INFORMED CONSENT
TO ACT AS A RESEARCH SUBJECT IN:

ALZHEIMERS DISEASE NEUROIMAGING INITIATIVE-2 (ADNI-2)
ADC-039

FOLLOW-UP SUBJECTS

- **Site Investigator(s):** **[Insert Site Protocol PI Name]** **TEL**: **[Insert PI Telephone]**
  [Insert Site Subinvestigator Name(s)]
- **Location:** **[Insert Site Name]**
  [Insert Site Address]
  [Insert Site City, ST Zip]

This consent form describes a research study called the Alzheimer's Disease Neuroimaging Initiative-2 (ADNI-2) and what you may expect if you decide to participate. You are encouraged to read this consent form carefully and to ask the person who presents it any further questions you may have before making your decision whether or not to participate. This study is being sponsored by the Northern California Institute for Research and Education (NCIRE), through a grant from the National Institute on Aging (NIA).

PURPOSE AND GENERAL PLAN OF THIS STUDY

You are already participating in the original ADNI1 or ADNI-GO protocols - research studies designed to look at the usefulness of imaging studies and biomarker tests, together with measurements of memory, thinking and daily functioning, in the future conduct of studies that will focus on the identification and treatment of Alzheimer's disease at an early stage. This ADNI-2 study aims to produce more data to be stored for these kinds of future research studies. This consent explains the tests and procedures that will be performed over the next 60 months.

This study will look at three different groups of volunteers:

ADNI-1 Subjects		ADNI-GO Subjects
CN	**LMCI**	**EMCI**
Cognitively Normal	**Late Mild Cognitive Impairment**	**Early Mild Cognitive Impairment**
ADNI-1 volunteers with no apparent memory problems	ADNI-1 volunteers with late and mild memory problems	ADNI-GO volunteers with early memory problems (referred to in this study as "early mild cognitive impairment" or EMCI)

You must have an individual (spouse, friend, or relative) who is willing to continue to act as your Study Partner and:

- Accompany you to all of the study visits
- Communicate changes in your health status over the period of this study.

DESCRIPTION OF STUDY PROCEDURES

If you agree to participate, you will come to the clinic for an additional 3-6 study visits over the next 48 - 60 months.

During this study, Dr. **[Insert Site PI Name]** and his/her staff will be monitoring your condition.

IN-CLINIC EVALUATIONS

You will be asked not to eat or drink anything for up to 12 hours prior to coming to the clinic for annual visits. This includes all food and drinks such as coffee, tea, milk and juice (water is OK). Also, do not use any substances which contain nicotine such as cigarettes, chewing tobacco, nicotine gum and nicotine patches. This time will vary depending on what procedures you will be having done each day. If there are difficulties scheduling follow-up visits, some assessments may be collected by telephone. The Initial visit, however, must be completed in-person with both you and your study partner. Study staff will discuss your visit activities and schedule with you.

Summary of Clinic Visit Activities

	Initial	On-Going Annual and/or Biennial Visits**
Medical History	✔	
Vital Signs (Blood pressure, pulse, respiration rate, weight and temperature) will be recorded	✔	✔
A list of any medications and vitamins you are taking will be collected	✔	✔
Memory & Thinking Skills, daily functioning and behavior tests	✔	✔
Depression Test	✔	✔
Blood draw for research labs and sample banking	✔	✔
Adverse Experiences collected	✔	✔
Magnetic Resonance Imaging (MRI) Scan	✔	✔ *
Florbetapir F 18 Positron-Emission Tomography (PET) Scan	✔	✔ *
Lumbar Puncture (LP)	✔	✔ *

* LP, MRI and PET scans will be conducted every two years. The schedule for PET scans and LPs may vary based on your previous participation in ADNI-GO. Study staff will discuss this with you before each visit.

** LMCI and EMCI participants will be seen annually; CN participants who have converted to EMCI, LMCI or AD will be seen annually; CN participants who have **not** converted will be seen every two years (biennially).

