| | |
|---|---|
| **Official Title:** | Locus-coeruleus function in normal elderly and AD risk |
| **NCT Number**: | NCT04403165 |
| **Study Number:** | s20-00002 |
| **Document Type:** | Informed Consent Form |
| **Date of the Document:** | • August 22, 2022 |

NYU Langone MEDICAL CENTER

# Research Subject Informed Consent Form

**Title of Study:** Locus-coeruleus function in normal elderly and AD risk

**Principal Investigator:** Dr. Ricardo Osorio
Department of Psychiatry
NYU School of Medicine
145 East 32nd Street NY 10016
Tel: (212) 263-3255

**Emergency Contact:** Dr. Ricardo Osorio
(212) 263-3255

## 1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and- benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

## 2. What is the purpose of this study?

Recent research suggests that Alzheimer’s disease (AD) begins decades before symptoms develop. Tau neurofibrillary tangles (proteins that build up in the brain) can be found in certain brain areas starting around midlife, suggesting that AD can start earlier than previously thought due to the changes in the brain. In this study we’re going to conduct brain scans of people between the ages of 55-75 to see if the buildup of these proteins affects sleep and thinking ability.

## 3. How long will I be in the study? How many other people will be in the study?

This study consists of 4-5 visits over the course of 6-7 months. A total of 30 subjects will be invited to take part in this study.

## 4. What will I be asked to do in the study?

Before any research procedures are done, you will be asked to read and sign this consent form. If you agree to participate, the following tests and procedures will be done:

**Visit 1**

**Location:** Center for Sleep and Brain Health
145 E. 32nd Street 8th floor, New York, NY 10016

- You will sign this consent form and fill out additional documents
- **Cognitive Testing:** A combination of standardized oral and paper and pencil tests will be

administered to you to assess areas of memory, perception, attention, concentration, language, reasoning, comprehension, problem solving skills, etc.

- **Clinical Interview:** A physician will ask questions regarding your overall health, cognition, and family history. A 10-minute mini memory test will be administered. A physical examination looking to assess reflexes and balance will also be administered.
- **Sleep Interview:** You will be asked a series of specific questions about your sleep such as usual sleep and wake times, sleep duration, concerns, and surveys to determine insomnia or excessive sleepiness. We will also ask you about your family history including whether you have relatives who have AD and their ages.

**Visit 2**

**Location:** Center for Sleep and Brain Health
145 E. 32nd Street 8th floor, New York, NY 10016

- **Fasting blood draw:** We will collect blood for clinical labs (approximately 67.5 cc) and in order to obtain ApoE genotyping (this will be explained further later on in the consent form). You will be given breakfast after the draw.
- **Neurological and Physical:** You will have a physical, neurological, and psychiatric examination along with collection of vital signs (heart rate, blood pressure, temperature, and breathing rate) and medical history including medications you take and surgeries you have had.

**Visit 3**

**Location:** Mount Sinai Integrative Sleep Center (MSISC)
11 E 26th St #13, New York, NY 10010

- You will undergo an overnight sleep study at the center. During the sleep study, we will measure your brain waves with an electroencephalogram (EEG) as well as eye movements and muscle movements using small wire sensors taped to your scalp, face and legs. You will wear a vest over your ribs and abdomen to measure breathing movements. EKG leads will be applied to your chest to measure your heart rate. A clip on your finger (pulse oximeter) will measure the oxygen level in your blood. These devices are not uncomfortable and should not disturb your sleep. Your breathing efforts will be recorded with a nasal cannula, which is a small plastic tube placed in your nostrils.
- Before you go to bed, you will be asked to complete a **picture memory task** which takes about 15 minutes. This picture memory task contains some images that are emotionally evocative to represent a wide variety of events and objects.
- The morning after the sleep study, you will do a **Psychomotor Vigilance Test (PVT)** for 20 minutes. The PVT is a sustained-attention reaction-timed task that measures the speed with which you respond to a visual stimulus, which in this case will be black dots in a grey background. For the Picture test, you will be asked to complete a picture memory task which takes about 15 minutes.This contains some images that are emotionally evocative to represent a wide variety of events and objects. You will be preforming both tests in a quiet room without distractions.
- After a 10 minute break, you will be asked to complete another picture memory task similar to the one you did the night before
- We will provide you with breakfast

