

**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Title: **General MRI Protocols**

Principal Investigator: Shaokuan Zheng, Ph.D.

Co-Investigator(s): Keith Cauley, M.D., Ph.D.

Sponsor: N/A

Research Subject's Name: _____ Date: _____

Invitation to Take Part and Introduction

You are invited to volunteer for a research study. You are being asked to take part because you have previously expressed an interest in participating in this investigation.

Purpose of Research

Magnetic resonance imaging (MRI) is a test that uses a magnetic field and pulses of radio wave energy to capture pictures of organs and structures inside the body. The purpose of this research is to test different MRI variables/parameters that are interest to our studies. The image quality will depend on the experimental parameters that are changed, so experimental parameters should be optimized for better image quality.

Your Rights

It is important for you to know that:

Your participation is entirely voluntary.

You may decide not to take part or decide to quit the study at any time, without any changes to your work relationship with us.

You will be told about any new information or changes in the study that might affect your willingness to participate.

PROCEDURE

Prior to the experiments, you will be screened by a member of the MRI staff to make sure you do

not have metallic, magnetic, or electronic implants that may be unsafe in the MRI. This screening is to ensure your safety in the MRI. To this end, you will be asked to answer some questions. Prior to entering the scan room, you will also be scanned with a metal detector.

After clearing you of unsafe metallic and/or magnetic objects, you will be led into the MRI room. Although the research staff will be outside the MRI room during the scans, they can hear everything said in the room, and through the intercom system they can speak with you, in case you are experiencing some discomfort or want to ask a question. In general, the test will take around 1 hour to complete, but it may take up to 2 hours depending on the protocol being tested, in such cases your comfort will be closely monitored and if needed you will be allowed to take breaks or to ask us to stop the test.

This MRI procedure in this study is being done solely for the purpose of research. The purpose of this research is to test different MRI variables/parameters that are interest to our studies. The image quality will depend on the experimental parameters that are changed, so experimental parameters should be optimized for better image quality.

CONFLICT OF INTEREST DISCLOSURE

None

RISKS

Magnetic resonance (MR) imaging does not use radiation like an X-ray does. Instead, it uses a strong magnet and radio waves to collect images and data. There are no known risks associated with these techniques. However, serious risks may be present for people with:

- Cardiac pacemakers (a piece of equipment that has been surgically put in your body to help your heart beat)
- Aneurysm clips (clips in your brain)
- Vascular stents (tubes in your veins)
- Any filters, clips or other devices that have been surgically put in you for any reason
- Prosthetic heart valves (a mechanical devise that helps your heart pump blood)
- Other prostheses (a piece of equipment that replaces a missing part of the body)
- Neuro-stimulator devices (a piece of equipment that activates nerves)
- Implanted infusion pumps (a device that stays in your body and helps give you medicine)
- Cochlear (ear) implants (a device used to help you hear)
- Ocular (eye) implants (a device put in your eye to help you see)
- Known metal fragments or pieces in eyes
- Contact with shrapnel (pieces of metal from something that has exploded)
- Contact with metal filings (people who are sheet metal workers or welders could have this contact)
- Any surgeries where something metal was put in you
- Certain tattoos (please tell the study doctor if you have a tattoo so that we can make sure it is safe)

You will be asked about all of the items listed above and if you have any of them you will not be able to participate in this study. Major risks also can occur if certain metal objects are brought into the scanning area, as they can become dangerous and shoot quickly across the room. These types of items are not permitted in the scanning area. The exams do not hurt, and except for the loud sounds, you will not be aware that MRI scanning is taking place.

Although there are no known risks from these scans harmful effects could be found out in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs (and ear phone if possible) to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off during the MRI scan. Transdermal patches slowly deliver medicines through the skin. Some patches have metal in the layer of the patch that is not in contact with the skin (the backing). You may not be able to see the metal in the backing of these patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate area of the patch. Ask your doctor for guidance about removing and disposing of the patch before having an MRI scan and replacing it after the procedure. Tell the MRI facility that you are using a patch.

Most people experience no bad effects from the large magnetic field, but some people do report dizziness, mild nausea, headaches, a taste like metal in their mouth, double vision or feeling of flashing lights. These symptoms, if present, disappear shortly after leaving the MRI machine.

You may feel cramped inside the scanner. The technologist will be able to hear you at all times and you are free to end the scan at any time.

In rare cases, a very slight, uncomfortable tingling of the back can occur. This is due to the how quickly the magnetic field “switches” during some types of scans. If you have a tingling feeling you should tell the MRI technician immediately so that we can change the scan to avoid this. Although these safety measures will avoid all known risks associated with MR, this procedure may involve risks to you that we don’t yet know about.

In this study, the MRI scan is for research only. But, if we see something that is not normal, you will be told and asked to consult your doctor.

BENEFITS

There is no direct benefit to you from being in this study. However, your participation may help us provide improved imaging for others in the future as a result of knowledge gained from the research.

ALTERNATIVES

You can choose not to take part in this research study at any time. If you chose so during the course of MRI scanning the study will immediately terminate.

COSTS

There will be no cost to you from being in this research study.

CONFIDENTIALITY

Your privacy is important to us. Your research records will be confidential to the extent possible. In all records, you will be identified by a code number and your name will be known only to the researchers. Your name will not be used in any reports or publications of this study. However the UMMS Institutional Review Board and/or their representatives may inspect your medical records that pertain to this research study. We will not allow them to copy down any parts of your identifiable information (e.g. your name) or take any of your identifiable information from our offices.

YOUR PARTICIPATION IN THIS PROJECT IS ENTIRELY VOLUNTARY. YOU MAY WITHDRAW FROM THE STUDY AT ANY TIME.

YOUR EMPLOYMENT WILL NOT BE AFFECTED IN ANY WAY IF YOU DECIDE NOT TO PARTICIPATE OR IF YOU WITHDRAW FROM THE STUDY.

QUESTIONS

Before you sign this consent form, please feel free to ask any questions you may have about the study or about your rights as a research subject. If other questions occur to you later, you may ask Dr. Shaokuan Zheng at (508) 856-5122, the Principal Investigator. You may take as much time as needed to think this over. If at any time during or after the study, you would like to discuss the study or your research rights with someone who is not associated with the research study, you may contact the Administrative Coordinator for the Committee for the Protection of Human Subjects in Research at UMMS. The telephone number is (508) 856-4261.

CONSENT TO PARTICIPATE IN THE RESEARCH PROJECT

Title: **General MRI Protocols Test**

P.I. Name: Shaokuan Zheng, Ph.D.

Subject's Name:

I understand the purpose and procedures of this research project and the predictable discomfort, risks, and benefits that might result. I have been told that unforeseen events may occur. I have had an opportunity to discuss the risks and benefits of this research with the investigator and all of my questions have been answered. I agree to participate as a volunteer in this research project. I understand that I may end my participation at any time. I have been given a copy of this consent form.

_____ Date: _____
Subject's signature

STATEMENT OF PERSON OBTAINING CONSENT

I, the undersigned, have fully explained the details of this research study as described in the consent form to the subject named above.

_____ Date: _____
Signature of person obtaining consent

INVESTIGATOR'S DECLARATION

As the principal investigator or co-investigator on this study, I attest to the following:

- the nature and purpose of the study and study procedures, as well as the foreseeable risks, discomforts and benefits have been explained to the above-named subject
- this subject has been given the opportunity to ask questions and to have those questions answered by knowledgeable research staff
- this subject meets the inclusion/exclusion criteria for this study

I have considered and rejected alternative procedures for answering this research question.

PI Signature

Date