

NOTE TO INVESTIGATORS: This is the parent/guardian permission form with **HIPAA Authorization** included. We request that you submit to the RSRB a consent form where the text you have added is in black and all blue text is left unchanged.

We acknowledge there may be some deviations from the established language (all blue text) based on the nature of your study. Be sure to eliminate all brackets and eliminate this page before submission. Eliminate those paragraphs within the brackets which were for clarification.

[INSERT ELECTRONIC DEPARTMENT LETTERHEAD]

**Parent/Guardian Permission:**

**[Insert Title of Study]**

**Principal Investigator:** [Insert Name]

**Faculty Advisor:** [Insert or delete if not applicable.]

**This permission form describes a research study, what your child may expect if you give permission for he/she to take part and important information to help you make your decision. Please read this form carefully.**

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- There are risks from participating and you should understand what these mean to you.

**Introduction:**

Your child is being asked to take part in this study because [Specify condition, situation, circumstance or other reason for recruitment to study applicable.]

This study is being conducted by [insert investigator names] of the University of Rochester's Department of [insert department name].

**Purpose of Study**

The purpose of this study is to [Describe the general purpose of the study and include relevant background information in lay terms. If possible, limit the explanation to why study is being done to one or two sentences.]

**Description of Study Procedures**

If you decide to let your child participate in this study you will be asked to fill out a safety screening form to assess whether it is safe for your child to enter the MR room. It is important that you provide us with an accurate and up-to-date medical history, and when unsure to ask clarifying questions so that we can proceed safely. You will also be asked to fill in background questionnaire(s) as needed. Your child will then be asked to remove any metallic objects he or she may be carrying (for example, wallets, watches, earrings or piercings) and possibly to change clothing into a gown that we will provide (if

deemed necessary because of large zippers etc.). Then your child will be asked to lie still inside a MRI scanner. The MRI scanner is a large, tunnel-shaped machine. The MRI scanner produces a constant magnetic field that orients the molecules in your child's body. Pulses of radio waves are introduced to interact with the magnetic field of water molecules within the body, thereby generating detailed images of the body.

Your child will be asked to lie still on a table outside of the MRI scanner. His/her [head, or other body part if appropriate] will be kept still with padding so it cannot move; he/she should, however, be comfortable at all times. Once he/she is comfortable, the table on which he/she is lying will be moved inside the MRI scanner. The MRI scanner does not collect images at all times. Your child will know when the MRI scanner collects images because he/she will hear the thumping noise of the electrical switching of the magnetic field, and feel the associated vibrations. We will ask your child to stay as still as possible during these times (no sneezing, scratching, stretching etc). In between image collection, he/she will be able to stretch or move if needed. Your child will be able to communicate with us at all times via a built-in intercom. Your child will be holding an emergency bulb that he/she can squeeze at any time to let us know he/she wants to come out of the MRI scanner.

If you choose, your child will be able to see how it feels to be in a scanner by lying in the practice scanner which is not a real scanner but looks and sounds like one. Sometimes people feel more comfortable lying in the practice scanner first before they do the real scanner session. This will be your child's choice.

Once your child goes into the real scanner, he/she will be asked to lie still while [Describe the specifics of your study procedure here— Describe in plain language (i.e., using lay terms), step-by-step, what will be done or required of the research subject. Be concise; avoid describing study procedures in lengthy narrative form. All procedures should be listed in the consent form. If there are multiple steps, use sub-headings, bullets, tables, pictures, etc. Include where the study procedures will take place. If different procedures will take place at different locations, specify accordingly. If communication by email between study team and subject is intended (i.e., sending and receiving email), indicate in this section. See examples/sample language provided in the appendices of the RSRB's Guidance on Recruitment and Informed Consent.]

### **Number of Subjects**

Approximately [state total accrual goal (number) here] subjects will take part in this study. [If appropriate, give a short description about cohorts. If this is a multi-center study, provide figures for both the whole study and for local enrollment at UR (e.g., "Approximately 40 subjects from 4 study centers across the country will take part in this research. Locally, about 20 subjects will participate.")]

### **Duration of the Study**

Your child's participation in the study will last [Indicate the length of time of the individual subject's active involvement. If not previously stated in the procedures section, include

the expected time needed for study visits/procedures as well as the overall length of time.]

### **Risks of Participation**

[For each research procedure provide sufficient description of the risks to be consistent with protocol and application]

**Metal:** The MRI scanner produces a constant strong magnetic field, so if you have any metal implants and/or clips within his/her body they may shift position. Thus, if your child has such implants, it is hazardous to your health to participate in this study. Please provide us with as much information as you can, for example if your child has had surgery in the past, so that we may decide whether it is safe for his/her to be a subject. Metal earrings, metal body piercings, and necklaces must be removed prior to the study. Tattoos with metallic inks can potentially cause burns.

