

**MIAMI CHILDREN'S HOSPITAL**  
**CONSENT TO PARTICIPATE IN RESEARCH**

Auditory and Visual Functional MR studies in Sedated Children

Date: \_\_\_\_\_

**PURPOSE:**

You are invited to consent the participation of your child in a study of hearing and visual ability using Functional Magnetic Resonance Image. This procedure uses a strong magnet and radiowaves to make images of the inside of the body. This radiowaves produce signals that becomes stronger when your child are hearing or seeing In that way we can see the function of the brain. We expect to learn the best use of this new capability in imaging the function of the brain. In particular, we want to see whether this technique can *identify visual or auditory function despite the condition of sedation* of your son/daughter, involved in the current examination.

**PROCEDURE:**

Your son/daughter was selected as a possible volunteer for this study. If you decide to consent his/her participation, Dr. Bernal or a designated representative will describe the procedure to you. After accomplished the exam solicited for your child, he/she will be 10 to 20 minutes more in the exam room. During this time your son/daughter will receive tones, voice or images through headphones or special goggles, while the machine follows gathering information. During the whole procedure your child will be sedated. There wont be pain or discomfort for the patient. The intensity of the sounds and images have been tested before to guarantee they are in a secure range The stimuli will be: (checked in front)

- \_\_\_\_ 1. Passive display of flicker light on goggles
- \_\_\_\_ 2. Passive hearing of pure tones
- \_\_\_\_ 3. Passive hearing of mother sound (if previously recorded)
- \_\_\_\_ 4. Passive hearing of music
- \_\_\_\_ 5. Passive hearing of speech, non mother-voice

At the discretion of the principal investigator subjects may be taken out of this study.

**RISKS AND SIDE EFFECTS:**

The risk, if any, are the same of the main examination asked by his/her doctor. There are no known significant risks or side effects with this procedure at this time, since the radiowaves and magnetic fields, at the strengths used, are felt to be without harm. The exception is if your child has a cardiac pacemaker, or a certain type of metallic clip in his/her body. It is important that all metallic objects be removed from your child prior to approaching the high field strength magnet, as these objects may be attracted to the magnet. There are conservative Federal guidelines for radiowave exposure and our examinations fall within those guidelines. We feel these are safe levels. You will be told if any new information is learned which may affect the condition or influence your willingness to continue the participation of your child in this study.

**BENEFITS:**

There are no overt direct benefits to you or your child for participating in this study. You will contribute to the development and testing of new methods of examination. This contribution will increase our understanding of the development of brain function and might help patients with

various mental and neurologic disorders. WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

**ALTERNATIVES:**

None

**ADDITIONAL EXPENSES:**

None are expected, but if something happens requiring additional care, you are responsible for the payment for that care.

**CONFIDENTIALITY:**

You understand that a record of your child's study will be kept at **Miami Children's Hospital**. Information from this study may be reviewed by the sponsor, the U.S. Food and Drug Administration (FDA), other governmental agencies or authorized agents of the hospital. The results of this research project may be presented at meetings or in publication, but you/your child's identity will not be disclosed.

**QUESTIONS:**

You have the right to have your questions answered during the research. If after discussing everything with the researchers you are not satisfied you may call Dr. Lifschitz (ext. 2563) the Chief of Staff or Dr. Michael Duchowny (ext. 2381) the Chairman of the Institutional Review Board which regulates research on patients.

**INJURY:**

There are not risks of injury in this procedure as was mentioned before. Nevertheless in the event that injury occurs as a result of this research, treatment available at Miami Children's Hospital will be provided, but you will be responsible for payment for the treatment.

**YOU WANT TO STOP PARTICIPATING**

You/your child may refuse to participate in the research, and you may stop you/your child participation at any time. Just tell the nurse or doctor you do not want to continue. If you do so, the medical care of your son/daughter will continue as usual.

**PERMISSION TO PROCEED:**

Your signature indicates that you have read in your language (\_\_\_\_\_) and understand the above information; that you have discussed this study with the Principal Investigator and his or her staff; and that you have decided consent the participation of your child in this research based on the information provided and that a copy of this form has been given to you. **Please do not sign anything until the nurse or doctor is with you.**

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**CONSENT TO PARTICIPATE IN RESEARCH**

**INFORMED CONSENT:**

I, \_\_\_\_\_ hereby freely consent to place \_\_\_\_\_ Your Name..... Patient's Name..... in the research study "**AUDITORY AND VISUAL FUNCTIONAL MAGNETIC RESONANCE IN SEDATE CHILDREN**".

**I have read and understand this "Consent to Participate in Research" and am fully aware of what I am signing. I have received a copy of what I am signing. I know that I can withdraw my permission to participate at any time without compromising hospital care to my child.**

\_\_\_\_\_  
Signature of Parent or Guardian, or ..... Date .....Signature of Witness .....Date  
.....

.....of patient >age 13....

**I certify that I have reviewed the contents of this form with the persons signing above. I have explained the known risks and benefits associated with this study. In my opinion, the persons signing above understand the contents of this form.**

\_\_\_\_\_  
Physician's Name (typed or printed) .....Physician's Signature .....Date

\_\_\_\_\_  
Witness' Name (typed or printed) .....Witness' Signature .....Date