**Visit 4 - OPTIONAL**

**Location:** NYU Center for Biomedical Imaging
660 1st Ave, New York NY 10016

- **Lumbar Puncture (LP) with fluoroscopy** Also known as a spinal tap, this procedure will be performed after the night of the in-lab sleep study. During the LP, a thin, hollow needle will be
- introduced through the lower back into the fluid space within the spine and 15 cc (1 tablespoon)

of cerebrospinal fluid (CSF, the fluid that insulates the brain and spinal cord) will be removed. In order to reduce discomfort from the insertion of the needle, a cooling spray (ethyl chloride) will be sprayed over the area where the needle will be inserted.

- This procedure is performed by a neuroradiologist under sterile conditions. An X-ray (fluoroscope) will be used to guide the placement of the needle in order to avoid contact with sensitive tissue such as bone and the small veins in the region and to minimize discomfort. Afterwards, you will be advised to sit comfortably in a chair for at least 30 minutes without bending from the waist or twisting from the waist to minimize the risk of headache.

*This procedure is optional. Please indicate whether you would like to opt-in or opt-out to the following procedure. Your decision does not impact your study participation or medical care.*

**_____Yes, I would like to take part in the lumbar puncture**

**_____No, I would not like to take part in the lumbar puncture**

**Please sign your initials:___**

**Visit 5**

**Location:** NYU Center for Biomedical Imaging
660 1st Ave, New York NY 10016

You will have a PET-MR scan of your brain at the Center for Biomedical Imaging. PET/MR scans combine two types of imaging methods: Positron Emissions Tomography (PET) and Magnetic Resonance Imaging (MRI). PET uses radioactive tracers to produce images that can inform us howa particular compound is used by tissue or for identifying unique cell-types, such as Tau, in this study. MRI uses magnetic fields and radio waves to produce images that can inform us about structures and function of tissue in the body. Combining both techniques provides more useful information while reducing the amount of radiation exposure compared to a PET/CT. Women will be asked to take a urine pregnancy test prior to the exam.

A small amount of tracer known as 11C-MRB will be injected into a vein in your arm before the scan begins and a 90-minute PET-MR scan will be performed after injection. Although MRB has been extensively studied for the past 10 years, the use of this tracer is considered investigational because it is not Food and Drug Administration (FDA) approved for use outside of a research study, such as this one.

Certain drugs of abuse may affect the tracer binding; e.g., cocaine, amphetamine, etc. Thus, participants will be warned not to take those drugs. In order to verify this, a urine toxicology test will be administered before the scan.

Since the scanner makes a loud tapping noise while it acquires the image, you will be offered earplugs. After the platform moves you inside the MRI tube, you will be able to speak through an intercom to the technician performing the exam. Inside the scanner, you will be lying on your back facing up. Your head will be held in place by foam pads. A blanket will cover your legs to keep you from getting chilly, and a foam pad will be beneath your knees for your comfort. In your hand, you will hold an emergency squeeze- ball. Squeezing this ball will allow you to alert the technician and the doctor that you want to communicate with them.

**OPTIONAL SAMPLE BANKING AND GENETICS RESEARCH**

With your permission, some of the blood and spinal fluid samples collected in this study will be stored indefinitely for future research on early diagnosis of AD and/or mechanism of neurodegeneration. Testing on your samples and your DNA extracted from them will not be used for clinical or individual purposes and results will not be shared with you. Science and medicine are continually advancing. New discoveries, experimental tests and ways of looking at your blood and genes might be developed in the future to provide valuable information associated with this research.

We can't predict what specific tests will be done or what the results will mean for your health or when they will be done. All this future information will be experimental and we therefore will not be able to share it with you.

