

Approval Date: 11/8/16

Expiration Date: 7/25/17

Initials: \_\_\_\_\_

Participant ID # \_\_\_\_\_

**INFORMATION AND ASSENT TO TAKE PART IN A STUDY TITLED:****Longitudinal Discovery of Brain Developmental Trajectories****(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., PhD****Phone: 845-398-5469****Russell Tobe, M.D.****Phone: 845-398-5432****PURPOSE: (Why are you here?)**

You are being asked to help in a study. Your PARENT/GUARDIAN 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 PARENT/GUARDIAN wants 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 five times. You may have already spent two days with us in a prior study, in which case you will come in three times for this study.

Visits 1 will last approximately 50 minutes. On this 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. During this visit we will also collect your height and weight, take your blood pressure, and take measurements using a tape measure. 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 while you are here and at home while you sleep. You should keep it on until your PARENT/GUARDIAN tells you to take it off.

Visit 2 will last most of the day, about 7 hours which is about as long as a day at school. We will have lunch for you and your PARENT/GUARDIAN on this visit. During this 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 to 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 lie as

still as possible while in the MRI machine.

In between Visits 1 and 2 we will ask you to complete some computerized questionnaires at home and answer questions about your mood, feelings, eating and sleeping habits, and different experiences you may have had in your life.

Visit 3 is a short visit where you will come in to have another MRI and answer some questionnaires on the computer. This visit will last about 3 hours. Since you will be here for such a short amount of time, lunch will not be provided on this visit.

Visits 4 and 5 will last most of the day (about 7 hours). We will give lunch to you and your PARENT/GUARDIAN for both of these visits as well. On these visits you will be asked to complete some more puzzles, questionnaires on the computer, and meet with staff to talk about your mood, feelings and different experiences you may have had in your life. You will also have another MRI on both of these visits. We will also measure your height and weight again and ask to take some blood from your arm using a needle. You can eat breakfast before these visits and can still participate in the study if you decide not to have your blood taken.

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

Yes, the needle we use to take blood from your arm may hurt a little. Attempting the blood draw is mandatory for participation. If you do not want to do the blood draw, 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. 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.

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 PARENT/GUARDIAN 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 helps 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 and only the people working on this study will be able to look at the information we collect. However, if the person who asks you questions thinks that you may hurt yourself or someone else, we may need to tell your PARENT/GUARDIAN or other 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. If the pregnancy test that you complete is positive, we will tell you this first. However, we will need to tell your PARENT/GUARDIAN after we tell you. If you do not want your parent to be informed, you can choose not to be in the study.

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.

On the 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> visits you will get paid \$100 and your PARENT/GUARDIAN will get paid \$25.

If we have a problem with the MRI machine and you come back again we would pay you \$25. Your parent will also get paid for answering questions.

**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 questions.

---

Printed Name of Child

---

Signature of Child

---

Date

---

Printed Name of Person Reading and Obtaining Assent

---

Signature of Person Reading and Obtaining Assent

---

Date