

INFORMATION AND ASSENT TO TAKE PART IN A STUDY TITLED:**Longitudinal Discovery of Brain Developmental Trajectories****Assent form – Children age 6 to 10**

Nathan S. Kline Institute for Psychiatric Research (NKI)

140 Old Orangeburg Rd, Orangeburg, NY 10962

Child's Name: _____ **Participant ID #:** _____

Project Directors: Dr. Michael Milham and Dr. Russ Tobe

PURPOSE: (Why are you here?)

You are being asked to help in a study. Your PARENT/GUARDIAN said it is okay 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.

Visit 1 is a short visit which will last about 50 minutes and you will learn about the study, sign this form if you want to participate, and we will answer any questions you may have about your participation. We will also collect your height, weight, and take your blood pressure using a small machine that listens to your heart rate. We will use a tape measure to measure your waist as well.

Visit 2 will last most of the day, about 7 or 8 hours, which is about as long as a day at school. We will give lunch to you and your PARENT/GUARDIAN on this visit.

In between your first and second visit, we will ask you and your PARENT/GUARDIAN to complete some questions on the computer about how you think and feel, as well as different experiences you might have had in your life. These can be completed at home whenever you have time in between visits and should take you about 1-2 hours to complete.

We will ask you to ride an exercise bike for a few minutes or until you ask to stop.

We will also ask you to wear a small watch called an actigraph in between your visits that measures how active you are and how much you sleep.

Visit 3 is a short visit where you will come in to have another MRI. This visit will last about 2 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 you lunch to you and your PARENT/GUARDIAN for both of these visits.

If you and your PARENT/GUARDIAN decide to be in this study, we will ask you some questions and give you some forms to fill out about what you are thinking, feeling, and doing. We will ask you and your parents some questions about your health and your 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.

We will measure your height and weight. We will take some blood from your arm. We ask that you try the blood draw. If you are afraid to have your blood

drawn, we will speak to the study doctor and see if you can still be in the study. You can have breakfast in the morning before coming in to the study.

We will also take pictures of your brain with a special machine that makes loud noises. These pictures of your brain help us to understand how your brain works while you are relaxing. We will have you practice holding still and listening to the loud noises in a special machine before we take the pictures.

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.

RISKS: (Will it hurt?)

We will use a needle to take blood from your arm that might hurt a little. Attempting the blood draw is mandatory for participation. If you do not want to have your blood taken, we will speak to the Research Doctor who will decide if you can continue 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 might be about using drugs or about sexual feelings. If you feel nervous we can take a break or you can skip a question and not answer it. You can always stop taking part in the study.

Having the pictures of your brain taken with the MRI 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 you have the pictures taken.

MRI SCAN: (What happens?)

We will take pictures of your brain with a special machine called an MRI. An MRI is kind of like a big, long white tube. You will lie down on a table and the table will slide back into the tube. The MRI pictures will take about one hour. Your PARENT/GUARDIAN can sit with you next to the tube if you would like.

When you are in the MRI we will take pictures of your brain. We will take some pictures while you look at a flashing checkerboard and some when we ask you to 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.

BENEFITS: (How may it help you?)

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

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

You can say “no” at anytime and not be in this study. If you do not want to do any of the tests or answer questions, it is okay to say no. No one will not be mad 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 parents 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.

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 third, fourth, and fifth days you will get \$100 and your PARENT/GUARDIAN will get paid \$25.

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

BEFORE SIGNING: Before you sign this form let me make sure I told you everything about taking part in the study.

- 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 have any questions about the study, you can ask Dr. Milham or Dr. Tobe.

Printed Name of Child

Signature of Child

Date

Printed Name of Person Reading and Obtaining Assent

Signature of Person Reading and Obtaining Assent

Date