STUDY PARTNER INFORMATION CONSENT

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»**

Introduction

You are being asked to participate as a **study partner** to a participant who is being considered for a research study called the "Alzheimer's Disease Neuroimaging Initiative 4 (ADNI4) study." Research participants have been participating in the ADNI study since its launch in 2004. ADNI is an observational research study, which means it has no study drug or intervention. The ADNI study is designed to look at the relationship between clinical, cognitive, imaging, genetic and biomarker tests to learn more about brain heath and the full spectrum of Alzheimer's disease (AD) from its earliest stages.

The ADNI study will enroll participants from 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

What will I be asked to do as a study partner?

- As a study partner, you are an important source of information about the participant. To provide meaningful and accurate information about the participant, you will need to

have regular contact with the participant – at least 2 hours per week. This can be in person, by phone or by computer.

- You will be asked questions about the participant's health, memory, thinking, ability to live life and emotional well-being at the beginning of the study and periodically throughout their participation in the study. The information that you provide is important to learn about any changes in the participant over time.
- You will be asked general questions about yourself (such as age and sex) as well as about your relationship to the participant.
- Participants in the CN or MCI groups are invited to complete memory tests and questionnaires online, using an electronic device such as a computer, tablet or smart phone.

  As a Study Partner, you will be invited to register with the participant. This is **optional.** You will be asked to review a separate consent form to participate.

  If the participant decides to complete the online memory tests and questionnaires, you may need to assist the participant with logging into the online testing platform (website).

How long will I be in the study? How many visits will I be asked to attend?

If you agree to participate as a study partner, you will be in this study for about 5 years. You will be asked to come into the clinic with the participant for their in-person visits. While it's preferred that you participate in person for these visits, we know that this is not always possible. If needed, you can participate over the phone instead of coming into the clinic with the participant. You will also join the participant over the phone for their scheduled telephone visits with study staff.

The exact number of visits that you will be asked to participate in will depend on the which group the participant is in, as well as if they are continuing their participation from the ADNI3 study, or if they are newly joining the ADNI study. In general:

- Participants in the **Cognitively Normal (CN)** group will have visits year, either in-person at the clinic or over the phone. In addition, CN participants will have brief phone calls every 6 months between visits, and will be invited to complete online memory testing every 6 months at home.
- Participants in the **Mild Cognitive Impairment (MCI)** group will be seen in person at the clinic every year, with brief phone calls every 6 months between in-person visits. Additionally, MCI participants will be invited to complete online memory testing every 6 months at home.
- Participants in the **Dementia (DEM)** group will be seen in-person at the clinic once a year for the first 2 years, and then will participate in telephone visits every year for the

last 2 years. In addition, they will have brief phone calls every 6 months between visits. Participants in this group will not complete memory testing online.

Please refer to the Schedule of Visit Activities tables for the participant for a complete list of visits and procedures.

Telephone Visits Instead of In-Clinic Visits

Participants in the ADNI study can, at any time, decide that they no longer want to come into the clinic for in-person visits and, instead, can decide to participate in the ADNI study over the phone only. This might happen at the time the participant is considering joining the ADNI4 study, after participating in prior ADNI studies, or this change might happen during their participation in the ADNI4 study.

The participant will be asked to review a separate consent form titled, "Telephone Visits in Place of In-Clinic Visits". This change, from in-person visits to telephone visits, will not change your agreement to be a study partner, and you will not be asked to sign a separate informed consent form.

Please refer to the consent form titled, "Telephone Visits in Place of In-Clinic Visits" if you would like more information about this.

Are there any risks?

Completing the study questionnaires about the study participant could make you uncomfortable or anxious.

There may be other risks that are currently unknown. We will share any important information that is discovered during the study with you. This includes new information that may influence your willingness to continue taking part in the study as a study partner.

Will I be paid? What are the costs?

«Compensation»

You will be paid $50 for study activities that you complete in association with your participant's study schedule. For visits where the participant is seen in-clinic and you complete tasks (answer questions about the participant), you will be paid according to the following schedule:

- $50 for completing the tasks associated with the Initial Visit (Rollover Participants) or $50 for the Baseline Visit (New Participants).
- $50 for completing the tasks associated with annual follow-up visits where the participant is seen in-clinic.

As a Study Partner, you can complete tasks by attending the in-person clinical visits with your participant or speaking with site staff over the phone for the corresponding visit.

The exact number of visits you will be asked to participate in will vary based on the participant's study group. You will not be paid when the participant has a "telephone visit" with site staff, even if you are present for that phone call (CN and DEM groups).

If you decide to stop being the participant's study partner, or if the participant does not complete the study, for any reason, you will only be paid for the visits you complete.

There will be no costs to you for your participation in this study as a Study Partner.

How many people will be in this study?

We expect about 1500 people and their study partners will participate in this study. It's estimated that about 750 participants will be continuing their participation from prior ADNI studies, and about 750 participants will be newly joining the ADNI study.

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 study partner;;
- 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.

Confidentiality

Information that can identify you will not be kept with the study data. Your privacy will be protected. Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctors, Alzheimer's Therapeutic Research Institute (ATRI) at the University of Southern California (the coordinating center for the study) or persons working on behalf of the ATRI, the sponsors (National Institute on Aging (NIA) and the Northern California Institute for Research and Education (NCIRE) and their representatives, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

What else should I know?

Participating in this study is voluntary. You can choose not to participate or change your mind about participating at any time, without penalty or loss of benefits to which you are otherwise entitled.

If for any reason you become unable to carry out your responsibilities, you or the participant should contact the study staff. You may be asked to help select a substitute who can take over for you.

You should also know that the study doctor can stop your participation without your permission and for any reason, for example: if you don't follow directions for participating in the study, if the study is stopped or for administrative reasons. If this happens, we will talk with you about the reasons why.

CONSENT TO PARTICIPATE – STUDY PARTNER

You have read all the information which describes your involvement as the participant'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. A copy of this consent form will be provided to you.

Participant Study ID: _____
(the ID of the participant for which you are the study partner)

Printed Name of Study Partner: _____

Date Study Partner Consent Obtained: _____

Printed Name of Person Obtaining Consent from Study Partner:_____

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