# Florida State University

**PARENTAL CONSENT TO PARTICIPATE IN A RESEARCH STUDY**
**[*Insert Title of Study*]**

### INFORMATION ABOUT THIS FORM

Please take the time to review this information carefully to ensure that you are informed of the nature of this research study. If you have any questions please direct them to the researchers of the study. Participation in this study is **voluntary,** and you or your child may choose to discontinue participation at any time. If you decide to allow your child to take part in the research you will be asked to sign this form. Before you sign this form, please be sure you understand what the study is about, including what your participation will entail, including the risks and possible benefits to you and your child.

#### GENERAL INFORMATION ABOUT THIS STUDY

#### Purpose of this study

You are being asked to allow your child to participate voluntarily in a research study. The purpose of this study is to *[insert the purpose of the study]*.

#### Number of study participants

If you decide to allow your child to participate in this study, your child will be one of *[insert the total number of subjects]* participants in this research.

#### Duration of this study

Your child’s participation will require *[insert the number of hours, days, weeks, months, etc.]*.

#### INFORMATION ABOUT STUDY PARTICIPANTS

#### Who may participate in this study?

Children between the ages of *[insert age range of participants]* may participate in this study. Subjects must be able to tolerate small enclosed spaces and have no medical devices or implants on or in their bodies.

Subjects will be excluded from any studies if they have any history of pacemakers or pacer wires, open heart surgery, artificial heart valves, aneurysm clips, cochlear implants, braces or extensive dental work, implanted electrical or mechanical devices, tissue expanders, foreign metallic objects from explosives, shrapnel or metalwork fragments, or artificial limbs. Subjects will also be excluded if they are pregnant, claustrophobic, have tremors or cannot lie still for 1-2 hours.

It is imperative that the metal screening form is filled out fully and accurately to ensure your child’s safety in a strong magnetic field.

### PROCEDURES

If your child’s metal screening form is approved, his/her participation will require *[explain tasks and procedures: subjects should be told about video or audio taping, assignment to study groups, frequency of procedures, and if any procedures are experimental]*.

### INFORMATION ABOUT RISKS AND BENEFITS

#### Risks

There are no known permanent negative effects from exposure to a strong magnetic field.

Temporary effects may be dizziness, nausea or a metallic taste in your mouth. Some pulse sequences can cause temporary peripheral nerve stimulation which causes mild discomfort but is not harmful. Some pulse sequences can cause heating of the body. If your child experiences any discomfort that they cannot tolerate, they will be given an alarm bell to notify researchers that they would like to discontinue the study. Participation in this study is **voluntary,** and you and your child may choose to discontinue your child’s participation at any time.

MRI produces very loud pulsating sounds. Your child will be required to wear earplugs or a headset to protect his/her hearing.

Participation in this study may involve some additional risks or discomforts. These may include the following: *[Explain risk, include physical, psychological, societal or economic risks and their likelihood. If there are no risks, please state that here]*.

#### Benefits

The following benefits may be associated with your child’s participation in this study: *[List benefits to subjects or society. If there are no benefits, state that here]*.

#### Compensation and Cost

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#### Confidentiality

Research records will be kept confidential. Research records will be numerically coded to remove any identifying information. Only the researchers in this project and persons directly employed in the MRI Facility will have access to this data.

Your child’s name will never be directly associated with your study information, **UNLESS** you agree to have your child’s scan reviewed by a radiologist, at no cost to you. (See section on Incidental Findings)

#### Incidental Findings

The MRI scan is being done to answer research questions, not to examine your child’s brain for medical reasons. This MRI scan is not a substitute for a clinical scan (the type a doctor would order). The research scan might not show problems that may be picked up by a clinical MRI scan. However, all research MRI scans will be read by a neuroradiologist (a doctor with experience reading MRI scans) unless your child has been scanned at FSU in the previous six months for children two and over, and previous three months if two or under.

Incidental findings are potential health problems that are discovered during the course of conducting research. At Florida State University Magnetic Resonance Imaging Facility, we have all neurological research MRI scans evaluated for incidental findings, **UNLESS YOU DO NOT CONSENT TO THIS EVALUATION**.

When your child’s scan is read, you will receive an e-mail letting you know you can download his/her MRI report from the Participant Portal Homepage. If we find an abnormality that requires follow-up, we may also mail a copy of the report to you, or contact you (with your permission) by phone to help answer questions.

Due to the very high sensitivity of MRI in detecting abnormalities, there is a risk of false-positive findings, identifying something on imaging studies that may or may not be important. This may result in anxiety and additional testing, possibly including a recommendation for clinical scans at your cost. The radiology report or other study data will not be put into your child’s medical record unless you provide it to his/her physician. If the radiology report becomes part of your child’s personal medical record, it may or may not have an effect on getting health insurance or life insurance in the future.

Please check the appropriate box regarding your decision to have your scan reviewed for incidental findings.

 **I DO** consent to have my child’s MRI scan reviewed for incidental findings.

 **I DO NOT** consent to have my child’s MRI scan reviewed for incidental findings.

#### Medical Treatment

Routinely, FIU, its agents, or its employees do not compensate for or provide free care for human subjects in the event that any injury results from participation in a research project. If your child becomes ill or injured as a direct result of participating in this study, contact his/her regular medical provider. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

### CONTACT INFORMATION

#### Who can I contact about this study?

Please contact the study coordinator or researcher below if you have any questions or concerns about this study, need to report an illness or injury, or if you cannot make your child’s scheduled appointment.

Principal Investigator

[Enter contact information]

Study Coordinator

[Enter contact information]

You may also address any concerns about a study to the Human Subjects Office located at 2010 Levy Avenue Suite 276, Tallahassee FL, 32306-2742. Or by phone at (850) 644-7900, Fax: (850) 644-4392, or email at jth5898@fsu.edu.

### SIGNATURES

#### Consent to Participate in the Research Study

I understand the information printed on this form and consent for my child to participate in this study.

I have discussed the procedures, risks, and benefits with research personnel and have had all of my questions answered.

I understand that I may ask questions at any time and that I am free to withdraw my child from the research project at any time. I understand that my child’s participation may be ended by the Principal Investigator or sponsor at any time.

I understand that I will be given a copy of this form for my records.

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Signature of Parent/Guardian Date

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Printed name of Parent/Guardian

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Printed name of Child

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Signature of Person Obtaining Consent Date