Your samples will be labeled with a 4-numeral subject ID, the initials that are given to all participants in our studies and with the date the sample was drawn. These labels will not contain names or any personal information. Codes will be kept in a password locked computer database on the PI's computer. Thus, only the PI and a person designated by the PI will have access to this information. Samples will be stored at the Center for Sleep and Brain Health located at 145 E 32nd Street for short-term storage. The samples will then be stored at Brooks Life Sciences in the Bronx for long-term storage. The PI and the study personnel designated by the PI will have access to the samples. Only the PI and authorized study personnel designated by the PI will be able to link the samples back to your identity. We will not conduct "true" genetic testing on your samples (testing to diagnose your predisposition to conditions for which you don't currently have symptoms).

If you agree now, but later decide you don't want your samples to be stored for future research, we ask that you contact the PI on page 1 of this form. Any unused samples will be destroyed.

Please choose one option below by writing your initials next to your decision:

____**YES**: I consent to the storage of my leftover samples for future research as described above

____**NO:** I do NOT consent to the storage of my leftover samples for future research as described above.

Identifiers will be removed from your identifiable data and specimens. After such removal the data and specimens may be used for future research studies or shared with other researchers and we will not request additional informed consent from you to use these data and specimens as we have noted here.

## 5. What are the possible risks or discomforts?

**Magnetic Resonance Imaging (MRI):** MRI uses a strong magnetic field to create images of the body. Because of the strong magnetic field, there are risks. These risks are detailed in this section.

One possible risk is burns to the skin. There is an increased risk of burns from devices that conduct electrical energy. These devices can include metallic objects, pulse oximeters, EKG leads, or skin tattoos. These devices can be either in or on the patient in order for a skin burn to occur. The FDA has found that 70% of all reported injuries from MRIs were burns to the skin.

To reduce this risk, all patients who are scanned in this study must complete thorough screening to ensure that no conductive materials are present in or on the patient's body. Additionally, the power limits of the magnet will be adjusted as necessary.

Another possible risk is that a metal object could be pulled into the scanner and hit you. You could be physically injured as a result.

To reduce this risk, everyone near the magnet will remove all metal from their clothing or pockets when in the scanning environment. The door to the scan room will remain closed during the exam for your safety.

There are no known risks or adverse effects resulting directly from exposure to MRI. However, subjects who have a pacemaker or metal objects in their body such as shrapnel or metal in the eye should not have the scan performed. If you have any question about metal implants or metal fragments in the body, you should inform the technologist or investigators before entering the magnet room.

**Fear of Confined Spaces**: Some people may feel confined and experience anxiety in the MR scanner.

If you are unable to tolerate being in the scanner, we can stop the scan immediately at any time.

**Noise Levels**: The MR scanner produces tapping sounds during operation, which may reach very loud levels. To minimize any discomfort from this noise, you will be given disposable earplugs to reduce the noise levels but will still allow voice communication with the scanner operator.

**MRI system failure (quench)**: In extremely rare cases, a magnet can lose its magnetism, in which case cooling fluids may be released noisily through escape valves and may collect in gas form in the scan room. The gas is not harmful in itself as long as fresh air is available. In this very remote event, you will immediately be brought out of the magnet room.

**Neurostimulation and heating**: Some subjects may experience muscle twitches or tingling sensations and/or a slight increase in body temperature during some types of scan activity. These are very unlikely under current MR guidelines.

**Physical, Neurological and Psychiatric Exams:** The main risk is a loss of privacy and discovering a condition that was not previously known. The questions we ask during these tests may also make you feel uncomfortable.

**Psychometric Testing:** There are no risks associated with cognitive testing. You may experience fatigue or test performance anxiety. Periodic breaks will be available during cognitive testing.

**Laboratory Analysis of Blood:** The potential risks of blood drawing may occasionally include pain, bruising, fainting, or a small infection at the puncture site. Sometimes a small amount of bleeding into the arm (hematoma) may occur.

**Heart Tracing (EKG):** The back of the electrodes is adhesive and may be uncomfortable when removed. There are no other risks associated with an EKG other than discovering a heart condition that was not previously known.

**Lumbar Puncture (LP):** Risks of LP may include pain, bruising, skin infection at puncture site, infection and swelling of the brain covering (meningitis) and post-spinal tap headache. Your participation in this study will involve exposure to radiation from this lumbar puncture. This exposure is not necessary for your medical care, is for research purposes only and is necessary to obtain the desired medical information. The effective radiation dose you will receive from these research scans is less than 1 mSv.

