Addendum Information and Consent Form

Amyloid PET Scan Early Frames Addendum Study

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 signing and dating this form 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.

About This Research

You are being asked to participate in an **optional** addendum study (or "add-on" study) that is a part of the Alzheimer's Disease Neuroimaging Initiative 4 (ADNI4) study, called the "Early Frames Addendum Study".

You are being invited to participate because you signed the consent for the main ADNI4 study, and you also participated in this same add-on study while you were participating in the ADNI3 study.

This addendum study will look at images taken during your PET scan procedure, immediately after the amyloid tracer is administered. This addendum consent form will give you information about the study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the Early Frames add-on study.

If you choose not to participate, this will have no effect on your participation in the main ADNI4 study.

Joining this add-on study is voluntary **(this means it's up to you, it's your choice)**. It will have no impact on your participation in the main ADNI4 study. Please take your time in reviewing this addendum consent form as you make your decision about participating in this add-on 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.

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

Why is this add-on research being done?

As a participant in the ADNI4 study, you will have or have had PET imaging using an amyloid tracer (florbetapir or florbetaben). As described in the main consent form, the amyloid tracer is injected through a vein in your arm and you are asked to wait for 50 - 90 minutes before your 20-minute scanning session. This is to allow the amyloid tracer to absorb into the body.

Instead of waiting, the Early Frames add-on study will conduct an additional 20-minute scanning session immediately following injection of the amyloid tracer, before the amyloid tracer has fully absorbed into the body. This is in addition to the 20-minute scanning session that will take place as a part of your standard amyloid PET scan.

No additional study visits or additional injections are required. If you agree to participate, the additional scanning will occur with your standard amyloid PET scan session.

How many people will take part?

All participants who participated in the Early Frames Add-On study in the ADNI3 study, and who also had one Early Frames Study PET scan, will be invited to participate again in the ADNI4 study. We expect this will be about 100 ADNI4 participants at select sites in the United States and Canada.

What will happen if I agree to participate?

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

If you decide to participate in this add-on study, you will take part in one additional scanning session. This will be scheduled at your next annually scheduled amyloid PET scan.

For the Early Frames scan session, you will be positioned in the PET scanner identically as you would be for a standard amyloid PET scan. A small amount of amyloid tracer will be injected in a vein in your arm. At the time of injection, the PET scanner will immediately begin taking pictures of your brain for approximately 20 minutes, this portion of the scanning is referred to "Early Frames", before the tracer has been completely absorbed in your body.

During your time in the PET scanner, you must hold your head as still as possible. After this scan, you will be removed from the scanner and will wait for the standard amyloid PET scan. You will be repositioned in the PET scanner, for the standard amyloid PET scan pictures, for approximately 20 minutes. During this time, you must hold your head as still as possible.

You will have a computerized x-ray (CT scan) to help align the positioning of your brain before each PET scan. After the scans are completed, you will be asked to drink fluids and empty your bladder.

You should not receive research PET scans if you are pregnant, have received radiation therapy, or have been in another research study involving radiation.

What are the risks of participating in this add-on study?

By participating in this add-on study, you will not be exposed to any additional radiation from the amyloid tracer and the risks related to the PET scan procedure described in the main consent form do not change. However, you will have an additional CT scan that includes a very low dose of radiation. This additional radiation exposure is not expected to produce a harmful effect.

The additional radiation exposure, combined with the 2 PET scans you will receive in one year from the ADNI4 study, is still well below the annual limited by the federal government by research participants.

If you have any questions about the risks related to PET imaging and the radiotracers, please ask the study staff or see the risks described in the main ADNI4 study consent form.

As with all research studies, there may be risks that are 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.

Are there benefits to taking part in this addendum study?

You will receive no direct benefit from participating in this optional addendum. We hope the knowledge gained will be beneficial to society in improving our understanding of risk for cognitive decline in older individuals.

What other choices do I have if I do not take part in this addendum study?

The alternative to participating in this study is to not participate in the Early Frames add-on study and continue with your standard ADNI4 study procedures.

What are the costs? Will I be paid?

Procedures related to the study will be provided at no charge to you. There will be no costs to you for participation in add-on study.

You will not receive additional payment for participating in the Early Frames add-on study, beyond what is described in the main consent form for completing the amyloid PET scan procedure.

What about privacy?

Your personal health information will be handled by the study doctor and staff in a confidential manner. Your health information will be used and disclosed as described in the main consent form for the ADNI4 study.

What will happen to my research data?

As described in the main consent form, all of your research data 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.

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 study doctors 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.

Is my participation voluntary?

Your agreement to have the additional activates described in this addendum consent form is completely voluntary **(it's up to you, it's your choice)**. You may discontinue participation in this part of the optional addendum for any reason at any time; this will not affect your participation in the main ADNI4 study. You may refuse to participate in this part of the study without a penalty or loss of benefits to which you are otherwise entitled.

To withdraw from this addendum study, you must notify the study doctor listed on page one of this consent form in person, by telephone, or in writing**.**

You should also know that study doctor can remove you from this addendum 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.

If you stop taking part in the main ADNI4 study for any reason, your participation in this addendum study will stop as well.

PARTICIPANT'S CONSENT

By signing and dating this consent form, you are agreeing to participate in the optional **Early Frames Addendum Study** and related data collection and are confirming the following:

- You have read all of the information in this Information and 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 doctor, nurses, or other staff members, as requested. You may freely choose to stop being a part of this addendum study at any time.
- You have received a copy of this Addendum Consent Form to keep for yourself.

Participant's Printed Name:_____

Participant's Signature:_____ **Date:**_____

Printed Name of Person Obtaining Consent:_____

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

****

If applicable:

❑ Check here if LAR not applicable

Legally Authorized Representative's Printed Name:

_____

Legally Authorized Representative's Relationship to Participant:

_____

Legally Authorized Representative's Signature:_____ **Date:**_____