

Subject Name

Sequence Number

CONSENT TO PARTICIPATE IN RESEARCH

Technical Advances in Magnetic Resonance

You are asked to participate in a research study by Mark Cohen, Ph.D., Susan Bookheimer, Ph.D., Joseph Demer, M.D., Ph.D., Steve Engel, Ph.D., Michael Green, Ph.D., Edythe London, Ph.D., John Stern, M.D., Zrinka Bilusic, M.S, Fred Sabb, B.S from the departments of Neurology, Psychiatry and Radiology and the Division of Brain Mapping at the University of California, Los Angeles. You have been asked to participate in this study because you are a healthy volunteer. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

Purpose of Study

This study is designed to evaluate and extend the effectiveness of advanced magnetic resonance imaging. Specifically, using this technology, we hope to accomplish the following:

- 1) To better understand the relationship between structure and function in the human brain and other structures of the head (for example, what the various parts of the brain or nervous systems do);
- 2) To better understand differences and similarities among different people regarding how the brain functions.
- 3) To improve our ability to use the technique of magnetic resonance imaging and spectroscopy (collectively called, MRI) in clinical care of patients and research studies.

The MRI device is a standard medical instrument. Certain aspects of the data collection software have been extended to improve performance.

Procedures

If you volunteer to participate in this study, we would ask you to do the following things:

You will be asked also to review the attached appendix ("*Magnetic Resonance Procedure – Appendix*") that describes the procedures involved in the study. Your understanding and approval of these procedures is required if you are to participate in this study. During the MRI scan, you may be asked to perform various tasks. Depending on the specific needs of the experiment, these may include:

- Looking at words or pictures on a computer screen;
- Listening to words or other sounds through headphones;
- Using buttons to respond to questions of a non-personal nature about the pictures or sounds;
- Moving your fingers, hands, arms or feet.

Anticipated Benefits to Subjects

You may receive no direct medical benefit from participating in this study.

Anticipated Benefits to Society

Information derived from these studies may help physicians diagnose and treat brain diseases more readily. These studies are expected to help provide basic insight into how the human brain functions.

Alternatives to Participation

This study is not being performed to improve your condition or health. Alternative procedures for making images of brain function are in use, or are being developed, that use radioactive tracers or which use surface electrodes. These procedures are not being used in this study because they use ionizing radiation or because they are not of sufficient image quality and/or dependability to offer distinct advantages over the methods used in this study.

Financial Obligation

Neither you, nor your insurance company, will be billed for your participation in this research.

Emergency Care and Compensation for Injury

If you are injured as a direct result of research procedures, not done primarily for your own benefit, you will receive medical treatment at no cost. The University of California does not provide any other form of compensation for injury.

Privacy and Confidentiality

The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during this research, will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); *or*
- if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Participation and Withdrawal

Your participation in this research is entirely VOLUNTARY. If you choose not to participate, that will not affect your relationship with UCLA (or the UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA.

Withdrawal of Participation by the Investigator

The investigators may withdraw you from participation in this research if circumstances arise which warrant doing so. The investigators listed above will make the decision and let you know if it is not possible for you to continue. The decisions may be made either to protect your health or safety.

New Findings

During the course of this study, you will be informed of any significant new findings (either good or bad) such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about participating. If such new information is provided to you, your consent to participate will be re-obtained.

Identification of the Investigators

If you have any questions about the research, or if you experience a research-related emergency, please contact any of the investigators listed below:

Mark Cohen, Ph.D.....(310) 980-7453	Susan Bookheimer, Ph.D.....(310) 794-6386
Joseph Demer, M.D.,Ph.D... (310) 825-5931	Steve Engel, Ph.D.(310) 825-6707
Edythe London, Ph.D.(310) 825-0606	John Stern, M.D.....(310) 825-5745
Zrinka Bilusic, M.S.(310) 794-5060	Fred Sabb, B.S.....(310) 206-4364

Rights of Research Subjects

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have any questions regarding your rights as a research subject, you may contact the Office of Protection of Research Subjects, UCLA, Box 951694, Los Angeles, CA 90095-1694, (310) 825-8714.

