Informed Consent to Act as a Research Participant in:

Study Title: Alzheimer's Disease Neuroimaging Initiative 3 **(ADNI3)**
Rollover Participant Consent Form

Supported by: Northern California Institute for Research and Education (NCIRE) with the Alzheimer's Therapeutic Research Institute (ATRI) through a grant from the National Institute on Aging (NIA).

Investigator: [enter PI full name]
[enter site name]
[enter site phone number]

About this Research

You are being asked to participate in an observational research study. Research studies are designed to gain scientific knowledge that may help people in the future. This consent form will give you information about the study to help you decide whether you want to participate. Please take your time in reviewing this form as you make your final decision about participating in this study. Ask your study doctor or the study staff to explain any words or information you do not understand. You may also discuss the study with your friends and family.

Taking Part in this Research Study is Voluntary

Participation in research is completely voluntary. You may choose not to take part in the study or you may choose to leave the study at any time without any penalty or loss of benefits to which you are otherwise entitled. Your decision will not be held against you or have any impact on the healthcare you receive at this institution.

Study Summary

Previously, you participated in the ADNI-2 research study, a study designed to look at the relationship between clinical, cognitive, imaging, genetic and biomarker tests over time, in order to understand the full spectrum of Alzheimer's disease (AD) from its earliest stages.

The ADNI-3 research study will continue to collect and store more of this kind of research data. Data from this research will continue to be used in the development of future research studies that focus on

the treatment of AD at an early stage.

This study will continue to follow participants from previous ADNI studies (ADNI-1, ADNI-GO, and ADNI-2), and also enroll new participants that fit into one of the following 3 study groups:

- **Cognitively Normal (CN) group:** participants with no apparent memory problems.
- **Mild Cognitive Impairment (MCI) group:** participants diagnosed with early or late stages of mild memory problems.
- **Mild Alzheimer's disease (AD) group:** participants diagnosed with a mild stage dementia.

The study will last up to 5 years, depending on which study group you fit into (CN, MCI or AD) with 3-6 study visits over the course of the study. The following things will happen during the study:

	Research procedures	**Potential risks**
	Blood draws Lumbar punctures (LP)	Pain and bruising from the needle stick Temporary back pain, headache (LP)
	PET scans (three different types) MRI scans	Radiation Exposure (PET scan) Anxiety or panic from being in a small space or hearing loud noises (MRI scan)
	Questionnaires and testing of your memory and thinking	Frustration or stress during testing
	Whole genome testing	Genetic information could be known by others
	Computer-based testing from home, and brief telephone calls to check-in	Frustration or stress during testing
	Broad sharing of all research data and samples for future research	Chance your information will be seen by someone else (not likely)
	Brain Donation (optional)	Minimal risk as procedure is performed after your passing

All participants in this study will need to have an individual (spouse, friend, or relative), called a "Study Partner", who is willing to:

- Accompany you to the study visits, either in person or be available by phone.
- Answer questions about your memory and daily functioning.
- Possibly assist you with logging in to a computer for computer based memory tests.

- Have direct contact with you either in person, by phone or by computer about 10 hours a week.

More detailed information about the study procedures can be found under *"Description of Study Activities."*

Detailed Information

The information on the following pages is more detailed information about this study in addition to the information listed above.

How many people will take part in this study?

This study is being conducted at about 59 clinical trial sites across the United States and Canada. If you are eligible and agree to participate you will be one of about 1070 - 2000 people enrolled.

How long will I be in this research study?

If you are eligible and agree to participate, your participation in this study will last between 3 and 5 years, depending on which study group you fit into.

How often you are asked to come into the clinic during this time will also be based on which study group you fit into:

- CN participants will come into the clinic every other year, with telephone checks occurring on alternating years, for up to 5 years. Some participants in the CN study group will be asked to come into the clinic sooner than every other year for additional PET scans (discussed later in the consent).
- MCI participants will come into the clinic every year for up to 5 years.
- AD participants will come into the clinic every year for up to 2 years and then will participate in brief telephone checks every 6 to 12 months until the end of the study.