**NET-[$^{11}$C]MRB PET-MR scans:** Your participation in this study will involve exposure to radiation from the PET-MR scan. This exposure is not necessary for your medical care, is for research purposes only and is necessary to obtain the desired medical information. The effective radiation dose you will receive from this research scan is approximately 2.67 mSv.

Radiation has been shown to cause cancer from exposures that are significantly higher than the additional radiation dose that a subject will receive by participating in this study. According to the ICRP, NCRP and HPS, the increased risk of health effects, such as cancer, from radiation doses of this amount is either too small to be observed or nonexistent. The total effective radiation dose that a subject will receive from this research study (from both the LP and PET-MR scans) is approximately 3.67 mSv, which is comparable to 1.2 year of the yearly dose from natural environmental radiation in the US (3.1 mSv), and within the limits of 50 mSV that is set by the FDA for individuals participating in basic research studies. The organ receiving the highest dose in this study is the gallbladder wall.

The NYULH Radiation Safety Committee has reviewed and approved the use of diagnostic radiation in this research study. Please inform your researcher if you have been exposed to radiation as a result of any other research studies. If you participate in future studies that involve the use of radiation, you should discuss the guidelines for radiation exposure with the researchers performing those studies.

**Sleep Studies:** The in-laboratory NPSG sleep study is identical to those performed in clinical practice and present almost no risks, as we will be using the standard diagnostic protocol for all subjects presenting to the MSISC with sleep complaints meriting a sleep study. The sleep study has no risks beyond the minor irritation that attachment of the recording electrodes on the skin occasionally may cause. Discomfort while sleeping may occur while taking the home apnea testing and wearing an actigraph.

**ApoE Genotyping:** There are potential dangers in obtaining DNA information. Genetic testing can generate information about your personal health risks and can cause or increase anxiety, damage family relationships, and/or compromise insurability and lead to social discrimination. To greatly reduce these risks, genetic results will be coded and no personal identification will link you with the genotype.

Since the genetic information gained is for research purposes only, the results will not be made available to anyone (including you and your physician). However, if you wish to learn your ApoE type, we can arrange for your genotyping and genetic counseling to be determined by an outside certified clinical laboratory. If you decide to do this privately, it is not part of this study and the costs of this service or the recommended counseling will be your responsibility.

Although every effort will be made to ensure that you do not learn the results of this test, there is the very unlikely risk that you may inadvertently gain this information. In this case, the primary risk of the genotyping would be a risk of social and psychological harm rather than a risk of physical injury. To minimize this risk, if you inadvertently learn the results of this genotyping you will be given the opportunity to discuss the test results, with a study physician. There is evidence that one type of the ApoE gene may be a risk factor for AD. However, ApoE genotyping is not a diagnostic test for AD and is not part of the recommended diagnostic evaluation for AD. There is no possibility of obtaining incidental (accidental) findings, such as paternity (parental origin) or information about diseases or conditions other than the ones in this study. It is highly unlikely that any genetic information we receive could cause embarrassment to you or your family members. If you experience discrimination because of the release of DNA related information you may contact the New York State Division of Human Rights at (212) 870-8624 or the New York City Commission of Human Rights at (212) 566-5493. These agencies are responsible for protecting your rights.

**Privacy risks associated with research involving genetic information:** There is a risk that someone could get access to the data we have stored about you. If those data suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse, but they may not give full protection. There may be other unforeseen privacy risks

We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them by coding your samples, limiting access to the samples and the information collected during your participation in the study, etc.

**Group risks associated with research involving genetic information:** Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes.

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers of over 15 people to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

## 6. Can I be in the study if I am pregnant or breastfeeding?

Because taking part in this study may harm an embryo, fetus, or breastfeeding baby, you should not become pregnant, breastfeed a baby, or father a child while participating in this study. Other risks may not yet be known.

