

ASSENT FORM – CROSS-SECTIONAL COHORT

STUDY TITLE: PEDIATRIC FUNCTIONAL NEUROIMAGING RESEARCH NETWORK

SPONSOR NAME: National Institute of Child Health and Human Development

SPONSOR STUDY NUMBER: HHSN275200900018C

INVESTIGATOR INFORMATION:

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WHAT IS RESEARCH?

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things. Being in research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.

WHY ARE WE DOING THIS RESEARCH?

In this research study we want to learn more about the way the brain works when you are paying attention to things around you, and when you are listening and talking.

We are asking you and other children like you with good grades to be in the research, because we want to know all about the normal human brain.

WHAT WILL HAPPEN IN THE RESEARCH?

1. First, you will come in and visit us so that we can show you the magnet that will take pictures of your brain.
2. When you go home, you will watch a video and listen to some noises on a CD. This will help you get ready for your next visit.
3. At your next visit, you will meet with a doctor who will make sure that you have good balance and reflexes. Remember when you are at the doctor and he taps your knee and your leg jumps? This is the kind of thing this doctor will be doing.
4. Also, we are going to test your ears to make sure you can hear everything really well.
5. Before we go near the magnet, we will ask you to take off all of your jewelry and other

metal things.

6. We may also put a cap, sort of like a swimmer's cap, on your head before you go into the scanner. We use some sticky stuff with the cap but it will easily wash out of your hair later. This cap measures your "brain waves" so we can tell if you are awake, asleep, or drowsy in the scanner.
7. You will lay down on a table that slides into the magnet, and the research staff will give you some headphones so that you can listen to sounds. They will also put your head in a coil, kind of like a tube with some openings in the sides. This coil is what helps the magnet take pictures of your brain.
8. The study staff will be able to hear you the whole time you are in the magnet, and they will talk to you sometimes, too. You will have a special button that you can press if you get scared and you want to be finished.
9. While the magnet is taking pictures, you will be asked to do some simple tasks. These might be things like tapping your fingers together, looking at pictures, or listening to stories.
10. When the magnet is finished taking pictures, we will come get you. Then, your visit with us is over and you get to go home.
11. We might ask you to come in for another visit within a few weeks of your first visit. If you come back, we will ask you to repeat some of the things that you did while the magnet was taking pictures. We want you to come in two times so we can get as many pictures of your brain as possible!
12. We might ask you to come in for another visit, too. At this other visit, we will do some testing in a room to help us find out more information about how well you read, learn, and move. Some of these tests will be like games, but others might be kind of hard. Remember to try your best but that if you get tired and want to stop, we will let you.
13. We might ask you to complete a questionnaire describing the development of your body on a scale of 1-5, compared to photographs of normal development through puberty.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this research may not help you right now. When we finish the research, we hope that we will know more about the way the brain works. This may help other children who have problems with their brain later on.



WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

The magnet that takes pictures of your brain is very safe. You might feel like the space that you are laying in is a little small, but if you don't feel good and want to stop, we will come get you right away. If you have the cap on your head, it can feel a little uncomfortable for a while, but please let us know if it does not feel good so we can fix or remove it. Also, we make sure that you don't have any metal on you before you go near the magnet. This is because the magnet pulls on metal and we don't want any bad things to happen.

WHAT ELSE SHOULD YOU KNOW ABOUT THE RESEARCH?

Being in the research is your choice. You can say Yes or No. It is OK to say No. No matter what you decide, we will still take good care of you.

If you say Yes now and change your mind later that is also OK. You can stop being in the research at any time.

If you want to stop being in the research, all you have to do is tell one of the doctors or nurses here at the hospital.

Take all the time you need to make your choice. Ask us any questions you have.

It is also okay to ask more questions after you decide to be in the research. You can ask questions at any time.

CHILD'S ASSENT

After you have read this form and talked about this research with your parents and the doctors or nurses you need to decide if you want to be in this research.

If you want to be in this research you should sign or write your name below.

Child's Assent

Date

Signature of Person Obtaining Assent

Date