University of Pittsburgh

HEAD
Head-to-head Evaluation of tau tracers in Alzheimer's Disease

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**University of Pittsburgh / "Longitudinal multicenter head-to-head harmonization of tau PET tracers (HEAD Study)"**
Protocol Number:	**22020056**
Principal Investigator:	**Tharick Pascoal, MD**
Telephone:	**412-586-9012** **1-866-212-2668 (24-Hour)**
Address:	**University of Pittsburgh** **Oxford Building** **3501 Forbes Ave** **Pittsburgh, PA 15213**

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 participant 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 offered the ability to leave the study if desired.

KEY INFORMATION

The following is a short summary of this research study to help you decide whether to participate. Information that is much more detailed is included later in this form.

- This is a brain imaging research study using positron emission tomography (PET) scans to look at two types of proteins in the brain. Scientists call these proteins "amyloid beta" and "tau." These proteins form abnormal deposits in the brain that are seen in Alzheimer's disease. Your participation in the research is voluntary.

- We wish to collect images on healthy elderly people, individuals with mild cognitive impairment and those diagnosed with Alzheimer's disease to help us learn how the buildup of amyloid and tau proteins may contribute to developing the disease and in normal aging. Healthy young individuals will be used as controls.

- This study is composed of 2 visits, separated by approximately 18 months. Each visit will require visits to the research institution over multiple days. During these visits, you will receive 3 PET scans, 1 magnetic resonance imaging (MRI) scan, blood draws, and undergo clinical assessments and cognitive testing. Details of all the research procedures are explained later in the document.

- We will be collecting images with two different PET scans measuring "tau" protein and one PET scan measuring "amyloid beta" protein in order to understand their relative contribution to identify Alzheimer's disease pathophysiology.

- During the PET and MRI scans, you will be asked to lie on your back and remain very still on the scanner bed while the scanner images your brain. In the PET scans, the radiotracers allow us to see how much of these proteins are accumulating in the brain and where they are located.

- There is no direct benefit to you for participation. Possible risks and side effects are related to the placement of the catheter in your vein, blood draws, discomfort during health and cognitive testing, the radiation exposure from the PET scans, the radiation exposure from the tau and amyloid radiotracers, and having to lie still during the scans. These risks are explained in more detail later in the document.

- You will be compensated for participating in this study. If you decide to withdraw during the course of study, you will be compensated for the measures completed to date.

- To participate in this study, you will be asked to read, sign and date this informed consent form before you are enrolled.

The full consent document follows this Key Information section.

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

This informed consent form is designed to help you understand the study as you talk with the study investigator(s). It should help you understand what will happen in the study, why the study

is being done, and what the risks or benefits are if you decide to be in the study. Your participation in the study is voluntary. If you decide to participate, you must sign and date this informed consent form before any study procedures are performed.

You are encouraged to discuss your decision with your friends and family. You can also discuss it with your doctors. If you have any questions after reading this informed consent form, you should ask your study investigator(s) for further explanation.

Why is this research being done?

Studies of human brains after death have shown that some people have buildup of a specific type of protein in their brains as they age. This protein is called "tau" and it can form "tangles." The relevance of this protein deposits on the functioning of the brain is not clear. The tangles are especially abundant in the brains of people who died with Alzheimer's disease (AD), and it is thought that the buildup of this protein play an important role in this disease.

In this study, we will compare different ways of measuring tau both in the brain and in the blood over time in healthy controls and individuals with cognitive impairment. To measure tau in the brain, we will use a brain imaging technology called positron emission tomography (PET) which is used in conjunction with radiotracers. A radiotracer is a radioactive drug given in very small amounts. The PET scan works by measuring how much of the radiotracer sticks the target (in this example, tau) in your brain, and where the radiotracer is located in your brain. The two tau PET radiotracers that will be compared are called Flortaucipir and MK-6240.

We will also perform PET scan using an amyloid radiotracer called PiB, a basic MRI battery of scans, a cognitive testing session, and a blood draw.

Who is being asked to take part in this study?

You are being invited to take part in this research study because you fall into one of four groups:

- Participant who is young (between 18 and 28 years of age) and cognitively healthy
- Participant who is older (between 50 and 90 years of age) and cognitively healthy
- Participant diagnosed with mild cognitive impairment (between 50 and 90 years of age)
- Participant diagnosed with Alzheimer's disease dementia (between 50 and 90 years of age)

This study is being performed at eight sites. Across all sites, there will be 40 young and cognitively healthy participants, 280 elderly and cognitively healthy participants, 200 participants with mild cognitive impairment, and 100 participants with Alzheimer's disease dementia.

