

**CONSENT/PARENT PERMISSION FORM TO PARTICIPATE
IN THE STUDY TITLED
“LONGITUDINAL DISCOVERY OF BRAIN DEVELOPMENTAL TRAJECTORIES”**

**Nathan S. Kline Institute For Psychiatric Research (NKI)
140 Old Orangeburg Rd, Orangeburg, NY 10962**

Participant Name: _____ **Participant ID:** _____

Project Directors: Michael Milham, MD, PhD, Russell Tobe, MD

THE PURPOSE OF THIS RESEARCH IS: The goal of this study is to understand more about our mental health by finding out how our brains are connected to how we think, what we feel and what we do. We want to see how our brains change from early childhood through young adulthood. We also want to see how our genes are related to the way our brain works. We will share data from this study with other scientists around the world as a way of making more discoveries about the way our brains work. As described more fully below, the data and scans will be provided in a form that does not include any identifiers except the County you live in.

THE FOLLOWING PROCEDURES WILL BE INVOLVED:

Before your child can be in the study you will be asked to sign this consent form and your child will be asked to sign an assent form.

If you choose for your child to be in this study, you and your child will complete 5 visits. Though individual experiences vary, the first visit will take approximately 50 minutes and the second visit will take approximately 7 hours to complete. In between the first and second visits, you and your child will be asked to complete some study assessments at home which are computer based and require internet access. This will take approximately 2 hours to complete. The third visit will take place within 3 weeks of the second, and will take approximately 1.5 hours. The fourth visit will take place within 15 months of the third visit, and will take approximately 8 hours. The fifth visit will take place within 15 months of the fourth visit, and will take approximately 8 hours.

If you and your child have already participated in the study “Discovery Science of Human Brain Function Across the Lifespan,” you will only complete study visits 3, 4 and 5.

On the first screening visit, you and your child will be asked to do these activities:

- Meet with research staff to go over this consent form and answer any questions you or your child may have. If you decide to participate in this study, you will sign this consent form indicating your participation interest and agreement and your child will sign an assent form.
- Give general information about you and your child such as your gender, ethnicity and education level.
- We will measure your child’s vital signs (blood pressure, pulse rate, height and weight), and take their waist and hip measurements.
- We may ask your child to wear a watch like device (actigraph) around their wrist in between the first and second visits. One of the study staff will provide you with details about when to wear the watch. This device will tell us about your child’s physical activity while he/she is awake and while they are sleeping.
- You and your child will be asked to complete some study assessments at home before the second visit. These are completed on the computer and require internet access. You will be asked questions about your child’s medical history, physical activity, eating habits, sleeping routine, and their recent and past behaviors. Your child will be asked questions about how he/she is feeling and behaving recently as well as in the past and about any stressful events they may have experienced. They will also be asked questions about social habits, nicotine use, substance use and sexual activity. All information is stored on a secure website and we will provide you with your personal login ID number. Although each individual experience may vary, these home-based computer assessments take approximately 2-3 hours to complete. NOTE: If you do not have internet access at home, we can arrange for you and your child to use a computer at NKI to complete these assessments.

On the second visit we will do the following:

- Give information about your child's medical history, including any medication they are taking, and any hospitalizations and surgeries
- We will collect a blood sample for blood tests (glucose, electrolytes, sodium, potassium, etc) as well as overall health of body organs (e.g., liver, kidney, and thyroid), and metabolic, inflammatory and hormonal levels. We will also collect a genetic sample. Your child may eat breakfast before the blood draw and does not have to fast.
- If your child is a female of child bearing age we will do a pregnancy test.
- Obtain a urine sample for drug testing if your child is age 11 and up. You and your child will be informed of the test results. If you or your child declines the drug test, your child can still continue in the study. Positive drug tests results will not affect participation in the study. If requested we can provide information for treatment referral to you and your child.
- We will measure your child's grip strength
- Test how your child plans things, how he/she remembers things, and the general information he/she knows.
- You and your child will be interviewed about how your child has been doing, how they have been feeling and behaving, and any stressful events they may have experienced
- Your child will be asked to ride a gym bike for 6 minutes.
- Lunch will be provided for you and your child.
- Your child will have a MRI scan. (see below for more information)
- Tests of how your child problem solves and processes information.
- Your child will be asked to complete several additional surveys about their mood, feelings, experiences and behaviors.

