

Research Participant Addendum Information and Consent Form



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

AMYLOID PET SCAN EARLY FRAMES ADDENDUM STUDY
Addendum Consent

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]

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 3 (ADNI3) called the **Early Frames Addendum 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 ADNI3 study. Please refer to the informed consent document you signed for the main study for information regarding benefits, treatment, compensation, confidentiality, and contacts.

Why is this add-on study being done?

As a participant in the ADNI3 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 in this add-on study?

Approximately 100 ADNI3 participants will be a part of this add-on study at select ADNI sites in the United States.

What will happen if I agree to participate in this add-on study?

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 2 additional scanning sessions – one at your next annually scheduled amyloid PET scan, and then again 2 years later.

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?

There are known, and possibly unknown risks associated with this study. You might experience all, some, or none of the side effects listed below. Let Dr. [INSERT PI NAME] know if you experience any side effects. You will be told of any new risks or significant findings that develop during the course of

this study.

Positron Emission Tomography (PET) Scan

The primary risk of PET scans is radiation exposure. This radiation exposure is not necessary for your medical care and is for research purposes only. The amount of radiation exposure you will receive from entire ADNI3 study is equivalent to approximately 5 to 7 years of radiation from natural environmental sources (e.g., the sun). This amount is well below the annual limit by the federal government for research subjects.

By participating in this add-on study, you will not be exposed to any additional radiation from the amyloid tracer. However, you may 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.

Other risks associated with PET scanning include fatigue and discomfort at having to remain in the scanner for up to a long period of time, and the discomfort and possible bruising associated with intravenous injections.

To minimize these risks, this study uses the lowest possible dose of radioactivity needed to obtain a clear image. All IV catheters are placed by medical professionals with extensive training and experience. If you experience anxiety or discomfort at any time while in the PET scanner, you can communicate via intercom with the technician at any time during the scan.

Risk of Florbetapir (amyloid tracer)

The most common side effects reported in studies using florbetapir lasted only a short time and included: headache, muscle or bone pain, increased blood pressure, nausea, fatigue, injection site reaction (bleeding, irritation, pain), anxiety, back pain, claustrophobia (fear of being in closed or narrow spaces), dizziness, feeling cold, insomnia (inability to sleep) and neck pain.

Less common side effects reported were: infusion site rash, altered taste in the mouth, itchiness, rash (hives), and flushing, but participants never experienced all of these side effects simultaneously.

Risk of Florbetaben (amyloid tracer)

The most common side effects reported in studies using florbetaben were injection site reactions consisting of erythema (redness of the skin), irritation and pain.

Pregnancy

Exposure to higher levels of radiation, above what you would be exposed to during this study, can cause damage to a developing fetus. Women of child-bearing potential cannot participate in the main

ADNI3 study or this Early Frames add-on study.

Risk of Loss of Confidentiality

All of the 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.

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?

This is not a treatment study. The alternative to participating in this study is to not participate in the Early Frames add-on study and continue with your standard ADNI3 procedures.

What are the costs of taking part in this addendum study?

Procedures related to the study will be provided at no charge to you. There will be no costs to you for participation in this addendum study.

Will I be paid for taking part in this addendum study?

You [will/will not] be paid for your participation in this study. If you withdraw from the study early, you will be paid for these expenses for the portion of the addendum study that you completed.

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 ADNI3 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 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 agreement to have the additional activities described in this addendum consent form is voluntary. 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 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.

Your participation in this addendum may also be discontinued by the study doctor without your permission.

If you stop taking part in this addendum, the study doctor or one of the staff members will talk to you about any medical issues regarding the stopping of your participation.

If you stop taking part in the main ADNI3 for any reason, your participation in this addendum study will stop as well.

STATEMENT OF 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 Subject 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.

By signing below, you voluntarily agree to participate.

_____ Study Participant Name (print)	_____ Signature	_____ Date
_____ Person Obtaining Consent (print)	_____ Signature	_____ Date
_____ Legal Representative / Next of Kin (print) <i>If applicable</i>	_____ Signature	_____ Date
_____ Witness Name (print) <i>If applicable</i>	_____ Signature	_____ Date