Protocol 170957

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UNIVERSITY OF CALIFORNIA - SAN DIEGO
INFORMED CONSENT
TO ACT AS A RESEARCH SUBJECT IN

Alzheimer's Disease Research Center (ADRC)
LONGITUDINAL STUDY

James Brewer, MD, PhD, Douglas Galasko, M.D., and their colleagues at the Alzheimer's Disease Research Center (ADRC) are conducting a research study to find out more about Alzheimer's disease (AD) and related dementias, a group of neurodegenerative diseases that eventually lead to loss of memory and intellect. This research study aims to gather information to help with the diagnosis of AD and other types of dementia, especially at the earliest stages. We will also follow the progression of these diseases with the purpose of discovering more about changes in the brain, risk factors, and causes of AD. You have been asked to take part because:

- You have AD or a related disorder; or
- You have symptoms suggesting that you may be at risk for developing Alzheimer's disease or a related disorder over time.
- You are a healthy adult without memory problems and are suitable to be part of a control or comparison group.

We will ask you to come with a study partner. Your study partner is someone who knows you well and will validate information we gather at your visits. It is important that you and your study partner understand the description of the research study before you agree to participate.

DESCRIPTION OF STUDY PROCEDURES

About 4000 participants will take part in the study. You will come to the ADRC for a detailed visit once per year. Components of this visit are described below.

If you agree to participate in this study, the following will happen to you:

1) You will be asked about your general medical history. We will review outside medical records

as needed. A physical and neurological exam will be performed. During a physical examination, your body will be examined to determine the presence or absence of physical problems. A neurological examination consists of evaluation of your thinking ability, muscle reflexes, sensation to touch, posture and walking. Your blood pressure, pulse, height and weight will be taken. You will be asked about any medications you are currently taking. You will take several tests to evaluate your ability to think, concentrate and remember. These tests are called 'neuropsychologic' tests that will be recorded for data entry and potential future research. We will also speak with your study partner to gather information about your daily activities, mood, sleep and behavior. This testing takes two to five hours to complete and will usually be done in one to two visits. This assessment process will be repeated once a year and continue until death or until you withdraw from the study.

2) Clinical Blood Draw. For the Year 1 visit, you will have blood tests to see if you have any abnormalities that may contribute to memory problems. These blood tests include Vitamin B12 and thyroid tests as well as glycohemoglobin (a blood test that measures the amount of sugar or glucose bound to hemoglobin). About 2 teaspoons of blood (10 milliliters) will be removed from a vein in your arm. If any abnormalities are reported, we will notify you for follow-up with your treating physician.

3) Research Blood Draws

a. BIOMARKER ANALYSIS - Another sample of blood (3 teaspoons or 20 milliliters) will be drawn for indefinite storage in the ADRC laboratory for future study of proteins or other markers in your blood. These samples will <u>not</u> be used for genetic testing (i.e., DNA).

b. GENETIC STUDIES. An additional sample of blood will be drawn for genetic studies. This will allow ADRC investigators to find out more about genes that may be related to aging, memory changes and dementia. Further research may help to identify additional genes that affect the risk of developing dementia, or influence the amount of memory change that occurs with aging. Understanding how these genes work could help to develop new ways to diagnose and treat these problems.

These blood samples will be used for research purposes only. You will not receive specific results of these tests, except in the very rare instance that we find a gene that causes a specific neurological disease. Hundreds of genes may be screened during the analysis of your blood. Most of these genes have no known biological function.

i. The cells of your body contain deoxyribonucleic acid or "**DNA**" for short. The DNA in most cells of your body is the same, and does not change during life. It

carries the code for the genes that determine your physical appearance such as the color of your hair and eyes.

ii. One of the tests we will do on your DNA is to measure which form of the **Apolipoprotein E (ApoE)** gene you have. Studies suggest that the form of ApoE may influence the risk of developing late onset AD. However, you should not consider this a "genetic test" for AD, since the results will not conclusively determine whether you or any of your relatives have or might develop AD. It is unknown if the form of ApoE affects the response to treatments for AD.