REVIEW OF PROCEDURES:

MRI SCAN:

An MRI is an electronic picture of your brain created using a strong magnet instead of x-ray energy. Each MRI will take approximately 45 minutes to complete. You will lie on your back and enter the MR machine for the study, during which time you will hear loud knocking noises. People with pacemakers, aneurysm clips, cochlear implants, or metal/foreign objects in their eyes are not permitted to undergo MR studies.

FLORBETAPIR F 18 POSITRON EMISSION TOMOGRAPHY (PET) SCAN:

You will undergo PET scans that will measure amyloid in the brain. Amyloid is a protein that is found in the brain in patients with Alzheimer's disease at autopsy. In this study, brain amyloid will be measured using PET with a radioactive substance, called "florbetapir F 18". A small amount of florbetapir F 18 injection will be injected in a vein in your arm, and after approximately a 50 minute waiting period you will be positioned in the PET scanner to take pictures for approximately 20 minutes. During your time in the PET scanner you must hold your head as still as possible.

You will have a computerized x-ray (CT scan) to help align the positioning of your brain before each PET scan. After the scans are completed you will be asked to drink fluids and empty your bladder. You should not receive research PET scans if you are pregnant, have received radiation therapy, or have been in another research study involving radiation.

LUMBAR PUNCTURE:

A lumbar puncture is a procedure in which a small amount of the spinal fluid that surrounds the brain and spinal cord (called cerebral spinal fluid or "CSF") is removed by inserting a needle in the lower back. You will be asked not to eat or drink anything (water is Ok) for at least 6 hours before the lumbar puncture visit. For this procedure, you will be positioned lying on your side and curled up in a ball, or sitting 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 CSF will be removed during each LP for analysis and storage. 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.

RESEARCH BLOOD DRAWS. Blood will be drawn for different purposes in this research study:

1) Measurement of Blood **Biomarkers –** You will be asked not to eat or drink anything (water is Ok) for at least 6 hours before biomarker blood draw visits.
2) **Genetic Research (if not previously collected)** – 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. Differences in DNA are called genetic variations. You are being asked to agree to allow us to study the genetic material as part of this research. Researchers may request another blood sample from you to test your DNA if there are quality issues with the first sample.

3) **Genetic Expression - RNA Research** – Genes in your DNA that are active produce ribonucleic acid or "RNA" for short. RNA from your cells can be measured to study the activity of genes. You are being asked to agree to extracting and testing of RNA from your blood at the initial clinic visit and Annual clinic visits.
4) **Immortalized Cell Line** (only if there were problems with your original samples) – Cell lines provide a living, growing source form which DNA can be extracted. Your blood may be used to create a cell line that will allow researchers to continue to study your genes for many years.
5) **Storage of DNA & RNA Samples** – You are being asked to agree to the storage of your DNA and RNA samples. Important research can be done in the future on samples collected today.

STUDY DISCONTINUATION

If for some reason the health care team removes you from the study, or if you decide to withdraw prior to the end of the study, you will be asked to return for a study discontinuation visit. This evaluation will include all of the procedures normally performed at an annual Clinic visit.

AUTOPSY | BRAIN DONATION

A lot can be learned about the human brain by studying it under a microscope. Therefore, we are asking each person that participates in this study whether they agree to brain donation for research (autopsy) at time of death.

You will be asked as the end of this consent form if you are interested in considering brain autopsy after death. You can decline an autopsy at time of death and still participate in this study. You will be asked to sign a separate Autopsy consent form.

SAMPLE STORAGE AND FUTURE USE

Researchers are working to find genes and other markers that play a role in the occurrence of Alzheimer's disease and aging-related disorders. Blood and CSF will be drawn for genetic and biomarker research tests, and DNA and RNA storage in ADNI-2. You are being asked to allow these samples to be stored indefinitely for these future studies of Alzheimer's disease and aging-related disorders. The results of these tests are important only for research, not for helping to care for you. For this reason, these results will not be released to you or your family. No data from your genetic tests will be sent to study sites. This is to protect you and your family's confidentiality.