**Pregnancy:** Exposure to MRI scanning might be harmful to a pregnant female or an unborn child. Although there are no established guidelines at this time about MR and pregnancy, you should be informed that there is a possibility of a yet undiscovered pregnancy related risk. If you know or suspect your child may be pregnant or if you do not want to expose your child to this risk, we recommend that your child does not participate in this study.

**Inner ear damage:** MRI scanning produces a loud tone that can cause damage to the inner ear if appropriate sound protection is not used. Earplugs or close fitting headphones will be provided to protect your child's ears.

**Claustrophobia:** When your child is inside the MRI scanner, the MRI scanner surrounds his/her body. Your child's [head, or other body part if appropriate] will also be positioned inside a close-fitting scanning coil. If your child feels anxious in confined spaces he or she may not want to participate. If your child decides to participate and begins to feel claustrophobic later, he or she will be able to tell us via the intercom and we will discontinue the study.

**Burns:** In rare cases, contact with the MRI transmitting and receiving coil or conductive materials such as wires, or skin-to-skin contact that forms conductive loops, may result in excessive heating and burns during the experiment. The operators of the MRI scanner will take steps, such as using foam pads when necessary, to minimize this risk. Any heating or burning sensations during a scan in progress should be reported to the operators immediately.

Besides the risks listed above, there are no other known risks from the magnetic field or radio waves at this time. If new findings about the risks of the MRI technique become available during the time of the study, we will let you know about them.

**Use of E-mail:** Transmitting your information by e-mail has a number of risks that you should consider. These include, but are not limited to, the following:

- a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
- b) E-mail senders can easily misaddress an e-mail.
- c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.

- d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
- e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
- f) E-mail can be used to introduce viruses into computer systems.

### **Benefits of Participation**

[Choose or modify **ONE** of the following sentences as appropriate to the specific study:]  
Your child will not benefit personally from being in this research study.

- OR -

Your child might not benefit from being in this research study. The potential benefit to your child from being in this study might be [List any direct benefits to the subject that might reasonably be expected from the research.]

### **Sponsor Support**

The University of Rochester is receiving payment from [insert sponsor name] for conducting this research study.

[The RSRB requires that all consent forms disclose which agencies or institutions (e.g., National Institutes of Health, Department of Defense, Center for Disease Control, State agencies, foundations or industry sponsors) are funding the research.

If the study is not being funded by an external agency (i.e., Department funds or personal funds) this section may be deleted.

If the Principal Investigator or any other study personnel have a conflict of interest management plan involving the study sponsor and the plan requires disclosure of the conflict in the consent form, insert disclosure statement here.]

### **Costs**

[Choose or modify **ONE** of the following sentences as appropriate to the specific study:]  
There will be no cost to you to participate in this study.

- OR -

Some of the tests/procedures/exams [specify what tests/procedures/exams] you will receive are standard care. You and/or your insurance company will be responsible for paying for any tests/procedures/exams that are done as part of your standard care. You are encouraged to discuss your coverage with your insurance provider.

### **Payments**

[Choose **ONE** of the following options, plus additional applicable language, as appropriate to the specific study:]

You/Your child will not be paid for participating in this study.

-OR-

You/Your child will be paid [\$XX] for taking part in this study. [Specify who will be paid the parent or the child for participation, if parents and children will each receive payment, list each individually. If payment will be received for participation, specify the amount, schedule of payment and conditions for payment (e.g., You/your child will receive \$100.00 for each completed study visit. You/your child will not be paid for visits that your child does not complete. You/Your child will be paid up to a total of \$1200.00.). When applicable, payments should be based on a prorated system.]

-OR-

You/Your child will receive [XX] hours of departmental research credit.

[If applicable] Payment received for participation in research is considered taxable income. If you receive payment for your child's participation in studies at the University of Rochester and its affiliates of \$600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS.

[If applicable] You/Your child will not receive any money that may result from any commercial tests or products that are developed as a result of this study.

### **Circumstances for Dismissal**

Under some circumstances, it may be necessary to discontinue your child's participation in the study. This will be done at the discretion of the investigators, and your child will be paid for the amount of time he/she have participated in the study. For example, we may discontinue your child's participation if your child does not follow the instructions given, or if your child is unable to perform the tasks given. Every effort will be made, however, to accommodate your child's concerns. [Provide additional details as necessary.]

### **Early Termination** [If applicable]

[List any consequences for subject self-withdrawal (e.g., adverse health/welfare effects) and procedures for orderly termination of participation.]

### **Compensation for Injury**

The University does not provide any payment for problems that could result from your participation in the study.

### **Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes [For studies with which protected health information (PHI) is being collected]**

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will [insert protection measures]. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one. [Note to Investigators: the Notice must be provided and receipt documented if this is the first contact with URMC and Affiliates (copies available on web).]

*What information may be used and given to others?*

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study (only if you will be collecting information from the medical record)
- Results of medical tests (only if you will be conducting medical testing, labs, imaging, etc.)