No information regarding your genetic or biomarker tests results will be entered into your regular medical record. If you are concerned about a potential genetic disorder, you should discuss this with your primary care doctor. You and your doctor may choose to test specifically for it, but this would require separate blood samples and would not be part of this research study.

If you agree to a research blood sample being drawn for ApoE genotyping and DNA banking, you will have approximately 10 teaspoons (50 mL) of blood removed from a vein in your arm over 2 visits. The white cells in your blood will be used to obtain genetic material (DNA).

Both research blood draw samples may be repeated periodically during your annual visits. ALL BLOOD and DNA samples will be coded by number and no identifying information will be stored with it. The sample will be stored in the ADRC laboratory at UCSD and your DNA also will be shared with the NIA-funded Alzheimer's Disease Genetic Consortium – AD Sequencing project (ADSP). All follow-up blood samples and DNA will be stored. Drs. Brewer and Galasko, their associates or successors in this study, will keep your DNA specimens and/or information derived from it indefinitely.

To review, you will have a total of approximately 16 teaspoons (80mL) of blood collected during your Year 1 visit. This collection may occur over two visits. For subsequent research visits, you will have approximately 15 teaspoons (70 mL) of blood drawn during sample collection visits. This is usually every other year.

4) Sample Storage & Future Use. Your samples and associated genetic and biomarkers tests will be maintained in specimen repositories and in scientific databases. These results are important only for research - not for helping care for you. For this reason, the results will not be released to you or your family.

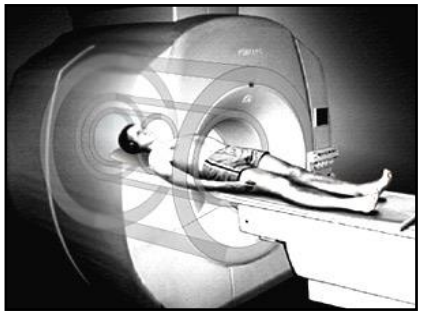
A blood sample or DNA collected for genetic studies from you will be sent to the National Cell Repository for Alzheimer's Disease (NCRAD) at Indiana University. Only your unique subject identifier will be used to identify your blood sample and research information about you. These de-identified samples are necessary for long-term research and will be stored indefinitely.

Your biological samples, including your DNA,* may be provided to researchers at academic institutions, hospitals, and biotechnology/pharmaceutical companies. De-identified (all identifying information has been removed) clinical and genetic data may be provided to the researchers requesting biological samples*. These researchers may perform analysis of the biological samples you have provided. As this is done for research purposes, you will not be given the results of this analysis.

Your genetic material may be used in research involving genetic manipulation to help develop new medicines. This includes new cell lines in the laboratory. Research from your samples and data and its derivatives may have significant therapeutic or commercial value. In the future, your derived cells or cell products may be transplanted into humans or animals. Your genetic material donation is being made without restrictions on who may receive or benefit from your genetic material donation. You must consent to all such future uses.

Results of the analysis of the biological samples* you have provided may be submitted along with the de-identified clinical data to a government health research database that will assist other researchers investigating various diseases, including Alzheimer's disease and dementia. This government health research database will have access limited to approved researchers. Your data may be removed at any time, upon your request. However, data that has already been distributed for approved research will not be retrieved.