Additionally, CN and MCI participants may take on-line memory tests using home computers every 3 months between clinic visits.

It is possible that additional funding will allow us to extend the study for an additional year. If this occurs, the study team will talk with you about this and you will be asked to sign a separate consent form at that time.

What will happen if I take part in this research study?

If you are eligible and agree to participate in this study, you will be asked to come into the clinic for an **Initial Clinic Study Visit** and then return every year or every other year for ongoing **Follow-Up Clinic**

Study Visits, depending on your study group.

At the beginning of your initial clinic visit, we will explain all of the study procedures and answer any questions that you and your study partner may have.

After you sign the consent to participate, we ask that you report all injuries, illness or reactions to study procedures to the study staff so that it can be recorded in your study records.

While you are in the study, you must agree to:

- Follow the instructions you are given.
- Come to the study site for all visits.
- Tell the study staff about any changes in your health.
- Tell the study doctor about all medications you are taking and check with the study doctor before you begin taking a new medication.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

During this study, Dr. [INSERT PI NAME] and their staff will be monitoring your condition.

Description of Study Activities

A table summarizing all study activities will be provided to you and your study partner. Visits may be completed over multiple days. Your study visit schedule may change over the course of the study. A member of the study team will contact you if there are any changes to your study schedule.

The following procedures will be done at one or more visits over the course of the study:

- We will ask about your general medical history at the start of the study. At future visits, we will ask you about anything that might have happened during the time between visits, such as changes in your health, any injuries or illnesses, or any reactions to study procedures.

- We will record your weight and vital signs (blood pressure, heart rate, breathing rate and temperature).
- We will ask you about any medications that you are currently taking, including any vitamins or supplements.
- You will be given written tests of your memory and thinking, and you and your study partner will be asked questions about your daily functioning and your behavior. You can skip any questions you do not want to answer, and you can take breaks if needed.
- If you are in the CN or MCI study groups, you may participate in computer-based memory testing, both in the clinic with the study staff and at home on your own. These testing sessions should take

about 10-15 minutes to complete.

During your clinic visit, you will take the computer-based memory tests under the supervision of the study team and then again, 14 days after your clinic visits, from a home computer.

You will then repeat the computer-based memory test every 3 months in-between clinic visits.

If required, a member of the study team will follow up with you by phone to confirm that you have completed the 3-month testing sessions.

You can use any computer or device that is connected to the internet and has sound capabilities to take the computer-based memory test. You can take the test at your home, at the home of a family member, at the library, etc.

If you do not have access to a computer, you will not be able to participate in this part of the study. Please let the study team know if you think you will not be able to participate.

If you are in the **CN** study group, during the "off" years that you do not come into the clinic one of your telephone checks will be a little longer and will include your study partner. Study staff will call you and your study partner and will ask you both about any current medications and vitamins you are taking and any changes in your health that you may have experienced since your last visit. Study staff will also ask your study partner questions about any changes in your behavior or emotional state. These telephone checks should take about 10 – 15 minutes to complete.

- All participants will participate in brief telephone checks every 6 to 12 months to discuss your current wishes with regards to brain donation (discussed later in the consent form) and should only take up 5-10 minutes of your time. This check-in can be done in-person during a regular ADNI in-clinic visit or during an already scheduled telephone check (described above). If you decide you are not interested in the brain donation program, you will not be called about this again. Blood will be drawn for biomarker and genetic testing, for Apolipoprotein E (APOE) and genome-wide genotyping, DNA and RNA research, and cell line generation. APOE is a gene that may be linked to the risk of development of AD. The genetic and biomarker research is described in more detail later in this consent form. You will be asked to fast overnight (a minimum of 6 hours) prior to coming to the clinic for this blood draw. This means no food or drinks such as coffee, tea, milk or juice (water is OK).

