

**INFORMATION AND ASSENT TO TAKE PART IN A STUDY TITLED:****Discovery Science of Human Brain Function Across the Lifespan  
(Children Ages 11-17 years)****Nathan S. Kline Institute For Psychiatric Research (NKI)  
140 Old Orangeburg Rd, Orangeburg, NY 10962****Participants Name:** \_\_\_\_\_**Participant ID #:** \_\_\_\_\_**Project Directors:** **Michael Milham, M.D.**  
**Russell Tobe, M.D.****Phone: 845-398-5469**  
**Phone: 845-398-6556****PURPOSE: (Why are you here?)**

You are being asked to help in a study. Your parents said it is okay for you to be in the study, now we are asking you if you want to be in the study. Even if your parents want you to be in the study, you don't have to if you don't want to. We are looking for kids to help us learn how the brain is connected with the ways people think and feel. We also want to learn about your genes, a part of your blood that you get from your parents when you are born.

**PROCEDURES: (What will happen?)**

For this study, you will come in two times. For the first visit, we will explain the study and go over all of the procedures you will be doing. We will answer any questions you may have and if you decide you want to participate in the study then you will sign this form indicating your agreement. We will also collect your height, weight, blood pressure and take some physical measurements.

During the second visit, we will ask you some questions about what you are thinking, feeling, and doing. We will ask you and your parents some questions about your health and your experiences growing up. Some of the questions may be about tough topics like feeling worried or using drugs. We will also ask you do some puzzles, look at pictures, and answer some questions.

As part of the data collected for the study we will ask you to pee in a cup so we can test for recent drug use. You and your parent/guardian will be informed of the test results. The drug test we use is the Alere iCup® DX which is not 100% accurate and only provides preliminary results. If you or your parent/guardian declines the drug test you can still continue in the study. We will take some blood from your arm using a needle. You can have breakfast in the morning before coming in for the study. We will also ask you to ride an exercise bike for a few minutes.

We will also take pictures of your brain with a special MRI machine that makes loud noises. These pictures of your brain help us to understand how your brain works while you are relaxing. We will ask you to lay as still as possible while in the MRI machine.

We will also have you wear something on your wrist that looks like a watch. It helps tell us how much you move around. We will have you wear it in between your first and second visits while at home doing your regular activities and while you sleep. You should keep it on until your mom or dad tells you to take it off.

**RISKS: (Will it hurt?)**

Yes, the needle we use to take blood from your arm may hurt a little. Attempting the blood draw is required for participation in the study. Some children are scared to have their blood drawn. If you decline the blood

draw for any reason, then we will speak to the Research Investigator, who will then decide if you can continue participation in the study. If you are worried about the blood draw, we can give you some cream that will make your arm feel a little numb before we do it. We may also use our Buzzy Bee on your arm, which will help make you more comfortable. It is you and your Parents choice if you want to use these while getting your blood drawn.

Sometimes people feel nervous about the types of questions we ask. Some of the questions may be about tough topics like feeling worried, using drugs, your sexual feelings, if you are sexually active, and about your sexual behaviors. If you are nervous, you can always take a break, choose not to answer a question or stop at any time. If you do not want to answer a question, you do not have to, just ask and we will skip it.

Having the pictures of your brain taken does not hurt. Metal is not safe in the machine, so we will ask you to take off your watch, belt, and anything else with metal before we take you in to take the pictures.

If you are a girl and you are pregnant or think you might be pregnant, we will not put you in the machine. If you are old enough, we will do a pregnancy test.

Some people who have tattoos feel a small tingling or heating on the area with the tattoo during the scan. If you have any tattoos and you notice a feeling like that please tell the person running the machine and we will stop.

**MRI SCAN: (What happens?)**

We will take pictures of your brain with a special machine. You will lie down on a table and the table will slide back into a large tube. Your mom or dad can sit with you next to the tube if you would like. While in the scanner we will take many types of pictures, including some while you view a flashing checkerboard and some while you are asked to briefly hold your breath. You may hear loud noises like knocking or beeping while the pictures are being taken. We will give you earplugs or headphones to make it less noisy. If you ask, we can stop the machine at any time and you can get out.

If you are a girl and you are pregnant or you think you might be pregnant, we will not put you in the machine. If you are old enough, we will do a pregnancy test.” You and your parent/guardian will be informed of the test results. If the results are positive you cannot have the MRI scan, but you can continue in the study. If you or your parent/guardian decline the pregnancy testing you cannot have the MRI scan, but you can continue in the study. Confidential pregnancy testing is available outside of NKI and if requested we can give you information about where you can go for the testing.

**BENEFITS: (How may it help you?)**

This study is not designed to benefit you. We hope that this study help other children in the future.

**ALTERNATIVE TO PARTICIPATING IN THE STUDY (Can you say “No”?)**

You can say always say “no” and not be in this study. You may choose not to answer anything we ask you. If you do not want to do any of the tests or questions, it is always okay to say no. No one will not be upset with you if you say “no” or if you say “yes” and then change your mind.

**CONFIDENTIALITY (Is this private?)**

Everything that is talked about is private unless the person who asks you questions thinks that you may hurt yourself or someone else. If we are worried about safety, we will tell the right adults to make sure everyone is safe. Also, if we think someone may be hurting you, we will also tell the right adults to keep you safe.

To help protect your privacy, we have obtained a Certificate of Confidentiality from the government that says we don't have to tell other people what you tell us, even if a judge asks us under court subpoena. However, you should know if you tell us that you or someone else may be in serious harm, we will take steps to get help, including notifying authorities.

**PAYMENT FOR PARTICIPATION (Do I get Paid?)**

Yes. You will get paid if you take part in the study. At the end of the first visit you will get paid \$15 and your PARENT/GUARDIAN will also be paid \$15. At the end of the second visit you will get paid \$75 and your PARENT/GUARDIAN will be paid \$25. After you complete the computer questionnaires you will be paid \$20 and your PARENT/GUARDIAN will be paid \$25. This money will be given to you at the end of your second visit.

You will also be paid \$25 for wearing and returning the actigraph watch in between your visits, and this will also be paid to you at the end of Day 2.

If there is a problem with the MRI machine and you come back for a third visit you get paid \$25.

**BEFORE SIGNING:**

- You have been told what needs to be done to be in the study.
- You have been told that you do not have to do any of the tests or answer any study questions, if you do not want to.
- You have also been told that you can stop any time you want, even after you start.

If you would like to learn more about the study, you can read your parent's permission form and ask Dr. Milham or Dr. Tobe questions.

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Printed Name of Child

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Signature of Child

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Reading and Obtaining Assent

\_\_\_\_\_  
Signature of Person Reading and Obtaining Assent

\_\_\_\_\_  
Date