

**CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY**

**PRINCIPAL INVESTIGATOR'S NAME:** XXXXXXXXXXXXXXXXXXXX

**PROJECT NUMBER#**

**STUDY TITLE:** XXXXXXXXXXXXXXXX

**INTRODUCTION**

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

This is a research study. Research studies include only people who choose to participate. As a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is simply an effort to make you better informed so that you may give or withhold your consent to participate in this research study.

This study is being sponsored by XXXXXXXXXX. In order to participate in this study, it will be necessary to give your written consent.

**WHY IS THIS STUDY BEING DONE?** This research project is designed to increase our understanding of XXXXXXXXXXXXXXXXXXXX. You are being asked to participate because you are a normal healthy adult. Your participation allows us to determine basic principles of XXXXXXXXXXXXXXXX. The data obtained through your participation will be included with that from other subjects as part of a scientific study to appear in the peer-reviewed literature.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?** We estimate that as many as XXX participants will take part in these investigations during the upcoming year.

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**WHAT IS INVOLVED IN THE STUDY?** You will be asked to come to Brain Imaging Center located on the first floor of the Melvin H. Marx Bldg. During the visit/visits you will perform a series of tasks such as XXXXXXXXXXXXXXXXXXXX. During these tasks we will acquire images (“pictures”) of your brain's structure and functional activity, and measure the composition of different brain structures.

**HOW LONG WILL I BE IN THE STUDY?** You will typically spend approximately XX minutes completing screening forms and/or questionnaires, XX minutes practicing the behavioral tasks, and the rest of the XXX-minute session will be used for MRI testing. [If multi-session study then insert details here]. You may ask any questions you have prior to signing this form and at any time during the course of the testing process. You will also be debriefed following your participation. You have the right to withdraw from participation at any point without penalty.

During these procedures you will lie on a table inside a special ‘MRI’ magnet. You will be asked to lie still and we will cushion your head with a foam pad or similar type of a cushion device. You will perform the tasks as directed by the investigator. All testing is carried out within the magnet and will be conducted by a trained technician or research investigator.

We are also studying ways to improve the quality of the MRI results. In order to do so, there are several other types of information that may be obtained during the session or in preparation for the MRI session. To prepare you for the study, you may be asked to perform the same or similar tasks in a MRI machine ‘simulator’ (this is a mock-up of an actual MRI – but is not a working MRI machine) to give you an idea of what it will be like to be in the actual MRI machine. During the real MRI study, your eye movements and eye fixation may be monitored (and the data recorded). Your heart rate and blood oxygen levels may be monitored using a non-invasive device that clips to your finger or ear lobe and your respiration rate may be monitored using a non-invasive device that fits around

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your chest. All of the monitoring is non-invasive. The data obtained can then be used with specific software to minimize the effect of eye motion, heart beating and breathing motion on the MRI results.

**WHAT ARE THE RISKS OF THE STUDY?** Unlike x-rays or CT-scans, MRI does not involve any ionizing radiation. However, the tasks may cause some fatigue similar to reading a book or doing homework. You may also experience discomfort from lying still. If this happens, please let us know and we will arrange for you to adjust your position. Additionally:

- The safety of MRI has been evaluated over the past 20 years and no short-term effects have been observed. However, the long-term effects of MRI on the body are not fully known. Some individuals with claustrophobia (fear of closed or confining spaces) may find the MRI equipment too confining. In that case, you can request to be removed from the scanner and this will be done immediately. If you have any concerns about this, you can be placed in a MRI simulator to determine if the confining aspects and noises are too uncomfortable.
- The MRI scanner makes sounds variously described as “thumping”, “pounding”, “banging”, “chirping” and “buzzing; these sounds can be loud. You will be required to wear protective earplugs and headphones during scanning to reduce the noise. However, you will be able to hear the technologist and he/she can hear your voice when you respond.
- The investigators for this research project are not licensed or trained diagnosticians or clinicians. The testing performed in this project is not intended to find abnormalities, and the images or data collected do not comprise a diagnostic or clinical study. The investigators and the University of Missouri are not responsible for failing to find abnormalities. However, on occasion the investigators may perceive possible abnormalities. When this occurs, the Brain Imaging Center

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will consult with a specialist. If the specialist determines that additional inquiry is warranted, a staff person from the Brain Imaging Center will contact you. In such case, you are advised to consult with a licensed physician to determine whether further examination or treatment would be prudent. The investigators, specialist, Brain Imaging Center and the University of Missouri are not responsible for any decision you make with regard to examination or treatment. Because the images collected for this research project do not comprise a diagnostic or clinical study, the images will not be made available for diagnostic or clinical purposes.

