

Research Participant Addendum Information and Consent Form



Study Title: Alzheimer's Disease Neuroimaging Initiative 3 (ADNI3)

Addendum Consent: 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]

Introduction

As a participant in the ADNI3 study, you have indicated that you no longer want to come into the clinic for continued in-person follow-up visits, but are interested in completing your time in the ADNI3 study over the telephone.

If you agree to participate, these Telephone Visits will replace your regularly scheduled In-Clinic visits. Your study partner will continue to participate in the study with you and will join you on the phone.

Anyone who decides that they no longer want to participate in the ADNI3 study in person is eligible to continue participating in the study by telephone only.

Please refer to the informed consent document you signed for the main study for information regarding benefits, treatment, compensation, confidentiality, and contacts.

What will happen during the Telephone Visits?

Before any study-related procedures are done, you will be asked to read and sign this informed consent form addendum.

- 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.
- If you are a participant in the CN study group, you will continue to participate in the brief phone checks on your “off” years when you were not scheduled for an in-clinic visit. These brief telephone checks are described in the main consent form and are noted in the Visit Schedule below as “Telephone Checks”.

The Telephone Visits should take approximately 30 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 your 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 Visit	Year 1	Year 2	Ongoing Brain Donation Phone Checks
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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.*

How long will my participation last?

The total number of telephone visits you and your study partner will complete will depend on how many in-clinic visits you completed in ADNI3. As such, your participation could last between 1 and 5 years.

What are the risks of participating?

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.

You will be told of any new risks or significant findings that develop during the course of this study.

Are there benefits to taking part in this study?

You will not personally benefit by participating in these Telephone Visits. 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 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 these Telephone Visits. If you withdraw from the study early, you will be paid for these expenses for visits that you completed.

What about privacy?

Your personal health information and research data will be handled by the study doctor and staff in a

confidential manner. Your information will be used and disclosed as described in the main consent form.

As with the main ADNI study, all the data collected 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 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.

Is my participation voluntary?

Your participation in these telephone visits is entirely voluntary. You have the right to refuse to participate. You may discontinue participation in this study at any time without risk to the medical care you receive at this institution.

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.

You will receive a copy of this addendum 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

[INSERT LOCAL SITE NAME]

**Legal Representative / Next of Kin
(print) If applicable**

Signature

Date

Witness Name (print) If applicable

Signature

Date