UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
Consent to Participate in a Research Study
For Remote Blood Cohort Participant

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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Introduction

As a participant in the ADNI Digital study, you are invited to take part in the next phase of the study, which is the ADNI Blood Biomarker study. In this study, the researchers are collecting blood samples to study biomarkers found in the blood that may be associated with Alzheimer's disease, aging, and other health conditions. You will be compensated $70 for providing a blood sample.

The ADNI study is comprised of three phases:

1. The ADNI Digital study, which is 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 ADNI Blood Biomarker study. The purpose of the Blood Biomarker study is to determine your eligibility for the ADNI In-Clinic study. Your participation will also lead to improved ways to diagnose Alzheimer's Disease.

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, Fordham University, and The Mount Sinai Hospital.

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 the next phase of the ADNI4 study, or 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?

We expect the ADNI Blood Biomarker study will collect a blood sample from 6,000 participants who are part of the ADNI Digital study. The data provided will lead to improved ways to diagnose and treat Alzheimer's disease. If the results from the study data show you are eligible, you may be invited to participate in other phases of the ADNI study.

What you can expect if you decide to join

If you agree to participate:

- You will be asked to schedule a blood draw at a nearby Quest Diagnostics Patient Service Center (Quest). We request that you schedule the blood draw for within 30 days of joining the ADNI Blood Biomarker study.
- You will receive an email with information from the ADNI study about how to schedule your blood draw at Quest. The email will contain a link to schedule online, as well as a phone number that can be used for Quest scheduling.
    - The email will also include an order confirmation information page that is unique to you.
- On the day of your appointment at Quest:
    - We request that you fast (do not eat or drink anything other than water) for at least 6 hours before you have your blood drawn.
    - You will bring the email that includes your order confirmation page to the Quest location.
    - A Quest specialist will draw 28 mLs (milliliters) of blood, which is less than 2 tablespoons, from a vein in your arm.
    - This should take about 30 minutes at Quest to complete, though travel to/from Quest may require additional time.
- Upon confirmation of completing your blood draw, you will be emailed a $70 electronic gift card (eGift card).

If the results from the study data show you are eligible, you may be invited to participate in the next phase, the ADNI In-Clinic study. You do not have to agree to join the ADNI In-Clinic study - participation in research is always voluntary.

If you are not eligible to join the ADNI In-Clinic study or are eligible but choose not to participate, we may ask you to provide additional blood samples in the future. Your participation over time allows us to better understand brain health and aging. We may contact you every 2 years (up to 5 years) and ask you to return to a Quest location to

provide the ADNI Blood Biomarker study with another blood sample. Your participation is voluntary.

Continued Participation in the ADNI Digital Study

As a participant in the ADNI Blood Biomarker study, we will continue to contact you every 6 months to complete the online questionnaires and memory tests that are part of the ADNI Digital study. Those online activities should take less than 20 minutes to complete. As a member of the ADNI Blood Biomarker study, you qualify to receive a $25 electronic gift card (eGift card) for completing questionnaires and memory tests at your future "visits" to the ADNI Digital study website (all tasks must be completed for payment). Your continued participation allows us to understand brain health and memory over time.

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 samples and information to conduct this study. 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.

You will provide Quest with your name, date of birth, sex, and contact information (email and phone) to schedule your blood draw appointment, but your name and personal information will not be connected to your blood samples collected at Quest.

Genetic Testing

Researchers may use your blood sample to look at all of your DNA (this is called "whole genome sequencing"). DNA contains information that determines things like eye color or disease risk that are passed on from parent to child. Genetic information may be shared broadly in a coded form for future genetic research or analysis. We may give certain information about you to other scientists or companies not at our institutions, but we will not give them your name, address, phone number, or other identifiable information. Research results from these studies will not be shared with you.

What will happen to my blood sample?

- Quest will ship your blood sample to ADNI study affiliated labs that are being used in this research study for testing and analysis: (1) University of Pennsylvania, (2) Indiana University, (3) C2N Diagnostics.
- Your sample will be identified only by an ID number. No information that can identify you will be included with the sample.
- Your blood sample will be stored for future research at the University of Pennsylvania and Indiana University. Your samples will be coded to protect your privacy. Information that can identify you will never be shared with future

researchers. Your samples will be stored as long as researchers need them. More research may be done on your coded samples at a future date. You will not be notified when this additional research is done, and we will not ask for your permission again.

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 blood draw. Possible side effects include feeling light-headed, vein swelling, pain, bruising, bleeding in the spot where your blood is drawn, and/or a slight possibility of infection.
- 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.

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.

Benefits

This study is for research purposes only. Information learned from this study may help other people in the future. If the data or any new products, tests, or discoveries that result from this research have potential commercial value, you will not share in any financial benefits.

Participation Payment

After the ADNI study staff receives confirmation that the blood sample has been collected, you will be emailed a $70 eGift card from Tango.

Additionally, if you complete the blood sample portion of this study, you will be eligible to receive a $25 eGift card from Tango if you complete future “visits” as part of the ADNI Digital study (completing all online questionnaires and memory tests).

If your blood sample is not collected, you will not receive the eGift cards.

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.

Quest will collect some personal information from you such as your name, date of birth, and contact information when scheduling your appointment. The Tango eGift card vendor will receive your email address and first name in order to send you the eGift card.

The sponsor (The National Institute on Aging) or persons working with or on behalf of the sponsor, the laboratories, 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. None of your personal information will be shared if the results of this study are published or presented at meetings.

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 for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for taking part in the study;
- If it is discovered you do not meet the study requirements;
- If you are unable to complete the blood draw within 30 days of joining the study;
- For administrative reasons.

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. You can also print a copy of the Experimental Bill of Rights, which will be shown to you on the following page, or you can view it at this website: https://oag.ca.gov/sites/all/files/agweb/pdfs/research/bill_of_rights.pdf

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.