On the third visit we will do the following:

- Obtain a 2nd MRI scan from your child. (see below for more information)

On the fourth and fifth visits we will do the following:

- Measure your child's vital signs (blood pressure, pulse rate, height and weight), and take his/her waist and hip measurements.
- Obtain information about changes in your child's medical history, including any changes in medications he/she is taking, and any hospitalizations or surgeries that occurred since your child's last visit.
- Collect a blood sample to test blood counts, cholesterol, electrolytes (e.g., sodium and potassium), as well as overall health of body organs (e.g., liver, kidney, and thyroid), and metabolic, inflammatory and hormonal levels.
- Do a pregnancy test (for females of child bearing age).
- Obtain a urine sample for drug testing You and your child will be informed of the test results. If you or your child declines the drug test, your child can still continue in the study. Positive drug tests results will not affect participation in the study. If requested we can provide information for treatment referral to you and your child.
- Measure your child's grip strength
- Ask questions about how your child has been feeling recently as well as feelings he/she may have had in the past.
- Test how your child plans things and how he/she remembers things.
- Ask you and your child to complete surveys about your child's feelings and behavior.
- Ask your child to ride a gym bike for 6 minutes.
- Test how your child problem solves and processes information
- Breakfast and lunch will be provided to your child and lunch will be provided to you.
- Obtain an additional MRI scan from your child. (see below for more information)(4 total MRI scans completed)

You and your child may be asked to complete some study assessments at home if you would like. This is voluntary and if applicable should take less than 1 hour to complete.

Drug Use Test:

As part of the data collection for the study we will ask your child to provide a urine sample to test for recent drug use. The drug test we will use is the Alere iCup® DX which is not 100% accurate and only provides a preliminary result. You and your child will be informed of the test results. If you or your child declines the drug test, your child can still continue in the study. Results from this urine drug screen will be filed in your child's research record.

Stimulant Medication Usage:

As part of our protocol, we request that individuals being treated with stimulant medications for Attention Deficit Hyperactivity Disorder (ADHD) discontinue usage of the medication on the days of participation in this study. (Example: Ritalin, Adderal, Concerta) This request is based on our desire to minimize potential effects of the medication on our assessments of brain function. You can decide to discontinue your child's stimulant medication on the days of study participation if your child's physician has no objection to this. If you or your child's physician have concerns about the safety of discontinuation of the medication on study participation days, your child can still participate in the study, but it is important to let our staff know so that we can properly document your data record.

MRI:

MRI scanning makes pictures of your child's brain. During the scan, your child will lie down on a table that is like a bed, and the table will slide into the scanner. Once inside the scanner, it will start to take the pictures. Your child will be in the scanner for about 1 hour.

While your child is in the scanner, we will take many types of pictures, including some while he/she views a flashing checkerboard and some while he/she is asked to briefly hold their breath. We may also monitor their heart rate, breathing patterns, electrical signals of the brain activity (electroencephalogram, EEG), and level of relaxation. These items may include the following devices: a pressure belt placed around your upper abdomen, a clip placed on your finger, disposable sensors placed on your hand, disposable sensors placed on your chest and disposable sensors placed on your head. We may also ask your child to wear a pair of goggles to track his/her eye movements and blinks.

While the scanner is working, your child may hear noises, like knocking or beeping sounds. We will give your child ear-plugs or earphones to make it quieter. While your child is in the scanner, he/she can talk to the person who is running the scanner the whole time, and if your child asks, they can stop the scan at any time, for any reason.

If there is a problem with the MRI machine, we may ask you and your child to return to NKI for another visit, if you choose.