Data from your tests will not be revealed to sites that are participating in the clinical study, family members, insurance companies, employers, or other individuals or organizations. Although researchers will have access to de-identified individual data, any information gained from this research will be reported in anonymous summary form. The samples will be retained indefinitely. No information regarding the biomarker research will be entered into your regular medical record.

Study investigators will maintain and be responsible for deciding how your samples and the information obtained from them will be used. All links with your identity will be removed from the sample before it is

stored or shared. Only de-identified data, which does not include anything that might directly identify you , will be shared with ADNI members and the general scientific community for research purposes.

MRI SAMPLE STORAGE AND FUTURE USE

Your MRI images will be sent to the Laboratory of Neuroimaging (LONI) at the University of Southern California and Mayo Clinic, Rochester. Your imaging data will be labeled with a coded research identifier to protect your identity**.** Study investigators will maintain and be responsible for deciding how your data will be used for future research. All links with your identity will be removed from the data before they are shared. Only de-identified data, which does not include anything that might directly identify you, will be shared with ADNI members and the general scientific community for research purposes.

PET DATA STORAGE AND FUTURE USE

Your PET images and data will be sent to researchers at Avid Radiopharmaceuticals, the University of Michigan and the Laboratory of Neuroimaging (LONI) at the University of Southern California. Your imaging data will be labeled with a coded research identifier to protect your identity. Study investigators will maintain and be responsible for deciding how your data will be used for future research. All links with your identity will be removed from the data before they are shared. Only de-identified data, which does not include anything that might directly identify you, will be shared with ADNI members and the general scientific community for research purposes.

SHARING OF FINAL RESEARCH DATA

Data from this research will be shared with other researchers. Data sharing is important for further translation of research results into knowledge, products, and procedures to improve human health. All links with your identity will be removed from the data before they are shared.

RISKS

Your participation in this study and study procedures may involve risks that are currently unforeseeable due to the investigational nature of this study. Some of these unknown risks may be life-threatening or result in death. However, if any new risks become known in the future you will be informed of them. Participation in this study may involve some added risks or discomforts, which are outlined below.

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 and sterile conditions will be maintained. Up to 247 milliliters (16 ½ tablespoons) of blood may be taken over the course of this study, and your body will make up for the loss.

MRI. There are no known biological risks associated with MR imaging. 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. There is also a risk of injury if metal is brought into the imaging room, which might be pulled into the MRI

magnet. People with pacemakers, aneurysm clips, artificial heart valves, ear implants or metal/foreign objects in their eyes are not permitted to have an MRI.

FLORBETAPIR F 18 PET SCAN. Florbetapir F 18 Injection is approved by the United States Food and Drug Administration (FDA) to estimate amyloid levels in adult patients with memory problems who are being evaluated for AD and other causes of cognitive decline.

Florbetapir F 18 is an imaging agent which uses a small amount of radioactivity (radiation) necessary to create the PET scan image. It is used at very small doses, well below levels which have any known effect on the body. The radiation exposure from florbetapir F 18 is 0.43 rem from each PET scan.

To date, florbetapir F 18 has been tested in approximately 8,500 subjects in completed and ongoing research studies. The most common side effect in completed studies involving 555 subjects was headache. Additional uncommon (reported by 0.1% to 1.0% of subjects) side effects reported were: musculoskeletal (muscle and bone) pain, increased blood pressure/hypertension, nausea, fatigue, injection site reaction (bleeding, irritation, pain), anxiety, back pain, claustrophobia (fear of being in closed or narrow spaces), dizziness, feeling cold/chills, insomnia (inability to sleep), neck pain, infusion site rash, dysgeusia (bad taste in the mouth), pruritus (itching), urticaria (hives), and flushing.

- A needle will be used to inject florbetapir F 18 agent into a vein in your arm. Insertion of the needle may cause pain or a stinging sensation at the injection site. On rare occasions the insertion of a needle can cause bleeding, a blood clot, swelling or infection at the site of insertion.

