Consent to Take Part in a Research Study

And Authorization to Use and Disclose Protected Health Information

Telephone Visits in Place of In-Clinic Visits

Sponsor / Study Title:	**National Institute on Aging (NIA) / "Alzheimer's Disease Neuroimaging Initiative 4 (ADNI4)"**
Protocol Number:	**ATRI-011**
Principal Investigator: **(Study Doctor)**	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participants cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is providing consent for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant will be offered the ability to leave the study, if desired.

Why am I being invited to take part in this research study?

As a current or prior participant in the Alzheimer's Disease Neuroimaging Initiative (ADNI) study, you are being invited to take part in the telephone portion of the ADNI4 research study.

The telephone portion of the ADNI4 study is designed for participants who no longer want to come into the clinic for continued in-person visits. You are being invited because you have participated in a prior ADNI study (ADNI1, ADNI-Go, ADNI2 and/or ADNI3), or you are currently participating in the ADNI4 study and have decided that you no longer want to come into the clinic for in-person visits.

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

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.

The data from this research study will be shared broadly with the scientific community, so that other researchers can learn from people participating in the ADNI study. Information that can identify you will not be included with any of the shared research data.

Joining a research study is voluntary **(this means it's up to you, it's your choice)**. 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 want to discuss this study with your friends and family.

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 over the telephone.

To participate in these calls, you will be asked to have an individual (for example, 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 2 hours per week either in person, by phone, or by computer) and who can answer questions about your health, memory, and daily function, as well as can possibly assist you with logging into an electronic device for online memory tests.

How many people will take part?

The ADNI study is being conducted at about 65 research sites located across the United States and Canada. We expect about 1,500 people and their study partners will participate in this study, either in person or over the phone, across three groups:

- **Cognitively Normal (CN) group:** individuals with no apparent memory problems
- **Mild Cognitive Impairment (MCI) group:** individuals diagnosed with early or late stages of mild memory problems
- **Dementia (DEM) group:** individuals diagnosed with a mild stage dementia

How long will I be in the study?

Participants in the ADNI4 study are in the study for about 5 years. Exactly how long you will participate in the ADNI4 study over the phone will depend on how many visits you have completed, if any.

For example, if you've been participating in the ADNI4 study in-person for 2 years, you will complete the remaining 3 years over the phone and will not be asked to come into the clinic for your remaining visits. If you've been participating in the ADNI3 study in-person, and have decided to switch to phone visits for ADNI4, you will complete all visits over the phone and will be in the study for about 5 years.

What happens if I say yes, I want to participate?

If you say, yes, you want to participate: first, you will review this consent form with study staff and will tell the study staff if you want to participate or not. You can ask questions now or at any time during your participation in the study.

If you agree to participate, you and your study partner will participate in telephone calls with the study staff every 6 - 12 months. In this study, there are two different types of phone calls:

- Telephone Visits
- Brief Brain Donation Telephone Check-Ins

Each are described below.

You will be told of any new risks or significant findings that are found during this study which may cause you to change your mind about participating.

What is a Telephone Visit?

Telephone Visits are designed to replace your regularly scheduled visit, and will be conducted with your study partner and a member of the study staff. Telephone Visits should take approximately 30 minutes to complete.

At a Telephone Visit:

- We will review with you basic information about yourself, such as your age, job, and level of education (how much school you completed). If you provided this information during a prior ADNI4 visit, you won't need to answer these questions again.
- We will ask questions about your general health history, including if any of your relatives have had or have Alzheimer's disease (AD) or other medical issues. At future visits, we will ask you about any changes in your health that you may have experienced since your last visit.
- We will collect a list of your current medications. We will want to know about any medications, vitamins and/or herbal substances that you currently take or any medications that you may plan to start taking while participating in this study. At future visits (phone calls), we will ask you about changes to this list.
- You will be asked some questions to test your memory. Sometimes taking memory tests can make you feel anxious, upset, frustrated and/or tired. That is normal. You will be encouraged to keep going, but you are allowed to stop if you feel too upset.
- We also will ask your study partner a few questions about your memory and thinking.
- We will ask questions about your daily functioning, your mood, behavior and routines, including feelings of depression. This will include both you and your study partner filling out a questionnaire and returning it to the study coordinator by mail. If or your study partner you aren't able to mail the questionnaire back to us, it may be possible to complete this over the phone.
- We may talk with you or your next of kin about brain donation (discussed later in this

consent).