BLOOD COLLECTION AND GENETIC SAMPLE:

Blood collection is required for this study. A blood sample will be collected to test blood counts, glucose, electrolytes, sodium, potassium, cholesterol, etc., as well as overall health of body organs (e.g., liver, kidney, and thyroid), and metabolic, inflammatory and hormonal levels. We will also collect a genetic sample. For the genetic sample, we will collect about 4 teaspoons of blood. The blood sample, without your child's name, will be sent to the National Institute of Mental Health (NIMH) bank in New Jersey. Before your child's sample and data are sent to the NIMH bank, we will remove all identifiers (e.g. your child's name, birthdate, date of participation) – a process referred to as de-identification; ***the only exception is that the county your child lives in will be identified.*** We remove the identifying information from the sample to minimize the risk of the genetic information ever being linked back to your child. A special code is used to identify your child's sample in place of name or other identifiers, as this information is only kept at NKI. At the NIMH bank, the DNA will be taken from the cell line and used for scientific research now and in the future. The DNA and mental health information collected from your child will be stored at the bank. This will include information about your child's family structure, age, sex and any psychological symptoms, which is stored in a coded way to keep your child's identity a secret. NIMH will provide your samples (i.e. DNA, RNA, cell lines, potentially plasma fractions) to qualified scientists around the world to study how genes are related to mental health; this access is only granted after the researcher's institution and the NKI approve the researcher for data usage.

Deidentified data from this study as well as data derived from your child's blood such as genetic data may also be joined with other deidentified data and sent to a data bank that is supported by the National Institutes of Health (NIH) as more fully described below. Sharing this data is helpful because it allows for newer, larger questions to be studied. Your child's data will be made de-identified, which means that the information does not identify who your child is.

If your child is worried about the blood draw, we may offer him or her Lidocaine numbing cream, and/or a small device shaped like a bee that will help to minimize the pain associated with the procedure. These are methods commonly used to make the experience more comfortable. It is you and your child's choice whether to use these products or not while having their blood drawn.

If blood draw is declined, continued participation is at the discretion of the study investigators.

THE POTENTIAL RISKS OR DISCOMFORTS TO YOUR CHILD ARE:

Sometimes people may be uncomfortable about the questions in an interview. You and your child may always take a break during the interview, and may also stop at any time, for any reason. In addition, you and your child do not have to answer any questions that you do not want to answer and you do not have to do any parts of the study that you and your child do not want. Even if you want your child to participate, if he/she doesn't want to do so they can refuse. Several questionnaires included in the study include questions regarding your child's sexuality and sexual practices. If you have any concerns about you and your child being asked questions of this nature, please let study staff know, as they can be excluded. Additionally, if you or your child would like to learn about educational resources regarding these domains, please let our staff know and they will provide informative weblinks. You and your child can talk about any issues or concerns that come up during the study with the project director Dr. Michael Milham, who is a licensed child psychiatrist, or Dr. Russell Tobe, who is a licensed child psychiatrist, as well as any of the project staff for this study. Possible side effects from the blood draw are pain, swelling, bruising, or bleeding where the needle is put in the body and fainting.

