Participant Initials: _____
ID#: _____

CONSENT FORM TO PARTICIPATE IN THE STUDY TITLED "REAL-TIME fMRI NEUROFEEDBACK BASED STRATIFICATION OF DEFAULT NETWORK REGULATION"

Neurofeedback MRI Visit

NKI/RPCIRB
Approval Date: 11/8/16
Expiration Date: 7/4/17

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

Participant Name: _____ Participant ID: _____

Project Directors: R Cameron Craddock, PhD and Michael Milham, MD, PhD

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 also want to see how our genes are related to the way our brain works. Additionally, we want to understand more about the interaction between different parts (regions) of the brain and our ability to increase or decrease the activity of these regions. We will share data and scans from this study with other scientists around the world to be used in their research 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. People across the community and within the ages of 21-45 years old are being recruited for this study.

What will happen if I participate?
If you agree to be in this study, you will be asked to read and sign this consent form. Since you already completed our Discovery Science study, after you sign the consent form, you will come in for one visit, which will take approximately 3 hours.

On your visit you will be asked to do these activities:

- You will have an MRI scan (see below for more information)
- You will be asked to complete several additional surveys about your recent and past behaviors, habits, mood, and emotions.

You may be asked to complete some study assessments at home.

MRI
The MRI scanner uses a strong magnet and radio waves to obtain a picture of the brain. Before going into the scanner, we will ask you questions to make sure that MRI scanning is safe for you, give you a detailed description of what it will be like to be in the scanner, and answer any questions you have. Before you go into the scanner room, you will be instructed to remove all jewelry and other metal-containing objects.

Once in the room with the scanner, you will lie on a table that will slide into the scanner. We will ask you to lie very still for the entire duration of the scan. The scanning procedure will last no longer than 90 minutes. During scanning, the machine produces a loud knocking noise. This is normal. We will give you earplugs and/or earphones to make it quieter. During parts of the scan, you will be asked to perform some tasks, which may include some while you view a flashing checkerboard, and some where you are asked to briefly hold your breath.

While you are in the scanner, you can talk to the person who is running the scanner the whole time, and if you ask, they can stop the scan at any time, for any reason. While you are in the scanner, we may monitor heart rate, breathing patterns, electrical signals of your 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 or foot, disposable sensors placed on your hand or foot, disposable sensors placed on your chest and disposable sensors placed on your head.

THE POTENTIAL RISKS OR DISCOMFORTS TO YOU ARE: Sometimes people may be uncomfortable about the questions in an interview. You may always take a break during the interview, and may also stop at any time, for any reason. In addition, you 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 do not want. You 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. Russ Tobe, who is a licensed child psychiatrist, as well as any of the project staff for this study.

- **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 you have on or in your body may make it unsafe for you to be scanned. We will ask you some questions before the scan to make sure you do not have anything unsafe on or in your body, and we will ask you to take off objects with metal in them that you may be wearing (such as a watch or jewelry). If we find that you have something unsafe for an MRI scan in or on your body that cannot be removed, you 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 you have 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 you are a woman who could be pregnant and you agree to be in this study, it means that you believe that you are not pregnant. A pregnancy test will be available upon request, which will be performed at the NKI clinical laboratory. We recommend that you take advantage of this option if there is any chance that you could be pregnant.

THE POTENTIAL BENEFITS TO YOU OR TO OTHERS ARE: This research study will not directly help you. 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 medical care. 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.

IF YOU DO NOT PARTICIPATE IN THIS STUDY, YOU 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 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 you from this study, 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 you 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 to the Food and Drug Administration (FDA).

You should know that a Certificate of Confidentiality does not prevent you or a member of your family from choosing to share information about yourself or what you have done in this research. If an insurer, employer, or other person gets your written consent to have research information, then the researchers may not use the Certificate to hold back that information; this can only happen if you say it is okay first.

If researchers are worried about your safety they can give information that may identify you to the proper authorities to be sure that you are safe. If the person who interviews you feels that you may hurt yourself or someone else, he/she will let you know and will take whatever action is needed to keep you and anyone else who may be in danger safe, including telling you to speak to your doctor or therapist, so they can help you.

We will take measures to protect your privacy and the security of all your personal information. Your 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 you 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. Information resulting from this study will be used for research purposes and may be published; however, you 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. This 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 participation. The only exception is that the county you live in will be identified. We are doing this so the information cannot be linked back to you. 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 you. 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.

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 complete a data usage agreement that legally binds their institution legal liability for any misuse of data, including attempts to re-identify 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 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 PARTICIPATION: It is your choice to be in this study. If you agree to be in this study, you may change your mind at any time and stop being in the study. You may also choose not to answer any study question or not to be in certain parts of the study. If you choose not to be in the study, not to answer certain study questions, or to stop being in the study, there will be no problems or loss of help for you. Choosing not to be in the study, not to answer certain study questions, or to stop being in the study will not prevent you from receiving the services you would ordinarily receive from the Nathan Kline Institute. The Project Director may take you out of the study at any time if: s/he believes it is in best for you; you do not follow study directions and rules; there are surprising or serious side effects.

MEDICAL COMPENSATION FOR RESEARCH-RELATED INJURIES: Federal and New York State rules say that we must tell you 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 you have 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 you for research injuries. By agreeing to be in this research and signing this form, you do 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:
You will be paid $50 for this visit. You will also be reimbursed $10 per visit to cover transportation costs.

If some study procedures are not completed during any study visits, for any reason, you 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 chose to complete these additional procedures, you will be reimbursed $25 for your time.

ADDITIONAL INFORMATION: You may withdraw your consent for this research at any time by contacting Dr. Craddock at 646-625-4325 or Melissa Kramer at 845-398-5821.

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. In addition to the sharing of research results described above, you may say it is okay for us to share information from this study with other researchers at NKI/RPC. If you give permission, the information shared with other NKI/RPC researchers may include information that identifies you.

Please Initial One:

_____ 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 in the future for research, to give general information about the research, or to give information about the test on your sample that may help you or your family members:

Please Initial One:

- I will allow researchers to contact me 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 _____

Participant Initials: _____
ID#: _____

GENERAL CONDITIONS AND OTHER INFORMATION:

1. You will be told of any new findings that may influence your decision to participate in this research. Your choice to be in this study may be stopped by the Project Director if in his/her judgment it is not okay for you to continue.
2. If you have any questions about **your 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 you have a research-related injury at any time during your time in the study, you may call **Dr. Craddock at 646-625-4325, Dr. Tobe at 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 participate in the research study as described above.

_____
Print Name of Participant

_____ _____
Signature of Participant Date

I believe that this consent is freely given, by a study participant 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