

Use the following wording in HIC application and HIC consent forms:

Risks and Inconveniences

Magnetic resonance (MR) is a technique that uses magnetism and radio waves, not x-rays, to take pictures and measure chemicals of different parts of the body. The United States Food and Drug Administration (FDA) has set guidelines for magnet strength and exposure to radio waves, and we carefully observe those guidelines.

Your child will be watched closely throughout the MR study. Some people may feel uncomfortable or anxious. If this happens to your child, he/she may ask to stop the study at any time and we will take your child out of the MR scanner. On rare occasions, some people might feel dizzy, get an upset stomach, have a metallic taste or feel tingling sensations or muscle twitches. These sensations usually go away quickly but please tell the research staff if your child has any of these symptoms.

There are some risks with an MR study for certain people. If your child has a pacemaker or some metal objects inside his/her body, your child may not be in this study because the strong magnets in the MR scanner might harm him/her. Another risk is the possibility of metal objects being pulled into the magnet and hitting your child. To lower this risk all people involved with the study must remove all metal from their clothing and all metal objects from their pockets. We also ask all people involved with the study to walk through a detector designed to detect metal objects. It is important to know that no metal can be brought into the magnet room at any time. Also, once your child is in the magnet, the door to the room will be closed so that no one from outside accidentally goes near the magnet.

We want you to read and answer very carefully the questions on the MR Safety Questionnaire related to your child's personal safety. Take a moment now to be sure that you have read the MR Safety Questionnaire and be sure to tell us any information about your child that you think might be important.

This MR study is for research purposes only and is not in any way a complete health care imaging examination. The scans performed in this study are not designed to find abnormalities; however, we will provide the images of your child to a neuroradiologist to review. Based on his or her recommendation (if any), the principal investigator or consulting physician will contact you, inform you of the finding regarding your child, and if necessary, recommend that your child seek medical advice as a precautionary measure. We will make your child's images available to you and your physician. The decision for additional examination or treatment would lie only with you and your child's physician. The investigators, the consulting physician, the Magnetic Resonance Research Center, and Yale University are not responsible for any examination or treatment that your child receive based on these findings.

Contrast Risks and Procedures Statements.

Having an intravenous (IV) line placed is a very safe procedure. There is a slight chance that multiple needle-sticks will be needed to make sure the IV is placed correctly. Your child might feel a small amount of pain when the IV is placed but it does not last very long. A bruise or a minor infection might develop where the IV is placed. A bruise will go away by itself and it might help if you wrap a warm towel around your child's arm. Infections can also be treated if necessary.

The FDA approves the contrast agent Gadolinium for use with human participants. You need to know that there are certain risks associated with the use of that contrast. Some healthy

subjects (fewer than 3%) may experience mild nausea, headache or dizziness after the injection. These side effects usually go away themselves without need for treatment. There is also a risk of allergic reaction (less than 1%). An allergic reaction can cause hives and itching or difficulty breathing. In individuals with kidney dysfunction, the gadolinium can cause a serious condition called nephrogenic systemic fibrosis. This is why prior to the MR study your child will have to undergo blood work to make sure that his or her kidney function is normal. Detailed information on the contrast agent Gadolinium can be provided to you at your request.

You should tell your principal investigator: (1) if your child is pregnant or breast feeding, (2) if your child has a history of allergic reactions to MR or CT contrast agents, (3) if your child has a history of kidney disease, seizure, asthma, or allergic respiratory disorders, and (4) if your child has anemia or disease that affects red blood cells.