- **MRI RISK:** There are no known long-term risks with this kind of MRI scanning. The magnet of an MRI scanner, including this one, can cause electronic devices like pacemakers, beepers, and watches to break or stop working, and some metal objects can be pulled into the magnet. Certain medical devices (like pacemakers) or objects that your child may have on or in his/her body may make it unsafe for him/her to be scanned. We will ask you and your child some questions before the scan to make sure your child does not have anything unsafe on or in his/her body, and we will ask him/her to take off objects with metal in them that he/she may be wearing (such as a watch or jewelry). If we find that your child has something unsafe for an MRI scan in or on his/her body that cannot be removed, he/she cannot have the scan. It has been reported that a small number of people with tattoos may feel mild tingling or heating during the scan. If your child has tattoos and notice similar feelings, please tell the person running the scanner, and the scan can be stopped.
- **PREGNANCY RISK:** There are no known risks with having an MRI during pregnancy and MRI is done in pregnant women. However, we will not scan someone who is pregnant. You should know that if your child is a female that could be pregnant and you and your child agree to be in this study, it means that you and your child believe that she is not pregnant. We will do a pregnancy test for all girls of child bearing age who are in this study. The pregnancy testing will be done at the NKI clinical laboratory. You and your daughter will be informed of the pregnancy test results. If the results are positive your daughter cannot have the MRI scan, but she can continue participating in the study. If you or your daughter decline the pregnancy test she cannot have the MRI scan, but can continue in the study. Confidential pregnancy testing is available outside of NKI and if requested we can provide referral information to you and your daughter.
- **GENETIC RISK:** Some people may be worried about their genetic sample being tested for things that indicate they have a particular disease or medical problem. Others may be worried about genetic testing for a disease, such as breast cancer. At this time there is no plan to test your child's genetic sample for things that may tell us if your child or your family has a disease or medical problem. Your child's genetic sample will be kept for the future and may be used in future research studies. In these studies, we may test other genes that are involved in mental health. When this happens, we will take out all information from your child's genetic sample that can identify your child (except for County). We make every effort to make sure your child's data is de-identified, and that the only people who can get to the information that links your child to these samples are the principal investigator and NKI research staff. One limitation in the deidentification process is that the genetic codes themselves are unique for each person, and may one day be able to identify an individual - much the same way a fingerprint can. Given this reality, the NIMH Genetics Bank has a rigorous application process, which verifies that investigators are from institutions at which the ethics review board has been approved by the U.S. Department of Health and Human Services, and that the institution is willing to contractually accept legal liability for any misuse of data, including attempts to reidentify an individual.

In addition, Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against your child based on his/her genetic information. GINA does not protect your child against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance or by adoption agencies.

GINA also does not protect your child against discrimination based on a problem he/she already has. If you or your child would like to know more about it, you can talk about this with the project director of this study or you can go to the following website <http://www.genome.gov/10002328>

THE POTENTIAL BENEFITS TO YOUR CHILD OR TO OTHERS ARE:

This research study will not directly help your child. It is hoped that what is learned will help others in the future. These methods may be used in research to increase what we know about mental health problems. This study is for research only and is not any part of your child's medical care. The scans done in this study are not to find problems in the brain. The genetic information is for research only and has no value for your child's medical care and therefore, we will not give you and your child reports of his/her genetics.

The scans performed in this study are not expected to find any clinical abnormalities. However, the anatomical scans will be reviewed by a licensed, certified clinical radiologist. In order to protect your confidentiality, no personal information will be given to the radiologist. If the radiologist recommends any follow-up evaluations, the Principal Investigator or one of the research staff will contact you. The initial contact may be verbal (telephone or in-person) followed by a written notification documenting the nature of the finding and the kind of follow-up that is recommended. If requested, a copy of the images (on a CD) can be picked up by you at NKI or we can mail the CD to you or your physician. The decision as to whether to proceed with further examination or treatment is yours, along with your primary care physician. Costs for clinical follow-up are not budgeted in the cost of this research.

You may get feedback about your child's health from any laboratory tests done in this study from the study staff.

Following completion of the study visits, research data will be reviewed by a licensed mental health professional who will discuss any clinically-relevant findings and guide you in further referrals if needed. A written report will also be sent to you outlining this feedback.

IF YOUR CHILD DOES NOT PARTICIPATE IN THIS STUDY, HE/SHE MAY RECEIVE THE FOLLOWING ALTERNATIVE TREATMENT: Since this is not a treatment study, the alternative is not to participate.

CONFIDENTIALITY:

To help us protect your child's privacy, we got a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to give information that may identify your child, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to keep information that can identify your child private, except as explained below.

The Certificate does not stop the United States Government if they ask for information to review a federally funded project or to go the Food and Drug Administration (FDA).

You and your child should know that a Certificate of Confidentiality does not prevent you or a member of your family from choosing to share information about your child or what your child's has done in this research. If an insurer, employer, or other gets your written consent to have research information about your child, then the researchers may not use the Certificate to withhold that information; this can only happen if you say it's ok first.