Signature of Research Subject

I have read, or someone has read to me, and I understand the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form and the Subject's Bill of Rights.

By signing this form, I willingly agree to participate in the research it describes.

Name of Subject

Signature of Subject

Date

Signature of Investigator

I have explained the research to the subject, and answered all of his or her questions. I believe that he or she understands the information described in this document and freely consents to participate.

Name of Investigator

Investigator Signature

Date

Date of Preparation: 2/4/04
UCLA HSPC Number: 03-12-101
Expiration Date:

Magnetic Resonance Procedure – Appendix

You are being asked to review this appendix because you are participating in a research study that involves magnetic resonance imaging (MRI) with a specialized research instrument. The procedures may differ somewhat from conventional MRI exams because of the experiments that are part of the study for which you have volunteered.

This appendix describes only the activities and risks related to the MRI. The details regarding your participation in the research study are described in attached informed consent form. Your consent to participate in the MRI procedures is required before the magnetic resonance portion of the study may begin. You should read the information below and ask questions about anything you do not understand before deciding whether or not to participate.

Procedures

If you agree to undergo an MRI, the amount of time you spend on the MRI procedures will be from one to three hours. The amount of time you spend in the MRI device will be two hours or less. You will be asked to have a series of MRI pictures taken of your head. These pictures are made with an MRI device that uses radio waves and a large powerful magnet.

The MRI pictures will be made while you lie on a narrow bed that positions your head inside of a large magnet. During the MRI scan, you may be asked to perform various tasks. Please refer to the “Procedures” section of the attached study consent form for details regarding these tasks. During parts of the scan, you will be asked to remain very still for periods of up to 30 minutes (though most procedures will be much shorter).

The following may all be part of your exam, depending on the specific requirements of the research:

- You may be asked to complete a brief questionnaire that will require two to three minutes of your time. You have the right to refuse to answer any question that you may not wish to answer.
- You may be asked to answer questions about your medical history. In addition, the investigators may perform a brief medical evaluation of your health status (blood pressure, height, weight, pulse, etc.), as well as a brief standard physical neurological exam. The results will be used only in connection with the MRI procedure, and will not become part of your medical records.
- Electrical activity in your brain or eyes may be monitored during the study. This involves attaching small electrodes (EEG) to your skin or scalp. The electrodes are attached with a paste that can be removed easily using soap and water.
- During the procedure your eye movements may be monitored with a device specifically designed for this purpose. This device works at a distance from the eye itself and does not involve any direct contact or injury to your eyes.
- The electrical activity of some of your muscles may be monitored by an electrode attached to the skin over the muscle. This device would be attached with a paste that can be removed easily using soap and water. The procedure of attaching the electrodes generally takes two to three minutes.

Potential Risks and Discomforts

The MRI scanning procedure requires that you be confined in a small partially enclosed space. Some individuals find this to be uncomfortable and may feel claustrophobic or experience nervousness, sweating or other minor discomfort.

The sound of the MRI scanner can be quite loud. You will be given special ear plugs to minimize the noise. In addition, the magnetism of the machine attracts certain metals; therefore, people with these metals within their bodies (such as pacemakers, infusion pumps, aneurysm clips, metal prostheses, joints, rods, or plates) will be excluded from the study. The “metal” in dental fillings is less responsive to magnetism and is therefore allowed. The MRI technician will ask you if you have any metals within your body. **You will be expected to notify the investigator conducting the study of any metal in your body, other than dental fillings.**

There are no other known side effects resulting from exposure to the MRI scan. In the studies performed so far, there have been no significant risks reported in animals or humans for similar exposures. There may be risks that are currently unforeseeable.

Use and Sharing of Magnetic Resonance Data

All magnetic resonance data collected in the Brain Mapping Center are archived in digital form, and are subject to review for scientific purposes by the investigators and their colleagues, as part of ongoing efforts to extend and improve the technologies of Magnetic Resonance imaging and spectroscopy and our understanding of the brain. These additional uses of the data acquired from you will not include any identifying information about you

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