

Meeting Date: October 8, 2002
Expiration Date: October 7, 2003

NAME OF SUBJECT (please print): _____

INFORMED CONSENT FORM (MRI)

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

Adult Brain Function Imaging with MR (1.5T and 3.0T)

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

INTRODUCTION:

You are invited to participate in the study of the new technology in magnetic resonance imaging (MRI). **This includes new imaging software and radiofrequency coils. This new machine uses a strong magnet and radiofrequency magnetic field to make images of the inside of the body.** We expect to learn the best use of this new technology in imaging the function of the brain. 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. It is expected that up to 100 volunteers will be imaged over a duration of five years.

PROCEDURE:

You were selected as a possible volunteer for this study based on your completed pre-screening form which indicates you have no conditions which would preclude a magnetic resonance imaging procedure. If you decide to participate, Dr. Glover (650) 723-7577) or a designated representative will describe the procedure to you. **You will be asked to lie on a long narrow couch for a certain amount of time (up to two hours) while the machine gathers information. During this time you will be exposed to a magnetic field and radiofrequency and radiofrequency magnetic field. You will hear repetitive tapping noises, however, and will be required to wear earplugs or earphones to reduce the noise.** You may also be fitted for a bite bar in order to keep your head from moving during the scans. A bite bar is a mouthpiece specifically molded to fit one's mouth and securely attached to a positioning device, which you will be asked to bite during the scans.

You will be asked to either passively attend to or actively respond in one or more of the following experimental conditions:

1. Passive watching or listening to stimulus information
(e.g., visually presented checkerboard patterns, visually or auditorally presented words);
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. Moving specific regions of your body
(e.g., tapping your fingers);
4. Cognitive activity such as imaging moving parts of your body or moving through space
(e.g., mentally following a map).

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Risks:

There are no known significant risks with this procedure at this time since the 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 a cardiac pacemaker or a certain type of metallic clip in their body (i.e., an aneurysm clip in the brain); if a person has worked with metal or had a piece of metal removed from the eye(s); or if a person has shrapnel, bullets, or buckshot in their body.

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 and 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, 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.

If you are or are trying to get pregnant, the effects of the scan on a fetus are unknown and, therefore, we will not perform the examination at this time.

Some of the radiofrequency imaging coils and the imaging software being used to perform scans at the Lucas Center 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, and/or plethysmograph. 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.

(For the 3.0T magnet) Dizziness and nausea may occur if the head is moved within the bore of the magnet.

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.

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IMPORTANT CONSIDERATION:

If you have some type of implanted electrical device (such as a cardiac pacemaker), or if you could be pregnant, you will not be allowed to participate in this study. 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. You may withdraw from this study at any time. At the discretion of the protocol director, subjects may be withdrawn from this study for reasons such as failure or inability to follow study instructions, cancellation of the study, other administrative reasons or other unanticipated circumstances. Your participation in this research study is voluntary. The alternative is not to participate.

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 will contribute to the understanding of brain function and may help patients with various mental and neurologic 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.

CONFIDENTIALITY:

Any information that may be published in scientific journals will not reveal the identity of the subjects. Patient information will be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example, may inspect research records and learn your identity if this study falls within its jurisdiction. Your decision whether or not to participate will not affect your job status nor will it prejudice you in any way. If you decide to participate, you are free to withdraw consent and to discontinue participation at anytime without prejudice to you. At the discretion of the principal investigator subjects may be taken out of this study.

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RIGHTS:

If you have any questions, we expect you to ask. Dr. Glover (650) 723-7577 or his associates will be happy to answer them.

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 researchers 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. For further information, please call (650) 723-5244 or write the Administrative Panel on Human Subjects in Medical Research, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401. In addition, if you are not satisfied with the manner in which this study is being conducted or if you have any questions concerning your rights as a study participant, please contact the Human Subjects Office at the same telephone number and address.

COST AND COMPENSATION:

In some instances, payment may be made to volunteers per arrangement with the program director. Payment is not guaranteed to every person who participates in this study. There will be no additional cost for participation in this study.

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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; 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.

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

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 nontechnical 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

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