What procedures will be performed for research purposes?

Participation in this research study is completely up to you. Even if you say "yes" now, you can change your mind later; that is OK. You can also stop any of the procedures at any time. If you

decide not to participate, or if you later decide to stop participating, this will not affect the care you receive.

People in this study will have some tests or procedures that are not part of typical medical care but will help with our research. You will be asked to complete 2 sets of tests and procedures that will be approximately 18 months apart. We will make sure that your participation is as safe and as comfortable as possible. More information about these tests is described below.

Health and Cognitive Assessment (at baseline and at 18 months follow-up)
We will ask you about your health history and other things you do in your daily life. We may also need to look at your medical records or to ask other people in your life to help us answer some of these questions. We will ask you to answer questions and complete short tests that help us learn about your memory and other abilities. This will take several hours, working one-on-one with one of our study team members.

Blood Draw (at baseline and at 18 months follow-up)
A trained person will draw blood. This can be done either through a needle in your arm, just like you might have at your doctor's office, or at the same time as your PET scans, through a small plastic tube (IV) placed into your arm. While there may be some discomfort, it is unlikely. We will collect between 4 and 5 tablespoons (or 70 mL) of blood twice during the whole study. If you are getting a PET scan, the blood might be collected directly from the IV that will be placed for that procedure. If for some reason you cannot complete the blood collection at the first attempt, we can invite you to come back another time to try to collect your blood again.

Genetic Research: One important goal of this study is to determine genes that might influence risk of developing Alzheimer's disease (AD) and related dementias. Part of your blood may be used for genomic analyses such as whole genome sequencing. Whole genome sequencing involves determining the exact order of the base pairs (chemical letters) of your DNA. Other genomic technologies may be used and continue to be developed.

Retaining Samples and Data for Future Research: This study involves collecting samples and data that will be used for both planned study analyses and for future use. Your blood samples will be sent to the National Centralized Repository for Alzheimer's Disease and Related Dementias, a repository supported by the National Institutes of Health (NIH).

The samples and data will be coded to protect your privacy; no identifiable information will be used to label the research samples. The purpose of storing these samples and data is to make them available to scientists who are trying to develop new tests, treatments, and ways to prevent Alzheimer's disease. The information gathered through this study might also help us understand and treat other diseases. We hope that these samples and data will provide important information that will help patients and researchers in the future.
The samples, biomarker data, and genetic data generated from samples may be shared with other researchers at academic institutions, hospitals, private companies, and with federal repositories

without including any information that could identify you. Research records and raw data will be maintained for at least 7 years following final reporting or publication of the project.

These research data/samples may also contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and study site for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the study site, or their agents may realize.

The data, samples, and genetic data generated from samples may be shared with other researchers and with federal repositories, in a de-identified manner (without identifiers).

If you do change your mind and want to withdraw from the study, then you may request that your data and any unused sample be destroyed. To do so, please contact the Principal Investigator listed on the first page of this document. Please know that data and samples that have already been distributed to approved researchers will not be retrieved.

Magnetic Resonance Imaging (MRI) (at baseline and at 18 months follow-up)
An MRI scan will be used to take pictures of your brain. The MRI machine uses a strong magnet and radio waves to take pictures of your brain. It does not involve any radiation, blood samples or injections. Because you are going into a giant magnet, you will be asked to remove all jewelry and other metal-containing objects before entering the test room. A study staff person will also ask you some questions to confirm it is ok for you to have this scan done. For the MRI scan, you will be asked to lie down on a narrow table. The table will then slide into the MRI machine. During the scan, you will need to lie very still. You will hear loud noises, which are a normal part of the scan. Study staff can see and communicate with you throughout the entire procedure, and you can ask the study staff to stop the MRI at any time. The MRI will take about 60 minutes to complete. This MRI scan is done for research purposes only, but if something is seen on the MRI that may affect your health or well-being or that may require follow-up, it will be discussed with the study investigator and could possibly be shared with your primary care doctor, with your permission.

Based on your medical or work history, if there is a possibility that some metal object(s) may be present in your body or around your eyes, you may be required to have an x-ray to determine if you can safely have an MRI scan.

Positron emission tomography (PET)
PET scans measure specific chemicals in the brain. For this specific research study, these will be proteins that are known to accumulate in AD, which can be present or absent in different parts of the brain. The PET scanner takes pictures using a special dye, called a radiotracer, that contains radiation, which is similar to the radiation you get in a routine x-ray. A radiotracer is a very small amount of a drug that contains a radioactive substance measured in milliCuries (mCi). A “mCi” is a unit of radioactivity dosage. The radiation that is emitted from your body after the injection of this radiotracer is blocked to different degrees by different body tissues (bone, fat, muscle).