- You will undergo MRI scans. An MRI uses a large magnet and computer equipment to take electronic pictures of your brain. You will lie on your back and enter the MR machine for the scan, during which time you will hear loud knocking noises as the magnet does its work.

Each MRI scan will take approximately 45 minutes to complete. If the scan fails the quality control procedure and cannot be used, we will repeat the MRI scan.

- You will have up to **three** different types of positron emission tomography (PET) scans as part of the study. If the PET scan is not usable, you may be asked to complete another scan.

1) The first type of PET scan is called an **Amyloid PET scan**. This type of PET scan uses small amounts of a radioactive imaging agent to measure the amount of beta-amyloid in the brain. Amyloid is a protein that can be associated with the development of AD.

   The amyloid PET scan in this study using a radioactive imaging called florbetapir.

   The imaging agent will be injected through a vein in your arm. After the injection, you will sit for approximately 50 minutes before 20 minutes of scanning. During the scan itself, we will ask that you hold your head as still as possible. The technician will help you find a comfortable position for this.

2) The second type of PET scan is called an 18F-fluorodeoxyglucose or **FDG PET scan**. Only participants in the MCI and AD study group will undergo a FDG PET scan and only at the Initial clinic visit.

   The FDG PET scan uses a very small amount of a radioactive form of sugar to make a picture showing how active your brain is.

   We will check your blood sugar level before doing this scan. If it is too high we will have to delay the FDG-PET scan.

   You will be asked to fast for 4 hours before an FDG-PET scan. This means no food or drinks such as coffee, tea, milk or juice (water is Ok).

   After the FDG is injected you will rest for 30 minutes before a 30-minute scan session, again reducing head movement as much as possible.

3) The third type of PET scan is called a **tau PET** scan. The tau PET scan is performed using a radioactive imaging agent called, flortaucipir (^{18}F-AV-1451) which sticks to tau protein in the brain. A sticky version of the tau protein builds up in the brains of individuals with AD.

   Flortaucipir will be injected through a vein in your arm. You will rest for about 75 minutes after the injection, before lying in the PET scanner for a 30-minute scanning session. As with the previous types of PET scans, we will ask that you reduce head movement as much as possible.

   After the scan is finished, you will be asked to drink fluids before leaving the scan facility to help

empty your bladder.

A member of the study team will call you approximately 2-3 days after this tau PET scan to see how you are feeling.

- Right before each PET scan begins, you will undergo computerized x-ray (CT scan). The CT scan uses X-rays to take a picture of your brain (including bones) to help align the position of your head before each PET scan.

- A lumbar puncture (LP) will be performed. A lumbar puncture is a procedure that involves inserting a needle in the lower back, below the spinal cord, in order to collect a small amount of the spinal fluid that washes around the brain and spinal cord, called cerebrospinal fluid (CSF)

  During the procedure you will lie on your side curled up into a ball or you will sit on the edge of a chair or bed and lean forward.

  

  You will be asked to fast overnight (a minimum of 6 hours) prior to coming to the clinic for the LP. This means no food or drinks such as coffee, tea, milk or juice (water is OK).

  The lower part of your back will be cleaned with antiseptic. A local anesthetic will be injected into the skin of your lower back at the area of the lumbar puncture.

  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 (less than 1½ tablespoons) of spinal fluid will be removed for analysis and storage. Your body replaces this spinal fluid within 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 avoid 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.

Random Selection of Additional Tau PET Scan Visits

A percentage of participants in the CN and MCI study groups will be randomly selected to undergo 2 additional tau PET scans. This randomization will not occur until after you have completed your Initial clinic visit. If you are selected to come into the clinic for these additional tau PET scans and are not already scheduled for a follow-up clinic visit, we will also ask that you complete a follow-up clinic visit at that time as well.

A member of the study team will contact you after your Initial visit to let you know if you have been selected to undergo the additional tau PET scans and will let you know your updated visit schedule.

Genetic & Biomarker Research

During this study, your samples will be used to extract genetic material, including DNA and RNA, for genomic testing and for biomarker research.