*Who may use and give out information about you?*

- The study doctor and the study staff
- URMC and Affiliates

*Your information may be given to:*

- The Department of Health and Human Services
- The University of Rochester
- Include every organization or individual where data is shared (i.e., sponsors, sponsor agents [e.g., CRO], data monitoring committees, government agencies, foreign government regulatory agencies, companies, coordination centers, data management centers, other research sites, etc. who might receive, and/or use the information)
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private. [include for drug/device studies]

*Why will this information be used and/or given to others?*

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

*What if I decide not to give permission to use and give out my health information?*

Then you will not be able to be in this research study.

*May I review or copy my information?*

Yes, but only after the research is over.

*How long will this permission be valid?*

This permission will last indefinitely. [If you will destroy the records at a definite point that should be stated instead and should be consistent with what is listed in both your protocol and application.]

*May I cancel my permission to use and disclose information?*

Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

*May I withdraw from the study?*

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

*Is my health information protected after it has been given to others?*

No. There is a risk that your information will be given to others without your permission.

### **Confidentiality of Records**

The University of Rochester makes every effort to keep the information collected from your child private. In order to do so, we will [insert protection measures]. Sometimes, however, researchers need to share information that may identify your child with people that work for the University, regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

### **Conditions for the Use of E-mail** (If applicable)

The researcher cannot guarantee but will use reasonable means to maintain security and confidentiality of e-mail information sent and received. You and researcher must consent to the following conditions:

- a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
- b) E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
- c) E-mail communications between you and the researcher will be filed in your research record.
- d) Your messages may also be delegated to any member of the study team for response.
- e) The researcher will not forward subject-identifiable e-mails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.



- f) You should not use e-mail for communication regarding sensitive medical information.
- g) It is your responsibility to follow up and/or schedule an appointment if warranted.

**E-Mail Instructions** (If applicable)

- a) Avoid use of your employer's computer.
- b) Put your name in the body of the e-mail.
- c) Put the topic (e.g., study question) in the subject line.
- d) Inform the researcher of changes in your e-mail address.
- e) Take precautions to preserve the confidentiality of e-mail.
- f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

**Certificate of Confidentiality** (If applicable)

[For studies that have a federal Certificate of Confidentiality: Insert language provided by the federal agency that issued the certificate or insert the RSRB template language located on page 7 of the [Non-Biomedical Consent Form Template](#).]

**Contact Persons**

For more information concerning this research or if you feel that your child's participation has resulted in any emotional or physical discomfort please contact: [insert contact person's name] at [telephone number]

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 [insert country code (001) if applicable] for the following reasons:

- You wish to talk to someone other than the research staff about your child's rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

[If there are additional informational sources related to the study (e.g., client representatives, subject advocate or individuals at other study sites as appropriate), list

**Voluntary Participation**

Taking part in this study is voluntary. Your child is free not to take part or to withdraw at any time, for whatever reason. No matter what decision you and your child make, there will be no penalty or loss of benefit to which you or your child are entitled. In the event that your child does withdraw from this study, the information your child have already provided will be kept in a confidential manner. . [OR]

[Taking part in the study is completely voluntary. Your child is free not to take part or to withdraw at any time, for whatever reason. Your decision will not have any impact on

you or your child's participation in other studies conducted by [Federal agencies] and will not result in any penalty or loss of benefits to which you or your child are otherwise entitled]

**This is not a clinical evaluation**

The images of your child's [brain, or other body part if appropriate] collected in this study are not intended to reveal any disease state, in part because this MRI protocol is not meant for clinical diagnosis. Thus, your child's [brain, or other body part if appropriate] images will not be routinely examined by a clinical radiologist. However, if in the course of collecting images of your child's [brain, or other body part if appropriate] the MRI technologist or staff detect what could be a problem, we will let you know and give you referral information so you can get information about further diagnostic tests by a clinical radiologist.

\*\*\*\*\*

[Insert any checkbox options for future use of research data, future contact, audio/video recording, etc. If possible, checkbox options & signatures should appear all on one page.]

**SIGNATURE/DATES**

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

**PARENT/GUARDIAN PERMISSION**

I have read (or have had read to me) the contents of this permission form and have been encouraged to ask questions. I have received satisfactory answers to my questions. I agree to let my child participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

**PARENT/GUARDIAN:**

\_\_\_\_\_ **PRINT NAME**

**PARENT/GUARDIAN:**

\_\_\_\_\_ **SIGNATURE**

**DATE:** \_\_\_\_\_

**Child's Name:** \_\_\_\_\_

**Person Obtaining Permission**

I have read this form to the parent/guardian and/or the parent/guardian has read this form. I have provided the parent/guardian with a signed copy of this permission form. An explanation of the research was given and questions from the parent/guardian were solicited and answered to their satisfaction. In my judgment, the parent/guardian has demonstrated comprehension of the information.

\_\_\_\_\_  
Name and Title (Print)

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Name and Title (Print)