UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
Consent to Participate in a Research Study
For Remote Digital Study Partner

Sponsor / Study Title:	**National Institute on Aging (NIA) / "Alzheimer's Disease Neuroimaging Initiative 4 (ADNI4)"**
Protocol Number:	**ATRI-011**
Principal Investigator: (Study Doctor)	**Michael Weiner, MD**
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Address:	**University of California, San Francisco 4150 Clement St. San Francisco, CA 94121**

Introduction

The Alzheimer's Disease Neuroimaging Initiative (ADNI) is a research study directed by Dr. Michael Weiner of the Department of Radiology at the University of California San Francisco, along with others across the USA and Canada, and funded by the National Institute of Aging. The goal is to study brain aging in older adults to better understand Alzheimer's disease. This study examines how thinking and brain function change over time in order to improve diagnosis and treatment of Alzheimer's disease. The ADNI study began in 2004 and this is the fourth study cycle (ADNI4). This study is enrolling people who have little to no memory complaints, and people with dementia. In addition, we are interested in obtaining information about our study participants from a 'study partner' who knows the participant well. You were identified as a potential study partner of a person who is taking part in the ADNI study.

The ADNI4 study is comprised of three phases:

1. The ADNI Digital study: completed online.
2. The ADNI Blood Biomarker study: involves a blood draw at a local Quest Diagnostics Center.
3. The ADNI In-clinic study: involves visits to a local clinic for a range of additional tests and brain scans.

This consent form explains the Study Partner role in the ADNI4 Digital study.
This research study is being conducted by the Northern California Institute of Research and Education, in partnership with the University of California San Francisco, University of Wisconsin Madison, Fordham University, The Mount Sinai Hospital, and Novoic Ltd.

Your participation is voluntary. Read this information sheet carefully before giving your consent. If you have any questions or need someone to explain any words or information that you do not understand, you can call the ADNI study staff at the phone number listed on page one of this form.

If you agree, your information will be securely stored and you may be contacted to join other research studies. To print a copy of this consent form, please see the link at the bottom of this page.

Why am I being asked to join this study?

The ADNI Digital study plans to study how the use of online questionnaires and memory tests can help us better monitor and track brain health, memory, and aging over shorter periods of time. We expect up to 30,000 individuals to participate in this part of the ADNI4 study. Because you were identified by an ADNI participant as a potential study partner, you are being asked to participate. The data study partners provide will lead to improved ways to diagnose and treat Alzheimer's disease.

What can I expect if I decide to join?

The ADNI4 study participant who identified you as a potential study partner will be informed if you choose to join. As a study partner, you will be asked to answer questions about the participant (your family member/friend/loved one), including questions that address their everyday functioning and their memory. Researchers will have access to the data generated from your responses but will not be able to obtain your personal information. You and the study participant will not be able to view or access each other's study responses.

The study tasks will take you approximately 5-10 minutes to complete. We will invite you to return to the ADNI study website every 6 months to repeat these tasks for up to 5 years. Your participation over time allows us to better understand changes to brain health and memory.

Alternatives to participation

This research study is for research purposes only. The alternative is to not participate in this study.

How will my information be used?

Researchers will use your information to conduct this study. No personal information that identifies any individual will be shared on scientific presentations or publications in scientific journals.

We may also use the information collected for future research studies or share it with other researchers so they can use it for other studies. We will make all possible efforts to protect your privacy. We will not ask you for additional permission to share this information.

Potential Risks

There are risks to taking part in a research study. Some of the most likely risks for participation in this study include:

- Risk of a loss of confidentiality. The study staff is taking extra precautions to protect your information. There is a slight risk that there could be a breach in the security of research database systems resulting in the access of identifiable information. Safeguards are in place to minimize this risk.
- Questionnaires and memory tests may cause some individuals to become upset, frustrated, bored, or tired. As part of this research, you will be required to use one or more of the following: a personal desktop or laptop computer, phone, or tablet to visit the study website. If you visit the ADNI4 study website from your device, you can view the Privacy Policy which describes data collection and sharing that may occur before consent is provided. If you provide your consent to participate in the study, your data and privacy are covered by the terms listed below.

Are there any costs to me for taking part in this study?

No, there are no costs to you for participation in this study; you or your insurer will not be billed.

Possible Benefits

This study is for research purposes only. You may or may not benefit from participating in the study. Information learned from the study may help other people in the future.

Participation Payment

You will not be paid for participating as a study partner in the ADNI Digital study. If the ADNI4 participant is invited to participate in other phases of the ADNI4 study, you may be paid for your time.

Confidentiality and Data Protection

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. In order to carry out study activities, the information you provide will be shared with ADNI study staff at these institutions: the Northern California Institute for Research and Education, the University of California San Francisco, the University of Wisconsin Madison, Fordham University, and The Mount Sinai Hospital. Your contact information may be shared with ADNI study staff to keep you informed of research opportunities.

All information will be kept electronically on secure servers. To de-identify your data, you will be assigned a unique study identifier on all study documentation to ensure your anonymity and confidentiality. This unique study ID will be used in data that will be shared broadly for future research. Data sharing accelerates scientific discovery and encourages connections in research that may result in important new findings within the field. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

The sponsor (The National Institute on Aging) or persons working with or on behalf of the sponsor, and under certain circumstances the U.S. Food and Drug Administration (FDA), and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records.

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.

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.

If you wish to ask questions about the study, please call our ADNI study support team at 1-888-299-ADNI (2364) or email us at info@adni4.org. If you have questions about your rights as a research participant or if you wish to voice any problems or concerns you may have about the study, please call the UCSF Institutional Review Board at 415-476-1814.

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.

Voluntary Participation / Withdrawal
Your decision to take part in this study is voluntary. You may choose not to join.

If you decide to join, you can withdraw from the study for any reason at any time. Choosing not to participate in the study, or leaving the study after you join will not result in any penalty or loss of benefits to which you are otherwise entitled. You may contact the study doctor or the study staff to withdraw your consent, or withdraw electronically. However, any data we have already collected from you will remain part of the study records. The study doctor or the sponsor can stop your participation at any time without your consent.

Consent
I have read and understand the information in this informed consent document. I have had the opportunity to consider the information provided. I voluntarily agree to take part in this study and understand I may withdraw at any time, without giving any reason and without my medical care or legal rights being affected. I do not give up any of my legal rights by agreeing to this consent document.

You can print a copy of this consent form or view it at any time in the ADNI study website.

If you wish to participate, please click on the button below that says **'I Agree'** and follow the instructions.

If you do not wish to participate, please click on the button below that says **'I Decline'** and you will be directed away from this page.