

Safety Questionnaire

Do you have a pacemaker? Circle one: Yes / No

Do you have any surgical clips or instruments in your brain, spine, heart or blood vessels or eyes? Circle one: Yes / No

Do you have any metallic objects in your body such as piercings, metal fillings, fragments, shrapnel or bullets? Circle one: Yes / No

Does your work or other activities expose you to metal fragments that might get in your eyes or under your skin? Circle one: Yes / No

Do you have an artificial limb/prosthesis attached to your body? Circle one: Yes / No

Are you claustrophobic (do you become anxious in narrow, confined spaces)?
Circle one: Yes / No

Have you ever had brain or heart surgery? Circle one: Yes / No

Do you believe you have a brain condition that might require medical diagnostic testing? Circle one: Yes / No

Have you ever had an MRI before? Circle one: Yes / No

Name _____ Date of birth _____

Mailing address _____

Phone number _____ Email address _____

Driver's License # _____ (please bring license or other photo ID with you)

Additional comments: _____

Other History

Printed Name: _____

Date: ____ / ____ / ____

Age:	Weight:	Height:	Handedness (circle one)	Right / Left / Ambidextrous
Occupation				
Highest education level				
Eye-sight	Do you need glasses to watch TV?		Are you color-blind?	
Current Medications				
Frequency of alcohol use				
Recent use of marijuana or other recreational drugs				
Past Surgeries and Hospitalizations				
History of Head Trauma or Loss of Consciousness				
History of psychiatric illness or treatment				
Other Medical History				

Informed Consent Agreement

Functional MRI in Cognition and Emotion

You are being asked to participate in a research study. Before you give your consent to be a volunteer, we want you to read the following and ask as many questions as necessary to be sure that you understand what your participation will involve.

INVESTIGATOR

David R Hubbard, MD

PURPOSE OF THE RESEARCH

This research is designed to help us understand how the brain responds to thinking, feeling, and actions such as making choices.

DURATION OF PARTICIPATION IN THE RESEARCH

This study will last about one year and will include about 100 subjects.

PROCEDURES TO BE FOLLOWED DURING THE RESEARCH

If you agree to participate in this research you will attend one session. All procedures will be carried out at the Applied fMRI Institute. The total amount of time you spend on the procedures will be 60-90 minutes.

If you have a pacemaker, any metal in your body other than dental fillings, a serious medical illness, you will not be allowed to participate in this research because the MRI procedure may not be safe for you. You may be asked to change into hospital “scrubs.” You will be asked to remove ear rings, jewelry, hair pins, cell phones, credit cards, coins or other objects in your pockets.

The tasks will involve looking at pictures or brief video clips and/or listening to words or music and/or pressing buttons.

After and/or before the procedure, you may be asked to answer questions about your thoughts, feelings, or emotions.

EXPERIMENTAL PROCEDURES

You will be asked to lie inside an MRI scanner 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 magnet to create images. During the MRI scan, you will view or listen to various stimuli and may be asked to perform simple tasks. During parts of the scan you will be asked to remain very still for periods of up to 15 minutes. The MRI procedure generally takes 40-60 minutes.

RISKS

The MRI scanning procedure requires that you be confined in a small partially enclosed space. Some people find this to be uncomfortable and may feel symptoms of claustrophobia including nervousness, sweating or other minor discomfort. The sound of the MRI scanner can be quite loud, you will be given ear plugs, and head phones to minimize the noise. In addition, the magnetism of the machine attracts certain metals; therefore people with these metals in their bodies (such as pacemakers, infusions pumps, aneurysm clips, metal prostheses, joints, rods or plates) will be excluded from the research. 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 research of any metal in your body, other than dental fillings. Of particular concern is bits of metal in your eye. There are no other known side effects resulting from exposure to the MRI scan. In the studies performed so far, they have been no significant risks reported in animals or humans for similar exposures. There is no known pregnancy risk.

BENEFITS OF THE RESEARCH.

You will be debriefed about how your brain reacted to the stimuli presented to you. You will be provided with a copy of any publications about this study. You will otherwise receive no direct benefit from these studies. You should understand that this research does not provide medical, diagnostic information and does not screen for any illness or disease, including brain diseases.

ALTERNATIVES TO THIS RESEARCH

You may choose not to participate.

CONFIDENTIALITY

You have a right to privacy and all information identifying you will remain confidential, unless otherwise required by law. The results of this study along with any laboratory tests, x-rays, photographs, video tapes, and medical charts may be published in scientific journals, or be presented at scientific meetings as long as you are not identified and cannot reasonably be identified from it. However, it is possible that under certain circumstances data could be subpoenaed by court order. It is also not guaranteed that efforts to disguise identifying information with regard to case studies will keep your identity anonymous.

TREATMENT AND QUESTIONS

If you need medical treatment or have a research-related injury while participating in this study, you must contact your doctor or call [858 212-8074](tel:8582128074) (24-hour phone number). Should you have any questions about the research or any additional concerns, please contact Dr. David R Hubbard 858 444-3595 during normal business hours.

While you are a subject in this study, you must agree to follow the instructions of the research and to call your research investigator immediately if you become ill or experience any unusual or unexpected side effects.

While enrolled in this study, you should not participate in any other research project. This is for your protection against any possible adverse effects caused by the interaction of multiple study interventions. If you take any medicines (including over-the-counter medicines like cold

medicines), or have changed a medication you are taking now, you must inform the research investigator.

MANDATORY REPORTING OF CHILD OR ELDER ABUSE

California law mandates the filing and reporting of reasonable suspicions of child or elder abuse. Participation in this research could result in the investigator being required to report child or elder abuse.

SUBJECT COST OR COMPENSATION FOR PARTICIPATION

There is no cost. Compensation will vary by study.

SUBJECT RIGHTS AND RESEARCH WITHDRAWAL

Your participation in this study is voluntary. You may refuse to participate or withdraw once the study has started. It may be necessary in the event of early withdrawal for you to follow specific procedures set by your doctor. In either case, you will not lose any benefits to which you are otherwise entitled nor will you be penalized.

We have tried to explain all the important details about the study to you. If you have any questions that are not answered here, your study investigator will be happy to give you more information.

SIGNATURE AND ACKNOWLEDGMENT

My signature below indicates that I have read the above information and I have had a chance to ask questions to help me understand what my participation will involve. I agree to participate in the study until I decide otherwise. I acknowledge having received a copy of this agreement and a copy of the Subject's Bill of Rights. I have been told that by signing this consent form I am not giving up any of my legal rights.

Please print your name

Signature of Research Participant

David R Hubbard, MD
Researcher's Name

Date

858 444-3595
Contact phone number

Researcher's Signature

David R Hubbard, MD
Typed Name of Supervisor
Alliant International University
San Diego, CA 92131

Date

858 444-3595