If researchers are worried about your child's safety they can give information that may identify your child to the proper authorities to be sure that he/she is safe; the Certificate of Confidentiality does not stop researchers from doing this if they are worried about safety. If the person who interviews you and your child feels that he/she may hurt himself or someone else, he/she will let you know and will take whatever action is needed to keep your child and anyone else who may be in danger safe, including telling you and your child speak to your child's doctor or therapist, so they can help. Also, any suspected or known sexual or physical abuse or neglect of a child or possible violence to self or others will be reported.

We will take measures to protect your child's privacy and the security of all of your child's personal information. Your child's name and other identifying information will be maintained in locked files and/or restricted databases, available only to authorized members of the research team. All of the information we collect about your child will be coded with a unique research subject identifier (URSI) and will be kept on password-protected computers at NKI and at the Mind Research Network (MRN) facility. MRN is a company that backs-up our data for us and provides us with the software to complete the questionnaires on the computer. All files and email accounts are encrypted to further protect

you and your child's protected health information. Information resulting from this study will be used for research purposes and may be published; however, you and your child will not be identified by name in any publications.

After participation, this study may provide research data to the 1000 Functional Connectomes Project and its International Neuroimaging Data-sharing Initiative (INDI). This project is a data sharing effort that provides research laboratories at non-profit and for profit institutions (e.g., medical centers, universities, private research groups) with access to data contributed by imaging sites around the world. This data repository is on the Neuroimaging Informatics Tools and Resources Clearinghouse (NITRC), which is supported by the National Institutes of Health (NIH). The NIH is part of the U.S. Department of Health and Human Services (DHHS), which is an agency of the U.S. Government. Such data sharing is beneficial as it reinforces open scientific inquiry, encourages diversity of analysis and opinion and permits the creation of new, large, demographically diverse data sets by combining data from multiple sources. Willingness to participate in the sharing of de-identified data is a requirement for participation in this study.

Prior to submission to the 1000 Functional Connectomes Project, we will remove all identifiers, e.g. name, birth date, date of participation from the data obtained from your child's participation. ***The only exception is that the county your child lives in will be identified.*** We are doing this so the information cannot be linked back to your child. Additionally, we will remove all face information from the MRI images to eliminate any possibility of reconstructing a facial image. Each dataset will be assigned an identification number and the relationship between the anonymized code and original subject identifier will be destroyed, to ensure that the data contributed does not identify your child. Additionally, any investigators requesting access to information related to psychiatric, medical or behavioral assessments are required to have their institution complete a legally binding agreement to protect your privacy first and foremost.

As previously discussed in the Genetics Risk section, a key concern in the scientific community is the possibility that genetic and imaging samples themselves may one day be used to identify individuals – much the way a fingerprint can. In this regard, the NKI-Rockland requires that any investigator from an outside institution attempting to access clinically- or personally-sensitive information first sign a legally binding agreement that explains limits on use of the data and how data will be protected. Any institution or individual who signs this agreement is legally liable for any misuse of data, including attempts to reidentify an individual.

The Nathan Kline Institute/Rockland Psychiatric Center Institutional Review Board, Office of Human Research Protection, and New York Office of Mental Health among other government regulatory agencies may also have access to your child's records, and a copy of this consent form may be sent to the Director of Quality Assurance at Rockland Psychiatric Center for monitoring purposes.

TERMINATION OF YOUR CHILD'S PARTICIPATION:

Participation in this study is voluntary. You and your child decide whether to participate. Even if you would like your child to participate, your child can refuse participation. If you and your child agree to be in this study, you and your child may change your minds at any time and stop being in the study. You and your child may also choose not to answer any study question or not to be in certain parts of the study. Choosing not to be in the study, not to answer certain study questions, or to stop being in the study will not affect the benefits to which your child is otherwise entitled. The Project Director may take your child out of the study at any time if: s/he believes it is in best for your child; your child does not follow study directions and rules; there are unexpected or serious side effects.