There is currently no information on the effects of florbetapir F 18 on unborn children. However it is known that higher levels of radiation can cause damage to unborn children. This study excludes women who are able to become pregnant.

CT SCAN. You could also receive radiation of 0.2 to 0.4 rem from a "low dose" computed tomography (CT) scan which is used to help align the positioning of your head in the florbetapir F 18 PET scan. The total dose of radiation from each combined PET scan and CT scan will be approximately 0.9 to 1.1 rem. As a comparison, a diagnostic CT examination (e.g., as you might have for tumor or trauma imaging) delivers up to a 1.8 rem (unit of absorbed radiation). An average person receives 0.36 rem per year from natural and man-made radiation. Large amounts of radiation may increase the risk of developing cancer.

EVALUATIONS. Repeated evaluations of mood and mental status may be slightly frustrating or produce fatigue and boredom.

LUMBAR PUNCTURES (LP). In total, approximately 60 milliliters (about 4 Tablespoons) of spinal fluid may be taken during this study and your body will make up for the loss. During the procedure, you may have temporary pain and discomfort in your back. Headache may occur in people who undergo a lumbar puncture. Occasionally, a low pressure headache may develop, presumably due to leakage of spinal fluid. If this headache persists it may require additional treatment. Uncommonly a blood patch (injection of some of your blood into the lumbar puncture site to patch the spinal fluid leak) may be required. 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 that may affect the spinal cord or brain. The

risk of these is very small. To minimize these risks, the lumbar puncture procedure will be performed by Dr. _____ or by a neurologist specifically trained in the procedure.

BENEFITS OF PARTICIPATING IN THIS STUDY

There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study will help the investigators learn more about the usefulness of biomarker and imaging studies for the future prevention and treatment of Alzheimer's disease. The development of biomarker and imaging studies that track the development of Alzheimer's and reflect the change in people's bodies may help other people who have a similar medical problem in the future. This study will not make your health better.

ALTERNATIVE MEDICATIONS AND TREATMENTS

If you are currently experiencing memory problems, there are 5 drugs (tacrine, also known by the brand name Cognex; donepezil, also known by the brand name Aricept; galantamine, also known by the brand name Razadyne; rivastigmine, also known by the brand name Exelon; and memantine, also known by the brand name Namenda) approved for the treatment of Alzheimer's disease. Thus, alternatives to participation in this study include use of tacrine, donepezil, galantamine, rivastigmine, memantine or no treatment. If you participate in this study, and already take tacrine, donepezil, galantamine, rivastigmine or memantine, the drug may be continued during the study. However, starting tacrine, donepezil, galantamine, rivastigmine or memantine at any point during the course of the study is discouraged and should be discussed with your study doctor as you may no longer be able to participate in this study.

Participation in any other clinical studies with cognitive testing more than one time per year will not be permitted until your participation in this study has ended.

Another alternative is not to participate in this study and to continue under standard medical care, which may include receiving some of the above listed medications if you are experiencing memory problems.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION

Pursuant to local laws and regulations, your HIPAA research authorization may be incorporated into the body of the consent form or can be addressed in a separate document. Under HIPAA requirements, subjects must authorize the use of their protected health information (PHI). The **CONFIDENTIALITY** section is appropriate for incorporating some of the required privacy language. Other sections containing sample language relevant to HIPAA include **VOLUNTARY PARTICIPATION** and the **STATEMENT OF CONSENT**.

Please consult your IRB for site-specific requirements.

Sample HIPAA text is presented in **BOLD** below.
IF USING A SEPARATE RESEARCH AUTHORIZATION, OMIT THE BOLDED SECTIONS.