Genetic Research

The cells of your body contain deoxyribonucleic acid or "DNA" for short. DNA carries the code for the genes that determine your physical appearance such as the color of your hair and eyes. Genes in your DNA that are active lead to higher levels of ribonucleic acid stretches or "RNA" for short. RNA levels from your cells can be measured to study the activity of genes.

DNA and RNA will be extracted from your blood samples for genetic research related to AD and aging.

Genomic studies will be done. This means that researchers will look at your complete set of DNA, including all of your genes. You will not be told the results of any of your genomic testing, even if some of the genes are related to AD risk.

Biomarker Research

A biomarker is a specific physical trait used to measure the progress of a disease or condition. We will look at biomarkers in your blood and CSF to learn how they may be related to the progression of memory problems.

What will happen to my samples? Will they be used in the future?

Your samples will be sent to the laboratories at the National Centralized Repository for Alzheimer's Disease (NCRAD) at Indiana University and at the University of Pennsylvania.

Your samples will be maintained in these laboratories for many years. Your samples will be coded. Information that can identify you (name, address, social security number, etc.) will never be shared with future researchers and neither will the information that links the code with your identifiable information. Your samples will be stored as long as researchers need them. More research may be done on your coded samples at a future date. **You will not be notified when this additional research is done, and we will not ask for your permission again.**

Your samples may be provided to researchers at academic institutions, hospitals, and biotechnology/pharmaceutical companies studying various diseases including AD and aging.

Successful research using your samples could result in commercial or therapeutic projects with significant value, such as a product for the medical treatment of Alzheimer's disease or for diagnosing a mutation responsible for the disease. You will not share in any financial benefits of these uses.

Will I receive any of my study results?

*[Instructions to sites: If your site return results to participants, such as cognitive scores, MRI and/or PET scans in a participant's Electronic Medical Record, this section should be modified to reflect local practice. Additionally, re: Amyloid PET Results Disclosure, ADNI3 memo #28, please follow up with your local IRB on safe process/guidance on how to do so before modifying consent.]*We may learn things about you from the study activities which could be important to your health or to your standard of care. If this happens, the information will be provided to you, but you will not otherwise receive your study results.

This includes the results of your genetic and biomarker tests. 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 and will not be entered into your regular medical record. If you are concerned about a potential genetic disorder, you should discuss this with your personal 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 choose to participate in the ADNI Brain Donation Program (described later in this consent form), ADNI3 will generate a neuropathology research report that describes any findings that may be relevant to your brain health. Such findings may include a definitive diagnosis of Alzheimer disease and/or similar diseases that can lead to or contribute to dementia. This report will be made available to your family.

What will happen to my research data?

All of the data collected in this study including your clinical data, neuropsychological test data, MRI and PET scans, and your biomarker and genetic data will be sent to the Laboratory of Neuro Imaging (LONI) at the University of Southern California (USC) where they will be stored indefinitely and shared for future research. Your data will be combined with data collected during your participation in previous ADNI studies.

Your privacy will be protected. Your data will be labeled with a coded research identifier to protect your identity. Your name and other information which identifies you will not be linked to your research data.

All of the research data will be made available to qualified investigators at other scientific institutions around the world for research purposes.

Because this study is supported by the National Institutes of Health (NIH), the de-identified genetic data will be submitted to government health research databases for broad sharing with approved researchers. Broad sharing of research data will assist other researchers investigating various diseases, including Alzheimer's disease and dementia. All data will be de-identified, so it will not be possible to tell who you are from the data that is submitted. Upon request, your data may be withdrawn at any time. However, data that has already been distributed for approved research prior to the date of your withdrawal cannot be retrieved.

Global Unique Identifier (GUID)

Each participant in ADNI3 will receive a Global Unique Identifier (GUID). A GUID is a computer-generated alphanumeric code that is unique to each research participant.

In order to generate the GUID, study staff will enter 4 pieces of your personal information into a "GUID generator", your birth name, birth date, gender and city of birth, which will generate a unique code. This code will be sent to LONI where the GUID will be assigned and stored along with ADNI study data.

Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Sharing (Optional)

The Department of Defense (DOD) has funded a portion of the tau PET scans being conducted in this study. The tau imaging data from ADNI3 participants will be compared with tau imaging data from another study designed to look at the relationship between Post Traumatic Stress Disorder (PTSD) and Traumatic Brain Injury (TBI) and the development of AD. Because of this, coded Tau PET imaging data from consenting participants will be shared with the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. FITBIR is a central repository and resource for sharing data that was developed by the Department of Defense and the National Institutes of Health (NIH) to promote collaboration, accelerate research, and advance knowledge on the characterization, prevention, diagnosis and treatment of TBI. All data are coded, and identities will not be disclosed to the FITBIR Informatics System. You do not have to agree to have your data uploaded to FITBIR to participate in the ADNI3 study.

Lyft, Ridesharing Transportation Service (Optional)

Lyft is a network of drivers that pick you up and take you where you need to go. The ADNI study has provided transportation, through the Lyft Rideshare transportation service, to and from your study site for your in-person visits free of cost to you.

If you choose to use Lyft services, the following identifying information will be provided to the Lyft driver to make sure the right person is being picked up for a ride:

- Name
- Address of pick up location

- Phone number

Your Lyft drivers will not be notified of your participation in a clinical research study nor will they be provided with any personal health information.

Additionally, ATRI will be provided the following information; information that can identify you will be removed:

- Participant ID
- Details of ride (date completed, time, and location of pick up)

What side effects or risks can I expect from being in this study?

There are known and possibly unknown risks associated with this study. You might experience all, some, or none of the side effects listed below. Let Dr. [INSERT PI NAME] know if you experience any side effects. You will be told of any new risks or significant findings that develop during the course of this study.

Risks of Blood Draws

Removal of blood by a needle and syringe poses a small risk of infection or temporary pain or bruising at the site of the needle stick. Some people may experience fainting or dizziness.

To minimize these risks, experienced medical personnel will handle all the blood drawing procedures and sterile conditions will be maintained.

In total, approximately 438 mls of blood (about 30 tablespoons) may be taken over the course of this study. The exact amount will depend on the number of clinic visits your study group will participate in during the course of the study. Your body will make up for this loss

Risks of Lumbar Punctures

In total, up to 60 mls (little more than 4 tablespoons) of CSF may be collected over the course of the study. The exact amount will depend on the number of lumbar punctures your study group will undergo during the course of the study. Your body will make up for this loss.

During the lumbar puncture procedure, you may have temporary pain and discomfort in your back.

Headache may occur in about 5% of people who undergo a lumbar puncture. Less commonly, in about 1 - 4% of participants, a persistent low-pressure headache may develop, probably due to leakage of CSF. 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 CSF leak) may be required and should relieve the headache immediately.

Although very rare, it is possible that you may have an allergic reaction to the local anesthetic, like

lidocaine, used for the lumbar puncture. An allergic reaction would cause swelling and a rash on your skin where the anesthetic was injected. Please alert the study staff if you have ever had a reaction to local anesthetic before (especially if this occurred with a dental procedure).

Potential but rare risks of lumbar puncture include infection, damage to nerves in your back, and bleeding into the CSF space. The risk of these event occurring is much less than 1%.

To minimize these risks, the lumbar puncture will be performed by Dr. [INSERT NAME OF DOCTOR WHO WILL BE PERFORMING LP HERE] or by a person specifically trained in the procedure.

Risks of MRI Scans

An MRI may cause possible discomfort for people due to the loud knocking sounds 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 or implants are not permitted to have an MRI.

Risks of PET Scans

The primary risk of PET scans is radiation exposure. This radiation exposure is not necessary for your medical care and is for research purposes only. The amount of radiation exposure you will receive from this study is equivalent to approximately 5 to 7 years of radiation from natural environmental sources (e.g., the sun). This amount is well below the annual limit by the federal government for research subjects.

