NKI/RPC IRB
Approval Date: 11/8/16
Expiration Date: 4/13/17

Initials: _____
ID#: _____

PARENT PERMISSION FORM TO PARTICIPATE IN THE STUDY TITLED "DISCOVERY SCIENCE OF HUMAN BRAIN FUNCTION ACROSS THE LIFE SPAN"

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 late adulthood. We also want to see how our genes are related to the way our brain works. We will share anonymous data from this study with other scientist around the world as a way of making more discoveries about the way our brains work.

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 to be in this study, you and your child will complete 2 visits at NKI approximately 2 weeks apart, as well as some home based computer assessments. Though individual experiences vary, the first visit will take approximately 50 minutes and the second visit will take approximately 8 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.

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 you and your child will be asked to do these activities:

- 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); 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. Results of the drug test will be filed in the research record.
- 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.

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 will 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, or have your child continue in the study without the MRI scan.

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. Your child's information will be de-identified before it is sent to the NIMH bank. This means that no information that can be linked back to your child will be on the data we send them. Since we will not be able to tell what sample is your child's, we will use a special code for your sample that will be 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. 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. Your child's DNA and mental health information will be stored there in a coded way to keep his/her identity a secret. NIMH will provide your child's 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.

De-identified data from this study as well as data derived from your child's blood such as genetic data may also be joined with other de-identified data and sent to a data bank that is supported by the National Institutes of Health (NIH). Sharing de-identified data is helpful because it allows for newer, larger questions to be studied. Your child's data will be made completely de-identified, which means that there will be no information that can 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.

It is required that all participants attempt the blood draw. We understand that some children are fearful of this. If the blood draw is declined for any reason, 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. For children, they will be offered EMLA cream to numb the area where the needle is inserted to reduce discomfort.

- **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. 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 your daughter declines 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. The only people who can get to the information that links your child to these samples are the principal investigator and NKI research staff.

  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. If a member of the research team notices something on the MRI that could be a problem, the team member may ask a specialist, such as a radiologist or neurologist, to see if follow-up is needed. To keep your child's privacy, no personal information will be given to the specialist. If the specialist thinks follow-up is needed, the Project Director or a member of the study team will tell you. This may be on the telephone or in-person and then in a letter telling you what was found and the kind of follow-up that is recommended for your child. If you ask, a copy of your child's scan (on a CD) can be mailed to you or picked up in-person. It is your decision to follow-up or get treatment. Costs for follow-up are not part of this study.

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: This is not a treatment study. However, if you want clinical services for your child you will be provided with information about options for such services in or near your community.

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 themself 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 required for participation.

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:

You and your child decide whether to participate in this study. 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, not do any test or not to be in certain parts of the study. Choosing not to be in the study, not to answer certain study questions, not do any

test 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 any 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, The Research Foundation for Mental Hygiene, Inc. is 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.

If some study procedures are not completed during Visits 1 and 2, for any reason, you and your child may be asked by study staff to complete these at another time. This may involve completing 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 any incidental findings 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.

_____ _____

Print Name of Parent/Guardian Child's Name

_____ _____

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