- If you are in the **CN or MCI groups**, you will be invited to complete memory tests and questionnaires online, using an electronic device such as a computer, tablet or smart phone.

For one of the tests, your spoken responses will be recorded and analyzed to measure your language and memory. A transcription of these recordings will be made. A transcription means that your responses will be written out (transcribed) exactly as you said them. You will take these online memory tests every 6 months.

If you are already taking these memory tests as a participant in the ADNI4 study or the ADNI Digital Study, you will simply continue to take these tests. You will not need to sign up again.

To participate in this online testing, you will be asked to review and sign a separate consent form. Your study partner will be asked to register with you. **You do not have to agree to participate in this online memory testing to participate in the ADNI study.**

What is a Brief Brain Donation Telephone Check-In?

The purpose of these brief telephone check-ins are to discuss your current wishes with regards to brain donation (discussed later in the consent form) and should only take up 5-10 minutes to complete. Your study partner will join you for these brief telephone check-ins.

- The brief Brain Donation Telephone Check-Ins will take place every 6 months, and can be completed during an already scheduled Telephone Visit (described above).
- If you have already completed registration forms for brain donation, we will review the information provided and ask you about any changes to the information provided on these forms. This is important so that your plans are clear to the study doctor and study staff, and so that they can make sure your plans are followed.
- If you have not yet decided if you are interested in brain donation, we will talk with you or your next of kin about this.
- If you or your next of kin are not interested in brain donation, you will not participate in these brief phone calls.

Visit Schedule Summary:

As described earlier, your actual visit schedule will vary based on what visits were completed in the main ADNI4 study, if any. Study staff will talk with you about where you are in the process of the ADNI4 visit schedule.

	Initial Visit	Month 6	Month 12	Month 18	Month 24	Month 30	Month 36	Month 42	Month 48
Telephone Visit	X		X		X		X		X
Brief Brain Donation Telephone Check-In*	X	X	X	X	X	X	X	X	X
Online Testing (optional)**	X	X	X	X	X	X	X	X	X

*If you or your next of kin say yes or are undecided about the Brain Donation Program

** For participants in the CN or MCI group only

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 treatments for Alzheimer's disease. If you express interest in brain donation, your next of kin will be asked for permission to donate your brain at the time of your passing. 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, you will be asked to complete a few registration forms and will be contacted every 6 months to make sure that the information we have from you stays current (described earlier in this consent form as the "Brief Brain Donation Telephone Check-Ins"). You can decline to join the Brain Donation Program and still participate in the ADNI study.

Again, if you agree to participate in this study, it does not mean you are agreeing to participate in the brain donation program.

Will I receive any of my study results?

We may learn things about you that could be important to your health or to your care. If we do, this information will be provided to you. However, you will not receive your specific research test results unless there is a medically important finding.

What are the costs? Will I be paid to participate?

There are no costs for participation in this study.

«Compensation»

You will be paid to a $50.00 for completing each Telephone Visit. You will not be paid for completing the Brief Brain Donation Telephone Check-Ins.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***'after each visit', 'annually', 'bi-weekly', etc.***

If you have any questions regarding your compensation for participation, please contact the study staff.

Will I benefit from being in this study?

This study is for research purposes only. Information learned from the study may help other people in the future.

What happens to the information collected about me?

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review it. This includes information collected from you as a part of this research study as well as from your past, current and future medical records. 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 laws that have been issued to protect the privacy of research participants. These laws require that you give your permission to allow this access to your personal information. By agreeing to participate in this study, you are giving your permission for this. 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 or groups that may receive and share this information include:

- Study doctor, study staff and Institution
- The researchers and research staff conducting the study at all study sites

- Members of the Institutional Review Board (IRB) that reviews this study
- Study Sponsors, National Institute on Aging (NIA) and the 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
- Laboratory of Neuro Imaging (LONI) at USC who is the data repository for this study
- Data and Safety Monitoring Board (DSMB) and the study monitors who oversee the safety of this study
- Federal agencies with research oversight responsibilities and others required by law to review the quality and safety of this program, including the National Institutes of Health, Food and Drug Administration, Department of Health and Human Services, and Office for Human Research Protections

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 international, federal or state privacy and security rules.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your original medical record for verification of clinical study 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. If you do change your mind, please tell the study doctor in writing using the address 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. In California and any other state that requires an expiration

date, the Authorization will expire 50 years after you agree to this authorization unless you revoke it (take it back) sooner.

