NKI/RPCIRB
Approval Date: 11/8/16
Expiration Date: 8/10/17

Participant Initials: _____
ID#: _____

Adults (Ages 38-75) CONSENT FORM TO PARTICIPATE IN THE STUDY TITLED

"MAPPING INTER-INDIVIDUAL VARIATION IN THE AGING CONNECTOME"

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

Participant Name: _____ Participant ID: _____

Project Directors: Stan Colcombe, PhD; Russell Tobe, MD; Anna MacKay-Brandt, 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 want to see how our brains change over time as we age, and how physical activity and exercise impacts our mental health. We also want to see how our genes are related to the way our brain works. 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.

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. After you sign the consent form, the following things will happen:

If you choose to be in this study, you will complete a screening visit to make sure you are eligible to participate in future visits. If you are eligible, you will complete 2 study visits at NKI. After these are completed, you will revisit NKI each year for three more years to repeat those same two study visits (this totals 9 visits in all).

Year 1			Year 2		Year 3		Year 4	
Screening(Visit1)	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9

Each year, you will be offered to do some of your assessments on home computer. Though individual experiences vary, the screening visit (Visit 1) typically takes less than 1 hour to complete. Visit 2 will take approximately 8 hours to complete and Visits 4, 6, and 8will take approximately 6 hours to complete. Visits 3, 5, 7, and 9 will take approximately 2 hours to complete. Home based computer assessments take approximately 3 hours to complete, but can also be completed at NKI if that is your preference.

On the screening visit (Visit 1) you will be asked to do these activities:

- Meet with research staff to go over this consent form and answer any questions you may have. If you decide to participate in this study, you will sign this consent form indicating your participation interest and agreement.
- Give general information such as your gender, ethnicity, age and education level.
- Complete a 10 minute a memory and thinking screening.
- We will measure your vital signs (blood pressure, pulse rate, height and weight), and take your waist and hip measurements.
- Review of medical clearance for cardiovascular fitness assessment from your doctor.
- We may ask you to wear a watch like device (actigraph) around your wrist. We will ask you to wear the watch from this visit to the next. One of the study staff will provide you with details about when to wear the watch. This device will tell us about your physical activity while you are awake and while you are sleeping.

- You will be asked to complete some study assessments at home before the next visit. These are completed on the computer and require internet access. You will be asked questions about your medical history, nicotine use, physical activity, eating habits, sleeping routine, and your recent and past behaviors. 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 4 hours to complete. NOTE: If you do not have computer/internet access from home, we can arrange for you to use the computer at NKI to complete these assessments.

On study visits 2, 4, 6, and 8 to NKI you will be asked to do these activities:

- Give information about your medical history, including any medication you are taking, and your hospitalizations and surgeries.
- We will collect a blood sample for blood tests (glucose, cholesterol, electrolytes, blood counts, etc.) and a genetic sample.
- We will provide breakfast after we attempt to collect a blood sample.
- We will provide lunch during your visit.
- If you are a woman of child bearing age and you believe there is any chance you could be pregnant, a pregnancy test will be available upon request. If the results are positive you cannot have the MRI scan, but you can continue in the study.
- As part of the data collection for the study we will ask you 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 will be informed of the test results. If you decline the drug test, you can still continue in the study. Results from the urine drug screen will be filed in the research record.
- You will be asked to answer questions about how you have been feeling recently as well as feelings you may have had in the past.
- You will be asked to complete surveys about what you have been doing, how you have been feeling and behaving, and any stressful events you may have experienced. You will be interviewed about behaviors you may or may not have done during your lifetime.
- There will be tests of how you solve problems, how quickly you can process information, how well you remember information, and your general knowledge.
- You will have an MRI scan. (see below for more information)

On study visits 3, 5, 7, and 9 to NKI you will be asked to do these activities:

- **Participate in a cardiovascular fitness assessment (Wear comfortable clothes, such as sneakers, sweatpants, and a t-shirt, see below)**
- You may also be asked to complete any remaining assessments from the prior visit including home assessments.

A Special Note:

Some people who recently participated in and completed the study "Discovery Science Across the Human Lifespan" will be permitted to transfer into this study. In this case, you will have completed the Visit 1 procedures and will only need to complete Visit 3 in year 1 as outlined below. However, in addition to the standard Visit 3 activities listed above, you will also:

- Meet with research staff to go over this consent form and answer any questions you may have. If you decide to participate in this study, you will sign this consent form indicating your participation interest and agreement.

All other visits (4-9) will be the same as they would be if you had not participated in the study "Discovery Science Across the Human Lifespan".

Year 1	Year 2		Year 3		Year 4	
Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9

Medication Usage
As part of the protocol, you will be asked about any medication that you may be taking. However, you will not be asked to change or discontinue any of your medications.

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

While you are 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. We may also 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, disposable sensors placed on your hand, disposable sensors placed on your chest and disposable sensors placed on your head. We will also ask you to wear a pair of goggles to track your eye movements and blinks.

While the scanner is working, you may hear noises, like knocking or beeping sounds. We will give you ear-plugs or earphones to make it quieter. 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.

If there is a problem with the MRI machine, we may ask you 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 name, will be sent to the National Institute of Mental Health (NIMH) bank in New Jersey. Before your sample and data are sent to the NIMH bank we will remove all identifiers, e.g. name, birth date, date of participation. The only exception is that the county you live in will be identified. We are doing this so that the sample and information are not linked back to you. Since we will not be able to tell what sample is yours, 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 you will be stored at the bank. This will include information about your family structure, age, sex and any psychological symptoms. Your DNA and mental health information will be stored there in a coded way to keep your 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.

