Informed Consent to Act as a Research Subject in:

Study Title: Alzheimer's Disease Neuroimaging Initiative 3 **(ADNI3)**
Telephone Visits In Place of ADNI3 In-Clinic Visits

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 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.

Why am I being asked to participate?

You have participated in or are currently participating in the ADNI research studies (ADNI-1, ADNI-Go, ADNI-2 and/or ADNI-3) and have decided that you no longer want to come into the clinic for continued in-person follow-up visits.

With your permission, we would like to continue collecting information from you and your study partner over the telephone.

Allowing us to continue collecting information from you for a longer period of time is valuable and may

help researchers identify changes in memory over time.

How many people will take part in this study?

The main ADNI3 study is being conducted at about 59 clinical trial sites across the United States and Canada. Approximately 1070 – 2000 people will participate in the ADNI3 study, either in person or over the phone.

Who can participate in this study?

Anyone who decides that they no longer want to participate in the ADNI study in person is eligible to continue participating in the study by Telephone only.

To participate in these calls, you must have an individual (spouse, friend, or relative), called a "study partner" who can join you during these phone calls.

Your study partner should be someone who has regular contact with you (about 10 hours per week either by phone or by computer) and who can answer questions about your health, memory and daily function.

How long will I be in this study?

The total number of Telephone Visits you will participate in will depend on how many in-clinic visits you completed in ADNI3, if any.

There will be two types of telephone interactions: 1) **Telephone Visits**, and 2) **Telephone Checks**.

- **Cognitively Normal (CN)** participants will participate in the **Telephone Visits** every other year, with brief **Telephone Checks** every 6 to 12 months until the end of the study.
- **Mild Cognitive Impairment (MCI)** participants will participate in the **Telephone Visits** annually and brief **Telephone Checks** every 6 to 12 months until the end of the study.
- **Mild Alzheimer's disease (AD)** participants will participate in the **Telephone Visits** every year for up to 2 years and then will participate in the brief **Telephone Checks** every 6 to 12 month until the end of the study.

What will happen during the Telephone Visits?

- We will ask you about any medications that you are currently taking, including any vitamins or supplements.
- We will ask questions about any changes in your health that you may have experienced since your last visit.

- We will ask questions about your daily functioning and your behavior, which will include both you and your study partner filling out a questionnaire and returning it to the study coordinator by mail.
- Study staff will ask your study partner questions about any changes in your behavior or emotional state.
- Study staff will ask you about your wishes with regards to brain donation (discussed later in this consent).

These Telephone Visits should take approximately 30 minutes to complete.

What will happen during the brief Telephone Checks?

- You will participate in brief **Brain Donation Telephone Checks** every 6 to 12 months. The purpose of these Telephone Checks is 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 during an already scheduled Telephone Visit. If you decide you are not interested in the brain donation program, you will not be called about this again.
- For **CN participants**, in addition to the brief brain donation telephone checks described above, up to 2 of your Telephone Checks will be little longer and will take placed during the "off" years that you are not scheduled for a full Telephone Visit (see the Visit Schedule Summary below).

  At these **Telephone Checks** 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.

Visit Schedule Summary:

Your actual visit schedule may vary based on what in-clinic visits were completed in the main ADNI3 study, if any. Study staff will talk with you about where you are in the process of the ADNI3 visit schedule.

CN Participants:

	Initial Visit	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Ongoing Brain Donation Phone Checks**
Telephone Visit	X		X		X		
Telephone Check		X		X		X	X*

**Ongoing Brain Donation Telephone Checks occur every 6 to 12 months through the end of the study. If you are not interested in the brain donation program, you will not participate in these ongoing phone checks.*

MCI Participants:

	Initial Visit	Year 1	Year 2	Year 3	Year 4	Year 5	Ongoing Brain Donation Phone Checks
Telephone Visit	X	X	X	X	X	X	
Telephone Check							X*

**Ongoing Brain Donation Telephone Checks occur every 6 to 12 months through the end of the study. If you are not interested in the brain donation program, you will not participate in these ongoing phone checks.*

AD Participants:

	Initial	Year 1	Year 2	Ongoing Brain Donation Phone Checks
Telephone Visit	X	X	X	
Telephone Check				X*

**Ongoing Brain Donation Telephone Checks occur every 6 to 12 months through the end of the study. If you are not interested in the brain donation program, you will not participate in these ongoing phone checks.*

What is the 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, but 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 this study, and you can change your mind at any time.

What will happen to my research data?

All of the data collected in this study will be sent to the Laboratory of Neuro Imaging (LONI) at the University of Southern California (USC) where it will be stored indefinitely and shared for future research.

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.

Will I receive any of my study results?

[Instructions to sites: If your site returns result to participants, such as cognitive scores, this section should be modified to reflect local practice.]

We may learn things about you 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.

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.

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 be used to generate a unique code. This code will be sent to LONI where the GUID will be assigned and stored along with ADNI study data.

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

You will be told of any new risks or significant findings that develop during the course of 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 Loss of Confidentiality

All of the coded 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.

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

This is not a treatment study. The alternative is not to participate.

What are the costs of taking part in this study?

There is no cost to you for participation in this study.

Will I be paid for taking part in this study?

You **[will/will not]** receive payment for taking part in this study.

What happens if I am injured as a result of taking part in this 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.

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 National Institute on Aging (NIA), Northern California Institute for Research and Education (NCIRE), and the Alzheimer's Therapeutic Research Institute (ATRI) at the University of Southern California (USC) 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.).

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**
- **Laboratories for this study**
- **Data and Safety Monitoring Board (DSMB) and the study monitors who oversee the safety of 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

For the protection of 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

Is participation in this research study voluntary?

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 without risk to the medical care you receive at this institution.

You can decline brain donation and still participate in these telephone visits, and you can change your decision to participate (or not to participate) at any time.

If you decide you want to end your participation in the study early, you will be asked to call the study site for a final evaluation. This will include all of the procedures normally performed during the telephone visit. You may choose to complete the final study visit or not.

If you decide to withdraw from the ADNI3 study at any point or for any reason, we will still be able to use the information collected about you prior to your withdrawal from the study. To withdraw from the study, you must notify the study doctor listed on page one of this consent form in person, by telephone, or in writing.

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.

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.

If I have questions or concerns about this research, whom can I contact?

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]**.

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 understand that your participation in this research study is voluntary.

By signing this consent you are authorizing the use of your data 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 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.

You will receive a copy of this consent form.

You voluntarily agree to participate.

☐ **YES** ☐ **NO** _____ **Participant's Initials**

Study Participant Name (print)	**Signature**	**Date**
Person Obtaining Consent (print) *if applicable*	**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 join the participant on the 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)	**Signature**	**Date**