5) Magnetic Resonance Imaging (MRI) Scans. You will be asked to have an MRI scan of your brain. Optional additional MRI scans may be requested when appropriate but are not mandatory to participate in this study. An MRI scan will provide a detailed picture of the structure of your brain, which will allow ADRC investigators to find out more about how this relates to people's abilities to form and retain memories, solve problems, and other skills. We are particularly interested in the areas of the brain that help to create memories. Another goal

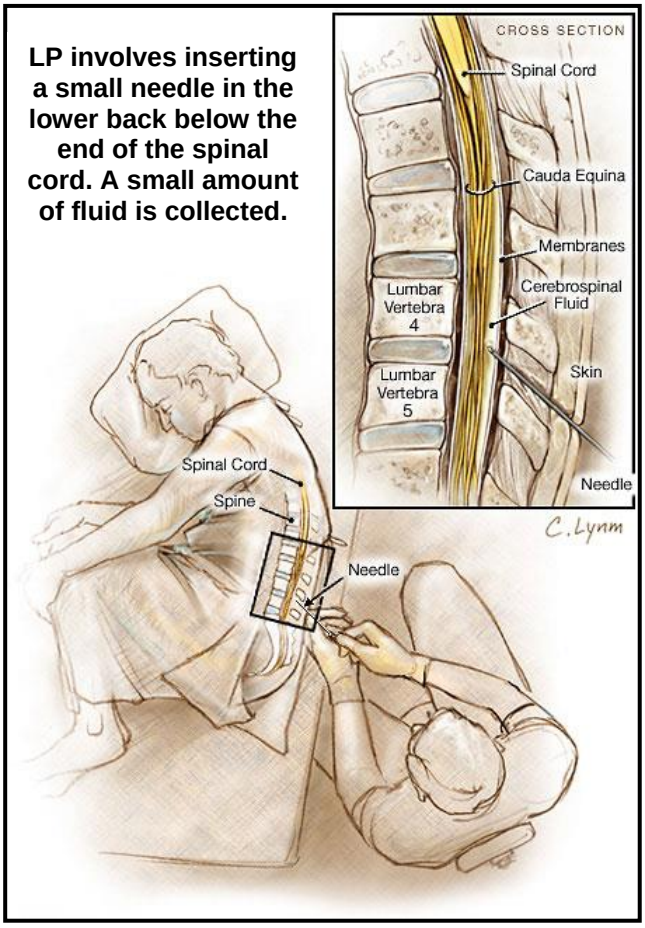


Sample MRI Machine

is to understand how different regions in the brain change as we get older.

Each MRI scan will take approximately 30-45 minutes to complete. The magnetic resonance scanner is a long narrow tube that is open on both ends. You will lie on your back and enter the MR machine, during which time you will hear loud knocking noises. You may become anxious while in the magnetic resonance scanner. If this happens to you, you can stop the procedure at any time. There are some additional risks associated with MRI and they are described later in the 'Risks' Section.

MRI scans will be stored indefinitely for research purposes. Personal identifiers (i.e., your name, address, etc.) will be replaced with a Subject ID number.



LP involves inserting a small needle in the lower back below the end of the spinal cord. A small amount of fluid is collected.

6) Cerebrospinal Fluid (CSF) Collection. You will be asked to undergo a research cerebrospinal fluid (CSF) draw (called a lumbar puncture - LP). Optional additional LP's may be requested when appropriate but are not mandatory to participate in this study. This will allow ADRC investigators to measure the levels of a number of different proteins (called biomarkers) in the CSF.

A LP is a procedure in which a small amount of CSF that surrounds the brain and spinal cord is removed by inserting a needle in the lower back. It is a routine neurodiagnostic procedure that we are using for research. You may come without eating, or having only a light meal before the LP. For this procedure, you will be positioned lying on your side and curled up in a ball, or sitting up and bent forward, whichever is easier for you. The lower part of your back will be cleaned with antiseptic. The doctor will inject local anesthetic (lidocaine, 1%) into the skin of your lower back. When the area is numb, a very thin needle will be inserted into the spinal canal in the lower back, well below the level where the spinal cord ends. About 20 milliliters (1½ tablespoons) of spinal fluid will be removed for analysis and storage. Undergoing the LP procedure takes approximately 10-30 minutes. Your body replaces this spinal fluid within 1-2 hours.

