric patterns, hearing words or tones);
2. Moving a part of your body (for example, tapping your fingers);
3. Performing other mental activities (for example, adding two numbers, imagining faces).

While lying in the scanner you will be asked to hold completely still, and padding may be used to stabilize your head or body. During the scanning you may also be asked to provide a response (for example, pressing a button or saying a word or phrase) after watching words or pictures on the screen in the scanner, or listening to words or other sounds through earphones.

Risks:

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MRI 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 operator/investigator 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 a research MRI scan performed.

In addition, watches and hearing aids should also be removed as these could be damaged. You will be provided a locker 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.

If you have kidney problems, please tell the operator/investigator.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is expected and should not be painful. Please contact the operator if it occurs.

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 counterparts that have been approved by the FDA.

There is a small risk of heating from devices used during the MRI examination and the cables associated with these devices. Please report any heating sensation immediately.

Dizziness or nausea 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 specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and Stanford are not responsible for failure to find existing abnormalities with 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.

Women of Childbearing Potential

If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk. To confirm to the extent medically possible that you are not pregnant, you agree to begin the study after the onset of your next menstrual period.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Tell the Protocol Director or research staff if you have some type of implanted electrical device (such as a cardiac pacemaker). You will not be allowed to participate in this study.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the 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. This is to

protect you from possible injury arising from such things as extra blood drawing, extra x-rays, the possible interaction(s) of research drugs, or other similar hazards.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not lose any benefits to which you would otherwise be entitled. You need simply notify the Protocol Director or his staff of your wish to withdraw.

The Protocol Director may also withdraw you from the study, without your consent for one or more of the following reasons

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

The risks of participating are those associated with MRI scanning, and are described on page 3. While MRI has been used routinely in diagnostic and research examinations since approximately 1980 with low incidence of side effects, continued use of this technology may uncover risks that are presently unknown.

POTENTIAL BENEFITS

There are no direct benefits to you for participating in this study. You will contribute 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 contribute to finding and defining suspected disease or normal anatomy and function.

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.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

The alternative to participating in this study is to not participate.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

If you decide not to participate, tell the Protocol Director. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

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.

The purpose of this research study is to obtain data or information on the safety and effectiveness of new MR imaging procedures; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
This research study is designed to examine new technology in magnetic resonance imaging (MRI). This includes new imaging software and radiowave antennae (RF coils). This new machine uses a strong magnet and radiofrequency magnetic fields to make images of the inside of the body. We hope to learn the best use of this new technology in finding and defining suspected disease or normal anatomy and function. The results of your scans may be included in any publications or presentations of the study, but your identity will not be disclosed.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Gary H. Glover, Department of Radiology, 1201 Welch Road, Stanford University, Stanford, Ca. 94305 (gary.glover@stanford.edu).

What Personal Information Will Be Used or Disclosed?

Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, MR Imaging information.

Our screening form requests the following information. This information is necessary for us to create accession numbers in Radiology's Information System. Each study needs to have the accession number to document that they have undergone a research MRI scan and that information is stored within Stanford Hospital's patient information files. This information is not disclosed to any other entity or person.

Name
Address
Telephone
Birthdate
Previous MRI studies
Medical Record Number (if they have previously been at Stanford Hospital)
Electronic mail address
Ethnicity

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Dr. Gary H. Glover
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2026 or when the research project ends, whichever is earlier.

_____ _____
Signature of Participant Date

_____ _____
Signature of Legally Authorized Representative Date

_____
Description of Representative's Authority to Act for Subject

FINANCIAL CONSIDERATIONS

Payment
No payment will be provided to you for participation in this study.

Costs
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 and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Gary H. Glover. You may contact him now or later at (650) 723-7577.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Gary H. Glover. You may contact him now or later at (650) 723-7577.

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 (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, MC 5579, Palo Alto, CA 94304.

Appointment Contact: If you need to change your appointment, please contact Dr. Gary H. Glover at (650) 723-7577.

Alternate Contact: If you cannot reach the Protocol Director, please contact Anne Sawyer at (650) 725-9697.

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;
- 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; 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.

May we contact you about future studies that may be of interest to you? ☐ Yes ☐ No

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, 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 of Adult Participant Date

_____ _____
Signature of LAR (Parent, Guardian or Conservator) Date

_____
Authority to act for participant

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Authority to act for participant

The IRB determined that the permission of one parent is sufficient for research to be conducted under 21 CFR 50.51, in accordance with 21 CFR 50.55

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 subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject 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 subject to ask questions and that all questions asked were answered.

_____ _____

Signature of Person Obtaining Consent Date