- No short-term effects to a fetus from this procedure have been observed. However, the long-term effects of MRI on the fetus are not fully known. Therefore, if you are sexually active and capable of becoming pregnant, you must use an effective method of birth control while participating in this research. If you are a subject in a multi-session study and become pregnant during the course of that study, you will no longer be able to participate in this MRI research study for the duration of your pregnancy.
- You **cannot** have an MRI if you have **any metal in or near your brain** such as an aneurysm clip or a cochlear implant, or other contra-indicated implants such as a pacemaker for your heart or metal-containing prostheses (like a ‘stent’ or a heart valve, hearing aids, etc.). For example, welders and metal workers may be at risk for a MRI because they may have gotten small metal fragments in their eyes. This would be dangerous inside the magnet. There are also possible risks for participants if metal objects are drawn to the magnet while a participant is within or near the bore. Accordingly, you will be asked to leave all jewelry and metal objects outside of the testing area. No loose metal objects will be allowed near the magnet. Many items of clothing contain metal hooks, wires, etc. and some of these cannot be worn in the MRI device. We have clean garments that you can wear in this case.
- There may be some unanticipated risks or side effects involved with your participation in this

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research study. Since 1981, there is no evidence that high magnetic fields endanger health on a short or long term basis. Therefore the potential health risk is thought to be minimal, if any.

**ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?** You may or may not personally benefit from participating in this study. However, by serving as a subject, you may contribute new information that may benefit the science of XXXXXXXX and people in the future.

**WHAT OTHER OPTIONS ARE THERE?** You may elect not to participate in this research study.

**WHAT ABOUT CONFIDENTIALITY?** All of the records and data from your participation will be kept confidential. (Insert details here] The results of your participation in this study may be used for publication or for scientific purposes, but neither your name nor your identity will be disclosed unless you give separate, specific consent to this, or unless required by law. The research records for this study may be reviewed by a funding agency, such as the Department of Health and Human Services or by the Food and Drug Administration or other regulating agencies.

[If relevant: In addition, if photographs, audiotapes or videotapes were taken during the study that could identify you, then you must give special written permission for their use. In that case, you will be given the opportunity to view or listen, as applicable, to the photographs, audiotapes or videotapes before you give your permission for their use if you so request.]

**WHAT ARE THE COSTS?** There are no costs for participation.

**WILL I BE PAID FOR PARTICIPATING IN THE STUDY?** You will be compensated at the rate of XXXXXX/hr. In the event of early withdrawal you will receive full compensation for the session.

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**WHAT IF I AM INJURED?** It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri. In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

**WHAT ARE MY RIGHTS AS A PARTICIPANT?**

**Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate.** If you decide to participate, you can change your mind and drop out of the study at any time without without prejudice to yourself. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, the investigator of this study may decide to end your participation in this study at any time after he/she has explained the reasons for doing so [if appropriate: “and has helped arrange for your continued care by your own doctor, if needed”].

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Health Sciences Institutional Review Board (which is a

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group of people who review the research studies to protect participants' rights) at (573) 882-3181.  
[And, if available, you may also list patient representative (or other individual who is not on the research team or IRB) and his/her contact telephone number.]

You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact [XXXXXXXXXXXXXXXX, phone XXXXXXXX]

You will receive a copy of this consent form upon request.

**SIGNATURE**

I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. I have read this consent form and my questions have been answered. My signature below indicates my willingness to participate in this study.

\_\_\_\_\_  
Subject/Patient\*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Legal Guardian/Advocate/Witness (if required)\*\*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Additional Signature (if required) (identify relationship to subject)\*\*\*

\_\_\_\_\_  
Date

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\*A minor's signature on this line indicates his/her assent to participate in this study. A minor's signature is not required if he/she is under 7 years old. Use the "Legal Guardian/Advocate/Witness" line for the parent's signature, and you may use the "Additional Signature" line for the second parent's signature, if required.

\*\*The presence and signature of an impartial witness is required during the entire informed consent discussion if the patient or patient's legally authorized representative is unable to read.

\*\*\*The "Additional Signature" line may be used for the second parent's signature, if required. This line may also be used for any other signature which is required as per federal, state, local, sponsor and/or any other entity requirements.

"If required" means that the signature line is signed only if it is required as per federal, state, local, sponsor and/or any other entity requirements.

**SIGNATURE OF STUDY REPRESENTATIVE**

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered questions regarding the study to the best of my ability.

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Study Representative\*\*\*\*

Date

\*\*\*\*Study Representative is a person authorized to obtain consent. Per the policies of the University of Missouri Health Care, for any 'significant risk/treatment' study, the Study Representative must be a physician who is either the Principal or Co-Investigator. If the study is deemed either 'significant risk/non-treatment' or 'minimal risk,' the Study Representative may be a non-physician study

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investigator.

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