If you are currently pregnant, you will not be able participate in the study. You should not become pregnant while you are participating in this study. If you are able to become pregnant, you will be required to use a medically accepted method of birth control while you participate in the study:

- Hormonal methods like birth control pills, patches, vaginal rings or implants
- Barrier methods such as condoms or a diaphragm used with spermicide (a foam, cream or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

If you become or you think you have become pregnant during the study, you must tell the principal investigator right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you will have to stop taking part in the study for safety reasons. The principal investigator may ask you to provide information about the outcome of your pregnancy and the health of your baby.

Note to Men

Because the effect of participating in this study on sperm are unknown, you will be required to use a medically accepted method of birth control while you participate in the study, using one of the applicable methods described above.

## 7. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

**Incidental Findings**

If any study procedure such as the medical, neurological, or neuropsychological evaluation reveals significant deficit or an emergent and previously undiagnosed medical condition, or if the blood assays, or PET/MRI scan reveal significant abnormalities, this information will be discussed with the subject and transmitted to their primary care physician. Every scan performed in this study is saved and handled under the standard PHI confidentiality restrictions and regulations employed for patients' information. Each scan is additionally reviewed by a radiologist, who might then detect an abnormality. If clinically useful information is uncovered, either the Principal Investigator or another clinician on the study will speak to you in person or on the telephone regarding the new information. A copy of the original image report will also be provided to you in person and you will be encouraged to follow up on the discovery with your treating physician outside of the study.

## 8. What are the possible benefits of the study?

We do not expect you to benefit directly from the research. The potential benefits to society include improved patient care if this study reveals new information about new biological mechanisms of AD risk.

## 9. What other choices do I have if I do not participate?

You are free to choose not to participate in the study. If you wish to still undergo a sleep study, you may contact us for further information.

## 10. Will I be paid for being in this study?

You will be paid $100 for the NPSG, $200 for the lumbar puncture and $300 for completing the PET/MR. If you chose to leave or are withdrawn from the study for any reason before finishing the entire study; you will be paid for each completed procedure described above.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (i.e. check, Clincard or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

## 11. Will I have to pay for anything?

All study-related costs are being paid for by a grant from the National Institutes of Health (NIH). You or your insurance company will not be charged or held responsible for the costs of tests and procedures you receive specifically for this study.

## 12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form. We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for NYU Langone Medical Center or NYU School of Medicine to provide compensation for a study injury. You do not give up your legal rights by signing this form.

## 13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits. If you choose to withdraw early, we will ask you to come in for a final visit, similar to Visit 1.

## 14. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health. You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

**Certificate of Confidentiality**
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or bio specimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

## 15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

**What information may be used or shared with others in connection with this study?**
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

**Who may use and share information in connection with this study?**
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: NIH/NIA
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites: Mount Sinai Integrative Sleep Center (MSISC)

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

**What if I do not want to give permission to use and share my information for this study?**
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

**Can I change my mind and withdraw permission to use or share my information?**

Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

**How long may my information be used or shared?**
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

**Data sharing among our studies**

Our plan is to be in full accordance with both NYU and NIH Data Sharing Policies. If you are currently enrolled in another study with the same PI(s), where the same cognitive, blood biomarker, or imaging data is being collected, then this data will only be collected once. This will eliminate the need to complete additional procedures that are identical and that may increase exposure to any risk, or make you uncomfortable. This will also be done in order to prevent the skewing of cognitive data via practice effect.

☐ Checking this box indicates my permission to store, use, and share my health information from this study among other studies under the same PI (Ricardo Osorio)

_____

**Subject Initials**

## 16. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information may include biological samples from the study. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

_____

**Subject Initials**

## 17. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community.

## 18. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**When you sign this form**, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

| Name of Subject (Print) | Signature of Subject | Date |
|---|---|---|

| Name of Person Obtaining Consent (Print) | Signature of Person Obtaining Consent | Date |
|---|---|---|

**STUDY PARTNER/INFORMANT INFORMATION**

In addition to obtaining information from you directly, it is important that we also obtain information about your history and symptoms from a close relative or friend. Ideally, this individual should accompany you during at least one of your visits to the Center, although they can be contacted by telephone if accompanying you is not feasible. Please check "yes" or "no" below, to indicate whether you authorize us to obtain information about you from the close relative or friend that you designate.

☐ Yes: Name of study partner: _____

Contact Information: _____

☐ No