Other risks associated with PET scanning include fatigue and discomfort at having to remain in the scanner for up to 30 minutes, and the discomfort and possible bruising associated with intravenous injections.

To minimize these risks, this study uses the lowest possible dose of radioactivity needed to obtain a clear image. All IV catheters are placed by medical professionals with extensive training and experience. If you experience anxiety or discomfort at any time while in the PET scanner, you can communicate via intercom with the technician at any time during the scan.

Risks of ^{18}F-FDG PET Scan

FDG is considered safe and there has not been a report of an adverse event (side effect) with this type of PET scan. Despite this information there is still a possibility of a rare allergic reaction.

Risks of Amyloid PET Scans: Florbetapir

The most common side effects reported in studies using florbetapir lasted only a short time and included: headache, muscle or bone pain, increased blood pressure, nausea, fatigue, injection site reaction (bleeding, irritation, pain), anxiety, back pain, claustrophobia (fear of being in closed or narrow spaces), dizziness, feeling cold, insomnia (inability to sleep) and neck pain. Less common side effects reported were: infusion site rash, altered taste in the mouth, itchiness, rash (hives), and flushing, but participants never experienced all of these side effects simultaneously.

Risks of Flortaucipir (^{18}F-AV-1451) PET Scan

The most common side effects in research studies include headache, injection site pain and increased blood pressure. All reported events were mild or moderate in nature and all research participants recovered from these events. You may experience side effects that we do not yet know about.

At this time the effects of flortaucipir (^{18}F-AV-1451) to a developing fetus are not known. It is however known that higher levels of radiation, above what you would be exposed to during this study, can cause damage to a developing fetus. Women of child-bearing potential cannot participate this study.

Risks of Testing & Questionnaires

Memory and cognitive testing may cause some individuals to become upset, frustrated, or tired. You have the right to decline to answer any questions that you feel uncomfortable in answering. You may ask to stop testing at any time for any reason.

Risks of Genetic Testing

Under some circumstances, it can be a risk for genetic information to be known by others. Variation in some genes is known to be directly related to risk of certain illnesses. In some cases, knowledge of genetic information could have negative psychological consequences or could affect access to or retention of certain benefits or entitlements. For example, the information could potentially be used against subjects if it were revealed to insurance companies or potential employers.

Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, other blood relatives and other members of your ethnic group. Consequently, it may be possible that genetic information from you could be used to help identify them. While information traditionally used to identify you will not be released (i.e. name, date of birth, address, telephone number), people may develop ways in the future that would allow someone to link your genetic or medical information back to you.

A U.S. 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. 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. You will not learn the results of the genetic portion of the study nor will the results be made available in your medical record. Furthermore, the researchers have adopted strict privacy and confidentiality procedures for maintaining your genetic information as described in this consent form.

Risks of Loss of Confidentiality

All of the de-identified data collected in this study will be shared broadly. There is a slight risk that there could be a breach in the security of research database systems resulting in the access of information. Safeguards are in place to minimize this risk.

There is also a risk that you could be identified from your MRI scan. In the future, new technologies could be developed that would allow someone to link study data back to you. All investigators who receive shared data must state that they will not attempt to identify any study participant.

Will my medical information be kept private/confidential?

Your study records will be kept confidential as required by law. In order to conduct the study, the study doctor will use and share personal health information (PHI) about you. Your PHI is information about you that could be used to find out who you are. This includes information already in your medical record, as well as information created or collected during the study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. The results of this research study will be presented at meetings and in publications. These results are presented in summary form and will not include any information that could directly identify you.

In the US, there are federal laws that have been issued to protect the privacy rights of research subjects. These laws require that you authorize the release of any PHI that may reveal your identity.

By signing this consent document for this study, you are giving permission ("authorization") to use and share your PHI and research records. You do not have to give this permission. However, if you do not, you will not be able to participate in this study.

