KF IRB STANDARD LANGUAGE

**Language for Magnetic Resonance Imaging Procedures**

**Procedure for Structural MRI**

Magnetic resonance imaging (MRI) uses a strong magnetic field and radio waves to take pictures of your (your child’s) brain. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRI, you (your child) will lie on a table that can slide in and out of the cylinder. You (your child) will be in the scanner about *(insert time)* minutes. You (your child) may be asked to lie still for up to *(insert time)* minutes at a time. While in the scanner you (your child) will hear loud knocking noises, and you (your child) will be fitted with earplugs or earmuffs to muffle the sound. You (your child) will be able to communicate with the MRI staff at all times during your scan,and you (your child) may ask to be moved out of the machine at any time.

It is very important for the experiment that you do (your child does) not move your (his/her) head or body inside the scanner. We will use padding, a vacuum bag or expanding foam around your (your child’s) head to help keep it in place.

**Procedure for Functional & Structural MRI**

Magnetic resonance imaging (MRI) uses a strong magnetic field and radio waves to take pictures of your (your child’s) brain. Functional MRI (fMRI) allows us to see what parts of the brain are used when you do (your child does) a task. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRI, you (your child) will lie on a table that can slide in and out of the cylinder. A device called a “coil” will be placed over your (your child’s) head. Before the scan, you (your child) will be told about the task that you (your child) will do during the scan and you (your child) may have the opportunity to practice. (*If applicable:*) There is a computer screen that you (your child) can see when you are (he/she is) inside the scanner. The screen will show you (your child) the information about the task to be performed.

You (your child) will be in the scanner about *(insert time)* minutes/hours. During the scan, you (your child) may be asked to do the study task or you (your child) may be asked to lie still for up to *(insert time)* minutes at a time. While in the scanner you (your child) will hear loud knocking noises and you (your child) will be fitted with earplugs or earmuffs to muffle the sound. You (your child) will be able to communicate with the MRI staff at all times during the scanand you (your child) may ask to be moved out of the machine at any time.

It is very important for the experiment that you do (your child does) not move your (his/her) head or body inside the scanner. We will use padding, a vacuum bag or expanding foam around your (child’s) head to help keep it in place.

**Procedure for Magnetic Resonance Spectroscopy**

Magnetic resonance spectroscopy (MRS) uses a strong magnetic field and radio waves to take pictures of various chemicals in your (your child’s) brain using an MRI scanner. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRS scan, you (your child) will lie on a table that can slide in and out of the cylinder. You (your child) will be in the scanner about *(insert time)* minutes. You (your child) may be asked to lie still for up to *(insert time)* minutes at a time. While in the scanner you (your child) will hear loud knocking noises, and you (your child) will be fitted with earplugs or earmuffs to muffle the sound. You (your child) will be able to communicate with the MRI staff at all times during the scan,and you (your child) may ask to be moved out of the machine at any time.

It is very important for the experiment that you do (your child does) not move your (his/her) head or body inside the scanner. We will use padding, a vacuum bag or expanding foam around your (your child’s) head to help keep it in place.

**Language for Risks associated with MRI, fMRI & MRS**

**Risks for MRI, fMRI & MRS:**

People are at risk for injury from theMRI magnetif they have pacemakers or other implanted electrical devices, brain stimulators, particular types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metallic prostheses (including metal pins and rods, heart valves, and internal hearing aids [cochlear implants]), permanent eyeliner, implanted delivery pumps, or shrapnel fragments. Welders and metal workers are also at risk for injury because of possible small metal fragments in the eye of which they may be unaware. You (your child) will be screened for these conditions before each scan you have (your child has), and if you have (your child has) any, you (your child) will not receive an MRI scan. If you have a question about any metal objects being present in your (child’s) body, you should inform the staff. In addition, all magnetic objects (for example, watches, coins, jewelry, and credit cards) must be removed before entering the MRI scanning room. You (your child) may also be asked to remove your (his/her) shoes. You will also be asked to complete an MRI screening form for each MRI scan you have (you child has).

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. Some may experience dizziness or paresthesia (tingling or numbness). The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, you (your child) should let us know right away. Please notify the investigators if you have (your child has) hearing or ear problems.

There are no known long-term risks of MRI scans.