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 study is completed. This means after all participants in the study have finished and the researchers have had a chance to look at the study data.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a copy of this completed form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Participant

_____

Date of Participant's Authorization

_____

Printed Name of Legally Authorized Representative (if necessary)

_____

Date of Legally Authorized Representative's Authorization

_____

Authority of Legally Authorized Representative to act on behalf of Participant

Global Unique Identifier (GUID)

A GUID is a computer-generated code made up of letters and numbers that is unique to each research participant. The GUID is a universal participant code that allows researchers to share data without exposing personally identifying information (information that can identify you) across research study databases.

To generate the GUID, study staff will enter 4 pieces of your personal information into a "GUID generator": your full name at birth, your date of birth, and your country and city of birth, which will be used to generate a unique code. This information will not be recorded on any document by study staff or shared with anyone, and will not go into your medical record.

If a GUID was generated for you during your participation in the main ADNI study, you will not need to provide this information again.

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:

- If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
- If you consent to the disclosure, including for your medical treatment;
- If it is used for other scientific research in a way that is allowed by the federal regulations that protect research participants;
- For the purpose of audit or program evaluation by the government or funding agency;
- 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.

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.

Will my study data be shared and used for research in the future?

Yes! 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 they will be stored indefinitely and shared for future research. The data collected from you in this study will be combined with the data collected from you in prior ADNI studies (ADNI1, ADNI-Go, ADNI2, ADNI3 and/or ADNI4).

Your privacy will be protected. Your study data will be labeled with a code. Your name and other information that can identify you will not be included with study data that is shared. All of the coded study data will be made available to qualified investigators at scientific institutions around the world for research purposes. 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.

None of your personal information will be shared if the results of this study are published or presented at meetings.

If companies make new discoveries using data from this study, you will not be paid for those newly discovered products or services.

Who is paying for this research study?

This study is being conducted by the 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).

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00064250.

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

Your decision to take part in this study is **(it is up to you, it's your choice)**. You may choose to not join. You may choose not to participate or, if you decide to join, you can withdraw from the study for any reason at any time without penalty or loss of benefits. You can inform the study doctor or study staff listed on page 1 of this form. However, please note that any information collected up to the point of your withdrawal will not be removed from the study.

You should also know that study doctor can remove you from the research study without your permission and for any reason, for example: if your study doctor determines it is in your best medical interest, if you do not follow study procedures, if the study is stopped, or for other administrative reasons. If this happens, we will talk with you about the reasons why.

PARTICIPANT'S CONSENT

By agreeing to participate, 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, study nurses, or other study staff members, as requested.
- You may freely choose to stop being a part of this study at any time.
- You allow the study doctor to use and disclose your personal health information as described in this document. Unless you give your permission to the use and disclosure of your personal health information, you cannot participate in this research study. If you refuse to give your permission, your medical care will not be affected.

Future Contact

There may be studies in the future that you may be eligible to take part in. Can we contact you in the future about these studies? The person obtaining consent will **initial** one of the following options that you choose:

_____ **Yes,** you may contact me about future studies

_____ **No,** you may not contact me about future studies

Brain Donation Program

Are you interesting in considering brain autopsy after death? You will be asked to complete separate registration forms in the future. Reminder: your next of kin will still be asked for permission to donate your brain at the time of your passing.

The person obtaining consent will **initial** one of the following options that you choose:

_____ **Yes**, I am interested in brain donation

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

_____ I am undecided at this time

You will be given a copy of this informed consent document to keep for your records.

Participant's Printed Name:_____

Date of Participant's Consent:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date:**_____

****

If applicable:

❑ Check here if LAR not applicable

Legally Authorized Representative's Relationship to Participant:

_____

Legally Authorized Representative's Printed Name:_____

Date of Legally Authorized Representative's Consent:_____