After the lumbar puncture is completed, you will remain in the clinic for about 30 minutes. You will be given something to eat and drink before you leave. You should not do any strenuous physical activity for the next 24 hours. This includes lifting, bending, doing housework and gardening, or doing exercise such as jogging or bicycle riding. Study staff will call you the day following your lumbar puncture to discuss how you are feeling.

Certain conditions, such as a history of a bleeding disorder, use of Coumadin, or a local back problem, may prevent you from participating in the LP portion of this study. Study staff will discuss these issues with you beforehand.

7) Autopsy. You will be asked to undergo an autopsy of your brain after you die. This examination of your brain may provide a conclusion about whether or not AD or a related disorder was found. This contribution may provide valuable information that may further our understanding of memory changes and aging. There is a separate consent form for brain autopsy.

8)

9) Blood Pressure and Arterial Stiffness Assessment: You undergo a non-invasive assessment of central blood pressures and arterial stiffness using a blood pressure device (pulse wave velocity (PWV)). This visit will take approximately 20 minutes. During this time, blood pressure will be taken on both your arm and upper leg. While blood pressure is being taken on the upper leg, you will be lying down and a hand-held device will be used to measure pulse in your neck.

10) Additional Research Studies. You will be asked if you are interested in getting information about additional research studies. We will ask you now and at each annual visit. If you are interested, we will contact you or your study partner with information about these studies, and you can decide whether to participate or not. These additional studies are separate from the longitudinal study and your decisions about them will not affect your ability to continue to participate in this study.

RISKS

Participation in this study may involve some risks or discomfort.

Blood Draws. Removal of blood by a needle and syringe poses a small risk of pain or bruising at the site of the needle stick, but this is temporary. Some people may experience fainting or dizziness, and there is also a slight risk of infection at the site of the needle stick. To minimize these risks, experienced medical personnel will handle all the blood drawing procedures.

Evaluations. Repeated evaluations of mood and mental status may be frustrating or produce fatigue and boredom. Frequent rest breaks are offered as needed.

MRI. The MRI scanner takes pictures of your brain based on electromagnetic waves. There are no known effects from exposure to magnetic fields. There is no radiation exposure as part of this procedure. An MRI may cause possible anxiety for people due to the loud banging made by the machine and the confined space of the testing area. You will be given a set of earplugs to help decrease the noise. There is also a risk of injury if metal is brought into the imaging room, which might be pulled into the MRI magnet. MRI scanning may not be appropriate under some of these conditions: cardiac pacemaker, aneurysm clips, artificial heart valves, brain clips, venous filter, history of sheet metal work or welding, aneurysm surgery, intracranial bypass, renal or aortic clips, prosthetic devices such as middle ear, eye, penile implants, or joint replacements, hearing aid, neurostimulator, insulin pump, IUD, pregnancy, vascular shunts or stents, metallic implants, pins, wires, or screws, permanent eyeliner, eyebrows or lip liner, or metal/foreign objects in the eyes, skin or body, A small number of individuals experience claustrophobia (fear of enclosed spaces) once inside. You will be able to signal the investigators with a squeeze ball device at any time to pause or stop the MRI or simply to ask questions. If you do suffer from claustrophobia, please notify the study doctor. You can also experience some discomfort and fatigue from lying in a confined space during the imaging. You will be asked about these factors before the MRI is performed.

There is an unlikely possibility that you will experience some muscle twitching in a limited location of your body due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, if this occurs and is bothersome, you may stop the scan at any time.

There is a possibility of an abnormal finding being identified on the MRI scan, which will receive a reading by a Radiologist. However, it is important to know that this MRI scan procedure is not sufficient for the clinical diagnosis of a possible brain disorder. Nevertheless, if significant findings occur, you will be notified and you may choose to follow this up with your primary care provider. You will receive a report of the clinical reading of your MRI by the Radiologist. You will not receive results of any of the research analyses we carry out on your MRI.