HIPAA-Required Elements Addressed Here:

- Description of information to be used or disclosed
- Persons authorized to use and disclose information
- Persons authorized to receive information
- Purpose of the requested use or disclosure of information
- Redisclosure information
- Expiration of authorization

DELETE THIS BOX FROM YOUR CONSENT

Research records will be kept as confidential as possible within the limitations of state and federal law. **Federal Privacy Regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or disclose your individually identifiable health information may include the study doctor, the study staff, the Institution, the study Sponsor, other research sites participating in this study, and the laboratories used in this study (Covance Central Laboratory, the University of California at San Francisco VA Medical Center, the Mayo Clinic in Rochester, the University of Michigan, the University of Pennsylvania, Avid Radiopharmaceuticals, Eli Lilly & Company and its representatives, the National Cell Repository for AD (NCRAD), the University of Southern California and the University of California, San Diego).** In order to analyze the data collected during this research study, all of the health information generated or collected about you during this study may be inspected by the study Sponsor and its authorized agents, the Department of Health and Human Services (DHHS) agencies and/or the Institutional Review Board (IRB). Because of the need to release information to these parties absolute confidentiality cannot be guaranteed. **Once your personal health information is released it may be redisclosed, at which point your health information will no longer be protected by federal privacy regulations.** The findings of this research will be presented at meetings or in publications; however, neither your name nor identity will be disclosed in those presentations. By signing this consent form, you are authorizing such access to your medical records. **This authorization will have no expiration -** data will be entered into linked study databases to be used from this date and going forward.

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.

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

GENETIC STUDIES: GWAS information and datasets are stored in the NIH databases under strict security provisions, including multiple firewalls, separate servers, and data encryption protocols. Data submitted to any databases are de-identified and coded, meaning it will not include anything that might directly identify you. 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. Data is being provided to the database for broad sharing to qualified investigators.

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be 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. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

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).

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.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. [The researchers should state here the conditions under which voluntary disclosure would be made. If no voluntary disclosures will be made, the researchers should state.]

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 will be paid $_____ upon completion of each clinic visit. In addition, subjects asked to have lumbar punctures will be paid $_____ per lumbar puncture completed.

All forms of medical testing – whether routine or experimental – involve some risk of injury. In spite of all safety measures, you might develop medical problems from participating in this study. You must report

any suspected illness or injury to the study doctor immediately. If such problems take place, the **[SITE INVESTIGATOR'S INSTITUTION]** will provide emergency medical treatment and will assist you in getting proper follow-up medical treatment. The Northern California Institute for Research and Education (NCIRE), its coordinating center and the National Institute on Aging (NIA) will not provide compensation for research-related injury. **IN ADDITION TO THIS STATEMENT ADD YOUR INSTITUTION'S SUBJECT INJURY CLAUSE HERE (you will / will not pay for subject injury, etc).**

If you have any questions regarding this research or if you believe that you may have experienced a research related injury or a reaction to the study medication, you should contact Dr. **[Insert Site PI Name]** (study doctor) at **[TELEPHONE]**.

If you have any questions about your rights as a research subject, you may call the **[SITE IRB's OFFICE]**, at **[TELEPHONE]** for more information about this or to report research-related problems

CONTACT PERSONS

You have the right to ask, and have answered, any questions you may have about this research. If you should have any questions about this research or feel that you have suffered from a research related medical problems at any time during this study, you may contact **[Insert Site Contact Name]** at **[Insert Contact Telephone]**.

If you have any questions about your rights as a research participant, you may contact **[Insert Site Contact Name]** at **[Insert Contact Telephone]**.

VOLUNTARY PARTICIPATION

Sample HIPAA text is presented in **BOLD** below.
IF USING A SEPARATE RESEARCH AUTHORIZATION, OMIT THE BOLDED SECTIONS.

HIPAA-Required Elements Addressed Here:

- Right to withdraw authorization

DELETE THIS BOX FROM YOUR CONSENT

Your participation in all aspects of this research study is entirely voluntary.

You have the right to refuse to participate, or may discontinue participation in this project at any time without jeopardy to the medical care you receive at this institution. There is also the possibility that the investigators may decide to terminate your study participation at any time. You will be informed of any new findings that may affect your continued participation. You may request that your data and any unused samples be destroyed. However, data and samples that have already been shared will not be retrieved.