Language Added to Parental Permission Form when minor is to undergo an MRI scan as part of a research protocol:

This research study requires that my child undergo an MRI scan. Before he/she is scheduled for the actual MRI scan, he/she will attend a screening and practice session where the scanning procedure will be explained and where my child will be screened to be sure that an MRI scan is safe for him/her.

When my child undergoes the MRI scan, I will be in a room next to the scanner where I can see my child. He/she will be able to talk to the MRI technician during the scan. If my child wants to end the scan for any reason, the scan will be stopped and he/she will be removed from the scanner.

Adolescents 13 to 17 will read and sign the parental permission form before being enrolled in the study. Children 12 and under will be provided with an age-appropriate assent form with a description of the study procedures and risks.

**Pregnancy Issues For Research MRI Scans**

It is not known if an MRI scan is completely safe for a developing fetus. Therefore, pregnant females will be excluded from MRI scanning.

  *Language for females 18 years and older:*

If you answer yes or “not sure” to the question below, your will be required to take a urine pregnancy test to participate in this study.

 Is there any chance that you can be pregnant? Yes [ ] No [ ] Not Sure [ ]

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature

*Language if minors will be scanned*

**Pregnancy Questions for Minor Females**

*For parental permission form:*

Relating to girls who are potential research subjects in this study that requires an MRI scan and who are 12 years old or older or who are younger than 12 and have had their first menstrual cycle:

 This study requires an MRI scan. Before my daughter can enroll in this research study a female research staff member will ask her to complete a pregnancy form that includes a question asking if there is any chance that she could be pregnant. Girls who are pregnant cannot take part in this study because it requires an MRI scan. If my daughter is uncertain about being pregnant and still would like to participate in this study, she can take a urine pregnancy test here at Kessler. If the test is negative, she may choose to enroll in the study. If the pregnancy test is positive, a female member of the study staff will inform her of the result and she will be offered counselling by a Kessler doctor. My daughter will be given the option of having a parent or guardian present while she completes the pregnancy form and during any counselling session.

**Language for Incidental Findings**

**Incidental Findings**

ALL RESEARCH PARTICIPANTS MUST UNDERSTAND THE FOLLOWING:

I understand that the brain images from this MRI study WILL NOT be used to diagnose medical problems.

The MRI scans that will be performed in connection with the study I am (my child is) participating in are not necessarily equivalent to the type of MRI scans more commonly used to diagnose medical problems. Many potentially serious medical problems may be undetectable on the scans performed in this study.

The MRI scans performed for this study are not designed to detect or diagnose medical problems. This means that an abnormality of the brain may go undetected in the brain images we collect. If I am (my child is) experiencing physical symptoms or otherwise have concerns about my (child’s) health, I should see my (child’s) primary care physician or specialist physician.

Because the purpose of the MRI scan is not to diagnose or identify medical problems I (my child) may have, neither Kessler Foundation, its researchers, staff or employees are responsible for identifying any medical conditions I (my child) may have.

If in reviewing the MRI scans, the study staff sees something that should be reviewed by a radiologist, the scans will be sent to a Rutgers radiologist for second review.  In that case, a Kessler physician will coordinate with the Rutgers radiologists and communicate any clinically important findings to me and (my child’s) physician.

By signing below I acknowledge my understanding of and agreement with the foregoing:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name

**Courtesy Copy for your Physician**

☐ I would like Kessler Foundation to provide a copy of my MRI scan results to my (child’s) physician. My (child’s) physician’s contact information is:

Please Print:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physician Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physician Address

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physician Telephone Number

☐ I do not want Kessler Foundation to provide a copy of my MRI scan results to my (child’s) physician.

**Language for Limited Access to Research Results**

By agreeing to (allow my child to) participate in this study, I do not waive any rights that I may have regarding access to and disclosure of my (child’s) records.

**Language for Medical Therapy for Injury**

**Medical Therapy for Injury**

If I participate (my child participates) in this study, I (he/she) will be exposed to certain risks of physical injury. Medical therapy will be arranged for me (my child) by the Principal Investigator for any physical injury to me (my child) that occurs as a direct result of my (child’s) participation in this research.  My health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical therapy.  I understand that I will be responsible for any portion of the cost of therapy not paid by my insurance or managed care provider.  No financial compensation is offered to me in the event of physical injuries sustained as a direct consequence of my (child’s) participation in this research.