Lumbar Punctures (LP). During the procedure, you may have temporary pain and discomfort in your back. Occasionally, a low pressure headache may develop after a LP, presumably due to leakage of spinal fluid. If this headache persists it may require an additional treatment called a blood patch. A blood patch involves injecting some of your blood into the lumbar puncture site to seal the spinal fluid leak. This often relieves the headache immediately. Although very rare, it is possible that you may have an allergic reaction to the local anesthetic (lidocaine l%) used for the lumbar puncture. This would cause swelling and a rash on your skin where the anesthetic was injected. Please tell us if you have ever had a reaction to local

anesthetic before (such as when you were visiting the dentist). Potential but rare risks of lumbar puncture include infection, damage to nerves in your back, and bleeding into the spinal fluid space. The risk of these is much less than 1%. To minimize these risks, the lumbar puncture procedure will be performed by Drs. Brewer or Galasko or a neurologist specifically trained in the procedure. Because there will be a restriction of caffeine on the morning prior to the procedure, you may experience a headache. You will be allowed caffeine after completion of the procedure.

Pulse Wave Velocity (PWV) measurements: No significant risks.

Unknown: Because this is a research study there may be some unknown risks that are currently unforeseeable.

DNA. Your samples will be used for research only and you will not receive specific results of these tests. However in the rare instance that we find a gene that causes a specific neurological disease, you have the option of being informed or not about these results. The decision to have such information revealed is highly personal, and can be stressful.

When samples and information about you and your family are sent to the National Cell Repository for Alzheimer's Disease (NCRAD), a unique subject identifier is assigned to this information. A unique subject identifier is a combination of numbers and/or letters that do not correspond to any information you have provided to us (i.e. birth date, age, name) and which is different for each person who participates in this study. NCRAD uses a secure computer system. There is a slight risk that there could be a breach of the security of this computer system resulting in the access of information about your family or medical history. Safeguards are in place to minimize this risk.

Some de-identified data may be provided to a government health research database for broad sharing to approved investigators. This information will be de-identified and will not contain any traditional identifiers (i.e. name, date of birth, address, telephone number). There is a slight risk that there could be a breach in the security of this database system resulting in the access of information. Safeguards are in place to minimize this risk.

A New 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. This law generally will protect you in the following ways:

a) Health insurance companies and group health plans may not request your genetic information that we get from this research.

b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
c) Employers with 5 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that these laws do not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Confidentiality. It is theoretically possible that participation in this study might affect your access to health insurance if information about your involvement and/or results of this study becomes part of your medical record. Therefore we will keep all study data out of your medical record by keeping this information separate, only in your research record. See Confidentiality section for further information.

DATA AND SAMPLE SHARING Dr. Brewer or Dr. Galasko and the ADRC participate in the National Alzheimer's Coordinating Center (NACC), where data from 29 Centers in our program is shared for scientific analysis. The NACC is part of our Alzheimer's Center Program, funded by the National Institute on Aging (part of the National Institutes of Health). Both NACC and the ADRC carry a Certificate of Confidentiality (see description below). The ADRC also collaborates with other academic institutions and companies in the biotechnology or pharmaceutical industries. The results of these analyses will not be shared with you, your caregiver or your heirs due to the exploratory nature.

With approval of Dr. Brewer or Dr. Galasko, your biospecimen samples including blood, plasma, DNA, cells, autopsy brain tissue and clinical data, including data from imaging, CSF, and genetic samples, might be shared for scientific analysis with these organizations. When these samples are shared, they will be identified with a coded number only. These shared data do not include any personal identifiers that might link them back to you.

Decisions about sharing will be made by Dr. Brewer or Dr. Galasko and a group of ADRC investigators in charge of stored specimens. These samples may be used in additional research to be conducted by the University of California or other academic centers or companies in the biotechnology or pharmaceutical industry. In the future, other companies may study your genes for similar or yet unidentified purposes related to AD.