You may also revoke the authorization to use or disclose personal information about your health. If you choose to withdraw your authorization, you must notify Dr. [Insert Site PI Name] in writing. Dr. [Insert Site PI Name]'s mailing address is:

[Insert Site Address]

Dr. [Insert Site PI Name] will still be able to use the information collected about you prior to your withdrawal from the study. Information that has already been sent to the sponsor cannot be withdrawn.

STATEMENT OF CONSENT

Sample HIPAA text is presented in **BOLD** below.
IF USING A SEPARATE RESEARCH AUTHORIZATION, OMIT THE BOLDED SECTIONS.

HIPAA-Required Elements Addressed Here:

- Right of Refusal

DELETE THIS BOX FROM YOUR 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.

By signing this consent you are authorizing the use of your data and biological materials for large scale, multi-center studies that will combine data from similar populations. These multi-center studies are being conducted by the Alzheimer's Disease Neuroimaging Initiative (ADNI), a neuroscience consortium of universities and research institutes. Your data and biological samples will be stored with a coded research identifier to protect your identity. Only de-identified data, which does not include anything that might directly identify you, will be shared with ADNI members and the general scientific community for research purposes. This data will be entered into study databases to be used from this date and going forward. Genetic data may be made available on NIH-approved, secure databases.

Unless you authorize the use and disclosure of your personal health information, you cannot participate in this research study. If you refuse to give your authorization, your medical care will not be affected.

You agree to participate in the **MRI** portion of this study.

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

You agree to participate in the **Lumbar Puncture** portion of this study.

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

You agree to participate in the **Florbetapir F 18 PET Scan** portion of this study.

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

You agree that **DNA testing** can be done on your blood samples.

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

You agree that **RNA testing** can be done on your blood samples.

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

You agree to **STORE and SHARE your CSF samples and other relevant clinical information**

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

You agree to **STORE and SHARE your blood samples and other relevant clinical information**

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

You agree to **STORE and SHARE your DNA samples and other relevant clinical information**

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

You agree to **STORE and SHARE your RNA samples and other relevant clinical information**

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

You are interested in **considering brain autopsy** after death. You will be asked to sign a separate Autopsy consent form.

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

You will receive a copy of this consent form.

_____ **Study Subject** (print)	_____ **Signature**	_____ **Date**
_____ **Authorized Representative** (print)	_____ **Signature**	_____ **Date**
_____ **Relationship to Study Subject**		
_____ **Person Obtaining Consent** (print)	_____ **Signature**	_____ **Date**

The signature section of your consent form should be modified to reflect your State, IRB and Institutional requirements for obtaining legally effective Informed Consent for Research. Requested signatures may include: the subject or the subject's legally authorized representative, the PI, the person obtaining consent and/or the witness, etc. pursuant to applicable local laws regarding substitute consent.

Please consult your IRB for site-specific requirements

STUDY PARTNER INFORMATION & CONSENT

As the subject's study partner, you have important tasks that need to be carried out in order for the study to be conducted in the safest and best manner possible. These responsibilities include:

1) You must go along with the subject to all clinic visits.
2) You are an important source of information about the subject. You will be asked questions in order to find out whether there are any changes in the subject.

You must agree to return with the study subject for his or her examinations and evaluations.

If for some reason you become unable to carry out your responsibilities, please tell the study coordinator immediately. You may be asked, if possible, to select a substitute who can take over your duties.

You have read all the preceding information which describes both the subject's participation in the study and your involvement as the subject's study partner. The study has been explained to you in detail. All your questions have been answered to your satisfaction.

You voluntarily consent to participate in this study.

Study Partner's Name (print)	Signature	Date
Person Obtaining Consent (print)	Signature	Date

The signature section of your consent form should be modified to reflect your State, IRB and Institutional requirements for obtaining legally effective Informed Consent for Research. Requested signatures may include: the subject or the subject's legally authorized representative, the PI, the person obtaining consent and/or the witness, etc. pursuant to applicable local laws regarding substitute consent.

Please consult your IRB for site-specific requirements

CLICK ON THIS BOX AND DELETE IT FROM YOUR CONSENT