The persons and entities that may receive and share this information include:

- **Study doctor, staff and Institution**

- **Institutional Review Board (IRB)**
- **Study Sponsors, National Institute on Aging (NIA) and Northern California Institute for Research and Education (NCIRE) and its representatives**
- **Alzheimer's Therapeutic Research Institute (ATRI) at the University of Southern California (USC) who is the coordinating center for this study and those working with ATRI to conduct this research study**
- **Department of Defense (DOD)**
- **Laboratory of Neuro Imaging (LONI) at USC**
- **Other research sites participating in this study**
- **Data and Safety Monitoring Board (DSMB) and the study monitors who oversee the safety of this study.**
- **Laboratories used for this study**
- **Government regulatory agencies (such as the FDA and the Office for Human Research Protections (OHRP))**

Some of these people, agencies and businesses may further share your personal health information if they need to. Once they share your information, it may no longer be covered by federal or state privacy rules.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your original medical record for verification of clinical trial procedures or data, without violating your confidentiality and only to the extent permitted by other applicable laws.

Do I have to agree to share my personal health information?

No. You can also change your mind at any time and notify the study doctor listed on page one of this consent form that you want to take away your permission to use and share your health information.

If you take away your permission, you will not be able to continue in the study. We will stop collecting any more information about you, but any information we have already collected will still be used for the research study.

Does my permission expire?

No. Your permission to use and share health data about you does not expire unless you cancel it.

Can I see the health information collected about me?

You have the right to review and copy the health information collected about you, however, you will not be allowed to look at your study related information until after the research is completed.

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.

Certificate of Confidentiality

To help us protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);

(2) if you consent to the disclosure, including for your medical treatment;

(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research participants

(4) for the purpose of audit or program evaluation by the government or funding agency

(5) if required by the Food and Drug Administration (FDA)

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Brain Donation Program

Much can be learned about the human brain by studying it under a microscope. This detailed examination of the brain after death is essential in determining the true causes of dementia. Brain tissue is necessary for diagnosis and for helping research into the causes and better treatment of Alzheimer's disease. Therefore, we are asking each participant in this study if they are interested in taking part in the brain donation program for research (autopsy) at time of death. With permission, the findings from this examination will be shared with your next of kin.

If you are currently enrolled in a brain or body donation program and you would like to participate in this program as well, we encourage you to discuss co-enrollment options with study staff.

If you are interested in brain donation, or unsure about joining, study staff will contact you every 6 to 12 months (one year) to discuss with you.

You can decline brain donation and still participate in the ADNI3 study, and you can change your decision to participate (or not to participate) at any time.

What other choices do I have if I do not take part in this study?

This is not a treatment study. The alternative to participating in this study is to not participate.

Starting a new medication at any point during the course of the study should be discussed with your study doctor.

What are the benefits of taking part in this study?

This is not a treatment study. There is no direct benefit to individuals who participate in this study. We hope the knowledge gained will be beneficial to society in improving our understanding of risk for cognitive decline in older individuals.

What are the costs of taking part in this research study?

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.

Will I be paid for taking part in this research study?

You [will/will not] be paid for your participation in this study.

What happens if I am injured as a result of taking part in this research study?

All forms of medical findings and treatments – 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.

If you need medical care because of something that happened to you as a result of being in this study, you should contact your study doctor right away. Your study doctor will explain your treatment options to you or tell you where you can get medical care.

The NIA, NCIRE and ATRI do 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 I have questions or concerns about this research, whom can I contact?

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.

Is participation in this research study voluntary? What if I want to withdraw?

Your participation in this research study is entirely voluntary. You have the right to refuse to participate, and you have the right to change your mind and decide to leave the study at any time in the future without jeopardy to the medical care you receive at this institution.

If you decide you want to end your participation in the study early, the study team will help you withdraw from the study safely. If you decide to withdraw, you may be asked to return to the clinic for a final study visit. This will include all of the procedures normally performed at a follow-up clinic visit You may choose to complete the final study visit or not.

You may also decide that you no longer want to participate in clinic visits and decide that you want to continue your participation in the ADNI3 study over the phone only. If this is your decision, we will ask you to sign a separate consent form.