If we want to use any of your samples for a <u>research purpose not described</u> in this consent form, we will send our request to the UCSD Institutional Review Board. This Board protects the rights and welfare of research subjects like you, and will determine whether or not we should contact you in order to participate in this new research.

We will measure a number of different proteins and other markers in your cerebrospinal fluid (CSF) sample. These include the amyloid-beta protein and total tau protein, both of which are related to changes in the brain that have been linked to aging and Alzheimer's disease. These measurements are being carried out to support our research. The laboratory that we use for these measurements is not an accredited or certified clinical laboratory, so we will not be able to provide you with the exact results of any of the CSF proteins or other markers that we measure

By signing this consent, you authorize this use and storage of both your data and your samples indefinitely. You may revoke this authorization by submitting a statement in writing to Dr. Brewer or Dr. Galasko. If you withdraw from the study, you will be asked whether you wish to revoke authorization for use of data or samples gathered up to that point. However, any of your samples that we have shared with other researchers may be impossible to destroy. If you decide that you do not want the samples gathered from you to be used for future research, Dr. Brewer and Dr. Galasko will do their best to stop any additional studies.

You may inspect the records of your participation in this project at any time. However, since the information we gather is for research purposes, it is quite complex and difficult to interpret. For this reason, we ask that a clinician be present at the time of this inspection to help you understand data collected during your participation in the study.

DEVELOPMENT FOR COMMERCIAL GAIN

The information obtained from your biomarker samples may have significant therapeutic or commercial value and may be used to develop a commercial test for AD or to develop tests for other disorders. You will not receive any compensation or other benefits as a result of future studies from these samples. If these samples are shared with other researchers, they will be identified only by a code number and descriptive data (such as age and gender). The results of these analyses will not be shared with you, your caregiver or your heirs due to the exploratory nature. By signing this form you are consenting to such uses. You do not, however, give up any legal rights by signing this consent document.

BENEFITS OF PARTICIPATING IN THIS STUDY

You will not benefit directly from this study. This study does not involve any treatment for the improvement or cure of AD or related dementias. However, by participating in this research study:

1. You will receive an annual exam at no cost to you. If you wish, we will share the results of the exam with you and anyone else you choose. This information may help clarify your diagnosis and the underlying cause of your symptoms. Our research clinicians will provide you with information about normal aging, AD, and other forms of dementia and discuss what you might expect in the future.

2. You will be able to meet with a licensed clinical social worker who can give you suggestions and advice about how to cope with problems associated with Alzheimer's disease and provide referrals to community resources.

3. You will also have the opportunity to learn about experimental drug studies which are taking place at our research center. These studies will be discussed with you to see if you are interested in participation.

4. You will be contributing to a body of knowledge about AD and related dementias and changes in the brain with age. This may help researchers learn more about the diagnosis, treatment, possible causes of AD and other dementias.
5. You will be contributing to the body of knowledge about arterial stiffness which might predict cardiovascular risk and future cognitive impairment.

COMPENSATION (MEDICAL/FINANCIAL) IN CASE OF ILLNESS OR INJURY

Procedures related to the study will be provided at no charge to you. There will be no costs to you for participation in this study. Subjects who undergo a lumbar puncture will be paid $100. If you travel more than 20 miles round trip to participate in this study, you may ask for travel compensation. We may provide up to $50 to assist you with your travel expenses at the current UCSD compensation rate. You may also claim out-of-pocket expenses incurred as a result of participating in a study, such as meals and parking.

If you are injured as a direct result of participation in this research, the University of California will provide any medical care needed to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the UCSD Human Research Protections Program at (858) 246-4777 for more information about this, to inquire about your rights as a research subject, or to report research-related problems.

CONFIDENTIALITY OF RECORDS

Research records will be kept confidential to the extent provided by law. All of the health information generated or collected about you during this study may be inspected by the Department of Health and Human Services (DHHS) agencies and/or the Institutional Review Board (IRB). Your identity and the

information collected will not be disclosed even to your primary care provider without your written consent. Confidentiality applies to both the data we collect and the samples that we store. Information about you will be kept confidential by using coded numbers and a locked file in a computer with restricted access. You will not be identified in any reports or publications.