Deidentified data from this study as well as data derived from your 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 data will be made completely de-identified, which means that the information does not identify who you are.

If you are worried about the blood draw, we may offer you Lidocaine numbing cream, 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 your choice whether to use these products or not while having your blood drawn.

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

Cardiovascular Fitness Assessment
For the cardiovascular fitness assessment, we will ask you to ride a stationary bicycle. At the start of the assessment, the resistance of the pedals will be low (easy to pedal), but will increase bit by bit over time, making it harder to pedal. While you are exercising, you will be asked to breathe into a tube or mask. We will measure the oxygen concentrations in your breath as the exercise becomes more difficult. This allows us to determine how well your body can use the oxygen in the air, and tells us about your aerobic capacity. You will wear a standard blood pressure cuff on your upper arm to measure your blood pressure and have a sensor on your finger called a pulse oximeter to measure your heart rate and oxygen levels in your blood. The test should take no more than 30 minutes, once you begin. This will tell us about how well your body can use oxygen while exercising, but is a research assessment. It is not designed to identify or diagnose any medical condition. Should you experience discomfort at any point you can stop. If you experience physical symptoms such as chest, jaw, neck,

or arm pain/discomfort, light-headedness, dizziness, difficulty seeing or talking, please tell a member of the research team. A nurse and physician will be available to help you.

We will also ask you to complete a walking test which involves walking a short distance and following verbal instructions such as reciting letters of the alphabet and walking at a comfortable pace.

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 (for example, several questionnaires included in the study include questions regarding your sexuality and sexual practices). Additionally, if you would like to learn about educational resources regarding these domains, please let our staff know and they will provide informative weblinks. You can talk about any issues or concerns that come up during the study with the project directors 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 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.

- **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 genetic sample for things that may tell us if you or your family has a disease or medical problem. Your 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 genetic sample that can identify you. The only people who can get to the information that links you 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 you based on your genetic information. GINA does not protect you 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 you against discrimination based on a problem you already have. If you 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

- **CARDIOVASCULAR FITNESS ASSESSMENT RISK:** The task will require you to exercise at increasing levels of difficulty. As with any cardiovascular activity, this exercise task will involve exertion. This exertion will cause an increase in breathing and heart rate and may also cause some discomfort such as

muscle soreness in the legs (during and/or after testing), and perspiration. Though rare, this exertion can place strain on the body that increases your risk for more serious medical conditions, such as fainting, angina, heart attack, or stroke. Should you experience a more serious medical condition, nurses and physicians are on site to help and we will activate appropriate medical care. However, even with appropriate medical care, some of these conditions are life-threatening and can be associated with death.

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. You may get feedback about your health from any clinical tests done in this study from the study staff. The scans done in this study are not to find problems in the brain. However, all MRI scans are reviewed by a specialist called a neuro-radiologist. Your name or other personal information is not revealed to the neuro-radiologist. If a concerning finding is noted on the MRI scan by the neuro-radiologist, study staff will contact you to notify you of the findings and their significance. Blood work results are reviewed by study physician and nursing services. You will be notified of any clinically significant blood work results. The genetic information is for research only and has no value for your medical care and therefore, we will not give you reports of your genetics. If you ask, a copy of the scan (on a CD), neuro-radiologist report, or blood work results 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.

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; the Certificate of Confidentiality does not stop researchers from doing this if they are worried about safety. 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 saying that you should 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. Willingness to participate in the sharing on 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 participation. 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.

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 Directors may take you out of the study at any time if: s/he believes it is in your best interest; you do 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 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:

V1 = $30 + $10 transportation
V2 = $ 100 + $45 for completion of home assessments + $25 return of actigraphy watch + $10 transportation
V3 = $75 + $10 transportation
V4 = $125 + $10 transportation
V5 = $75 + $10 transportation
V6 = $125 + $10 transportation
V7 = $75+ $10 transportation
V8 = $125 + $10 transportation
V9 = $75 + $10 transportation

If some study procedures are not completed during the first visit, for any reason, you may be asked by study staff to complete these at another time. This may involve 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 and/or use of your genetics sample at any time by contacting Dr. Colcombe at 845-398-5514 or Dr. Tobe at 845-398-6556. Dr. Colcombe would then tell the repository to remove your mental health information and genetic material. We will keep your identity a secret by using a code number that only Dr. Colcombe and the staff at NKI know. The repository can use this code number to remove your mental health information and genetic material, without ever knowing your name or other personal information. If you choose to have your sample removed, the NIMH will keep a note that the sample was destroyed by request. Research all ready started with your sample would not be stopped and published results would not be removed. However, all new research with your sample will not be possible.

COMMERCIALIZATION OF SAMPLES (GENETICS):
Your blood samples, DNA, and their results may be used to make commercial medical products. Cells that we get from your 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 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.

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:

_____ 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 any incidental finding with your sample that may help you or your family members:

Please Initial:

- 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 _____

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 would like to talk about **your rights as a participant in this study** with an institutional representative who is not part of this study, you may **contact NKI/RPC IRB 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. Colcombe (845) 398-5514, Dr. Tobe (845) 398-6556, or Melissa Kramer (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