MEDICAL COMPENSATION FOR RESEARCH-RELATED INJURIES:

Federal and New York State rules say that we must tell you and your child about our policy of payment for treatment of research injuries. All forms of medical diagnosis and treatment, whether everyday or new, have some risk of injury. If your child has an injury at Nathan Kline Institute as a direct result of being in this research, emergency medical care will be given and there will be help in finding follow up care. There is no promise to pay for medical care and there are no programs to pay your child for research injuries. By agreeing to be in this research and signing this form, your child does not lose any legal rights. The research staff, the Nathan Kline Institute, and The Research Foundation for Mental Hygiene Inc. are still responsible for negligence.

PAYMENT FOR PARTICIPATION:

For the first visit, your child will be paid \$15 and you will receive \$15. For the second visit, your child will receive \$75 and you will receive \$25. After completing the home based computer questionnaires, your child will be paid \$20 and

you will be paid \$25. This payment will be given at the second visit. You will also be reimbursed \$10 per visit to cover transportation costs. Your child will also get \$25 at visit 2 if you return the actigraph unit.

For each of the third, fourth and fifth visits, your child will be paid \$100 and you will be paid \$25. You will also be reimbursed \$10 per visit to cover transportation costs for each study visit. Lunch will be provided on Visits 2, 4, and 5.

If some study procedures are not completed during any of the visits, for any reason, you and your child may be asked by study staff to complete these at another time. This may involve completing procedures at home or an additional visit to NKI. If you and your child chose to complete these additional procedures, you will be reimbursed \$25 for your time.

ADDITIONAL INFORMATION:

You and your child may withdraw consent for this research and/or use of your child's genetics sample at any time by contacting Dr. Milham at 845-398-5469 or Dr. Tobe at 845-398-6556. Your child's sample or any part of it that has not already been used for research will then be destroyed.

COMMERCIALIZATION OF SAMPLES (GENETICS):

Your child's blood samples, DNA, and their results may be used to make commercial medical products. Cells that we get from your child's blood sample may be used to make a cell line that will be used to help find genes. These cell lines may have commercial value. You and your child are being asked to consent to these commercial uses. There are no plans to share any monetary benefits that come from the commercial uses with you and your child.

SHARING OF RESEARCH RECORDS:

Many of the studies being done at Nathan Kline Institute/Rockland Psychiatric Center get the same kinds of information, including MRI scans, surveys, mental health information as well as interviews about education, health and family background and psychological tests. You may say it is okay for us to share your child's information from this study with other researchers at NKI/RPC.

Please Initial:

_____ Yes, it is okay for these researchers to share information from this study with other NKI/RPC researchers.

_____ No, it is not okay for these researchers to share information from this study with other NKI/RPC researchers.

PERMISSION FOR FUTURE CONTACT

Please check with "Yes" or "No" to the questions below and write your initials if the researchers may contact you and your child in the future for research, to give general information about the research, or to give information about the test on your child's sample that may help your child or your family members:

Please Initial:

- I will allow researchers to contact me and my child in the future for research purposes.

YES ☐ NO ☐ Subject Initials _____

- I will allow researchers to contact me in the future to give general information about the research findings.

YES ☐ NO ☐ Subject Initials _____

GENERAL CONDITIONS AND OTHER INFORMATION:

1. You will be told of any new findings that may influence you and your child's decision to participate in this research. The choice for your child to be in this study may be stopped by the Project Director if in his/her judgment it is not okay for your child to continue.
2. If you have any questions about **your or your child's rights as a research participant**, please contact The Nathan Kline Institute/Rockland Psychiatric Center Institutional Review Board office at (845) 398-2199
3. If you have any questions, or if your child has a research-related injury at any time during his/her time in the study, you may call **Dr. Milham (845) 398-5469, Dr. Tobe (845) 398-6556, or Melissa Kramer at (845) 398-5821.**
4. **A copy of this consent form will be given to you, and a copy will be kept at in a locked file in the office of the researchers.**

I voluntarily consent to have my child participate in the research study as described above.

Child's Name

Print Name of Parent/Guardian

Signature of Parent/Guardian

Date

I believe that this consent is freely given, by the parent/guardian with sufficient capacity to consent, who has been given all information deemed necessary by the Institutional Review Board or requested by the study participant.

Print Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date