Biomarker samples, which include CSF and genetic samples, will be stored in the ADRC laboratory and maintained in a coded manner without any identifying information. Results from the ApoE genotyping will be shared with the NACC. The data sent to the NACC is identified only by a number and does not include your name, address, or other identifying information. This data coding protects your privacy. Data will not be revealed to family members, insurance companies, employers, or other individuals or organizations. Any information gained from genetic research will be reported in anonymous summary form. No information will be entered into your regular medical record. Both the ADRC and the NACC carry Certificates of Confidentiality (see below) from the DHHS.

We will provide you with a copy of the UCSD Health Insurance Portability and Accountability Act (HIPAA) Notice that describes use of your Protected Healthcare Information and medical records in relation to this research study.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or an individual's family members, or using such information for decisions regarding coverage, rates, or preexisting conditions. GINA also prohibits employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. Furthermore, the researchers have adopted strict privacy and confidentiality procedures for maintaining your genetic information as described in this consent form. You should be aware, though, that if your genetic information were accidentally released to the wrong source, federal law does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance or by adoption agencies.

CERTIFICATE OF CONFIDENTIALITY

A Certificate of Confidentiality has been issued for this project from the U.S. Department of Health and Human Services (DHHS). This Certificate will protect the Investigator(s) from being forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

This protection, however, is not absolute. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of

federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). It does not apply to any state requirement to report certain communicable diseases. In addition, researchers must report child or elder abuse to appropriate authorities.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Drs. Brewer, Galasko or the other investigators will not voluntarily, without your consent, disclose information that would identify you as a participant in this research project.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You are free to discontinue participation at any time without prejudice to your subsequent care, and are free to seek care from a health care provider of your choice at any time. You may refuse to participate or withdraw at any time by calling the ADRC at 858-822-4800. Drs. Brewer and Galasko will still be able to use the information collected about you prior to your withdrawal from the study. Information that has already been shared cannot be withdrawn. Your participation also may be stopped by the study doctors without your consent. If this happens, it might be due to your inability to participate in study related activities. If you are experiencing any distress from a procedure you are undergoing, you may ask to stop the procedure at any time.

CONTACT PERSONS

Dr. Brewer, Dr. Galasko or _____has explained this study to you and answered your questions. If you have other questions or research related problems, you may reach Dr. Brewer, Dr. Galasko or study personnel at 858-822-4800.

STATEMENT OF CONSENT

You have read (or have had read to you) the above description of this research study. You have been informed of the risks and benefits involved, and all of your questions have been answered to your satisfaction.

You agree to undergo a **lumbar puncture**

☐ **Yes** ☐ **No** _____ **Subject Initials**

You agree to undergo, **Store and Share** an **MRI of your brain**.

☐ **Yes** ☐ **No** _____ **Subject Initials**

You agree to have your annual assessments recorded for quality control and possible future research.

☐ **Yes** ☐ **No** _____ **Subject Initials**

You are interested in getting information about additional research studies and being entered into a Research Registry.

☐ **Yes** ☐ **No** _____ **Subject Initials**

You will receive a copy of this signed consent form, and a copy of the "Experimental Subjects Bill of Rights" to keep.

You agree to participate.

Subject's Name (print) **Signature** **Date**

Legally Authorized Representative (print) **Signature** **Date**
(If applicable)

Person Obtaining Consent's Name (print) **Signature** **Date**

STUDY PARTNER'S CONSENT TO PARTICIPATE

You have read this consent form and have been given a copy of it and "The Experimental Subject's Bill of Rights" to keep. You have had the opportunity to ask questions, and your questions have been answered to your satisfaction. You agree to serve as a study partner for the above named individual and to confirm the information we gather at each visit.

Study Partner's Name (Print) **Signature** **Date**