You may decide to withdraw from the ADNI3 study because you want to join a different study. If this happens, you may be able to return to the ADNI3 study once your participation in the other study has ended. If you return to the ADNI3 study, we will ask you questions about the study you participated in, including questions about the name of the study, how long you were in the study, if there was a study drug, and, if so, if you received study drug or placebo. You may not know all of the answers and that is Ok.

If you decide to withdraw from ADNI3 study at any point for any reason, we will still be able to use the information collected about you prior to your withdrawal from the study. You can also tell the study doctor if you want to withdraw your permission to have your samples stored for future research. Information and samples that have already been shared with researchers cannot be withdrawn.

To withdraw from the study, or to withdraw your permission for future use of your samples, you must notify the study doctor listed on page one of this consent form in person, by telephone, or in writing.

Study staff may end your participation in the study without your permission, for any reason. If this happens, we will talk with you about the reasons why.

STATEMENT OF CONSENT

By signing this page, you are confirming the following:

- You have read all of the information in this consent form, and you have had time to think about it.
- All of your questions have been answered to your satisfaction.
- You voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the study doctor, nurses, or other staff members, as requested.
- You may freely choose to stop being a part of this study at any time.
- You allow the study doctor and the sponsor to use and disclose your personal health information as described in this document.

You will receive a copy of this signed consent form to keep.

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 conducting by the Alzheimer's Disease Neuroimaging Initiative (ADNI), a neuroscience consortium of universities and research institutions. 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.

Contact for Future Studies:

As we continue to learn more about genetic markers and biomarkers, we would like your permission to contact you about possible future biomarker, genetic and family studies. May we contact you about future studies?

☐ **Yes**, you may contact me about future studies.

☐ **No**, you may not contact me about future studies.

Brain Donation Program

Are you interested in considering brain autopsy after death? You will be asked to sign a separate Autopsy consent form in the future.

☐ **Yes**, I am interested in or undecided about brain donation

☐ **No**, I am not interested in brain donation

Optional:

Do you agree to undergo the MRI procedures?	☐ **Yes**	☐ **No**	_____ **Initials**
Do you agree to undergo the FDG PET procedures?	☐ **Yes**	☐ **No**	_____ **Initials**
Do you agree to undergo the LP procedures?	☐ **Yes**	☐ **No**	_____ **Initials**
Do you agree to undergo the Amyloid PET procedures?	☐ **Yes**	☐ **No**	_____ **Initials**
Do you agree to undergo the Tau PET procedures?	☐ **Yes**	☐ **No**	_____ **Initials**
Do you agree that your Tau PET imaging data may be uploaded to the FITBIR database (only if you agree to undergo Tau PET scans)?	☐ **Yes**	☐ **No**	_____ **Initials**
You can use the Lyft services at any time during your participation in the study. Do you agree that your identifiable information, name, address of pick up and phone number can be provided to the Lyft driver?	☐ **Yes**	☐ **No**	_____ **Initials**

By signing below, you voluntarily agree to participate.

Study Participant Name (print)	**Signature**	**Date**
Person Obtaining Consent (print)	**Signature**	**Date**
Legal Representative / Next of Kin (print) ***If applicable***	**Signature**	**Date**
Witness Name (print) ***If applicable***	**Signature**	**Date**

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 have direct contact with the participant at least one day (a minimum average of 10 hours) per week.
2) You must be able to accompany the participant to all clinic visits, or be available via phone to answer questions from study staff.
3) You will be asked general questions about yourself (such as age and gender) as well as about your relationship to the participant. You also will be asked questions about the participant's health, memory, thinking, function and emotional well-being in order to learn about any changes in the participant.

If for any reason you become unable to carry out your responsibilities, please tell the study team 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 agree to participate as a Study Partner.

☐ YES ☐ NO _____ Study Partner's Initials

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

Person Obtaining Consent (print) ***If applicable***	**Signature**	**Date**