Therefore, a PET scan needs to be corrected for these different degrees of blockage. To do this, the PET camera also has a computed tomography (CT, or CAT) scanner built into it that uses low-dose x-ray radiation to determine the "correction factor." When needed, we will perform a low-dose CT scan of your head area to correct the PET scan. This low-dose correction CT scan will be done at the same time as your study PET scan and only takes a few minutes.

The PET scans are being collected strictly for research purposes.

Prior to scanning: When you arrive for your PET scan, a trained study staff member will put a small plastic tube (called a catheter) into a vein in your arm. In order to insert the plastic tube, the study staff person will first have to put a needle in your vein. If your blood draw or another PET scan are being done on the same day, this will only happen once.

After the radiotracer is given, you have to wait between 30 and 70 minutes to give it time to get to your brain, during which you can sit or recline quietly. Once enough time has passed, you will be taken in for the PET scan. You will lie down on a table and made as comfortable as possible. Your head will be supported to help you keep from moving while the PET scanner takes pictures of your brain. You will be asked to lie very still during this study. You can stop the PET scan at any time by saying "stop" or anything else that indicates that you want to get out of the scanner. Different radiotracers will be given, depending on which type of a PET scan is being done.

Amyloid PET Scan (at baseline and at 18 months follow-up)
15 mCi of radioactive dye called PiB will be given to you through the IV tube about 40 minutes before your PET scan. This radiotracer attaches to amyloid deposits in your brain. After the injection and the time needed for the dye to reach your brain, the PET scanning will start. It will take about 30 minutes. The entire process is expected to take approximately 1.5-2.5 hours.

Tau Flortaucipir PET Scan (at baseline and at 18 months follow-up)
10 mCi of radioactive dye called Flortaucipir will be given to you through the IV tube about 70 minutes before the PET scan. This radiotracer attaches to tau deposits in your brain. After the injection and the time needed for the dye to reach your brain, the PET scanning will start. It will take about 30 minutes. The entire process is expected to take approximately 2-3 hours.

Tau MK-6240 PET Scan (at baseline and at 18 months follow-up)
5 mCi of radioactive dye called MK-6240 will be given to you through the IV tube about 80 minutes before the PET scan. This radiotracer attaches to tau deposits in your brain. After the injection and the time needed for the dye to reach your brain, the PET scanning will start. It will take about 30 minutes. The entire process is expected to take approximately 2-3 hours.

If for reasons of your discomfort or because of technical problems the scanning procedure cannot be completed the day your scan is scheduled and no tracer was injected into your arm that day, you may be asked to return later to complete the scan. If you return, this "completion" day will again require the placement of a plastic tube in a vein in your arm and your participation in a

low-dose CT scan(s) to correct the PET signal. You will not receive more than one dose of corresponding PET tracer during one visit as a result of your participation in this study.

Monitoring/follow-up Procedures: Procedures performed to ensure your safety are called "monitoring" or "follow-up" procedures. After you leave the PET scanner, you will be observed in a comfortable room for at least 30 minutes. To promote the removal of the radioactive dye from your body and thus decrease radiation exposure, you will be instructed to urinate right after the scanning session is finished and then drink several glasses of water or other liquid (to minimize exposure to the bladder).

A study staff member will contact you by phone 5-10 days after the scan to ask if you've had any health problems or side effects during the first 5 days after the PET scan.

What are the possible risks, side effects, and discomforts of this research study?
Possible risks and side effects during this study are related to the placement of the catheter in your vein, blood draws, the radiation exposure from the CT scan, the radiation exposure from different radiotracers, having to lie still during the scans, and/or feeling uncomfortable answering questions about your health and memory. Study staff members involved in this study have been trained to minimize any risks. As with any experimental procedure, there may be adverse events or side effects that are currently unknown and some of these unknown risks could be permanent, severe or life-threatening.

Risks of Cognitive Testing:
Some of the questions you will be asked as part of this study could make you feel uncomfortable. There is a very small risk that you may feel a feel tired or upset during the testing. If that happens, you will be able to take a break and ask questions. While you will be encouraged to keep going, you can always stop if that is what you want to do.

Risks of the blood draws and placement of the intravenous catheter:
There is a common risk of bruising or soreness associated with catheter placement in your vein. There is an infrequent risk of lightheadedness or fainting associated with catheter placement in your vein. There is a rare risk of bleeding or infection associated with catheter placement in your vein. The study's use of trained personnel minimizes these risks.

Risks of Genetic Testing:
Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, other blood relatives and other members of your ethnic group. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. While information we now use to identify you will not be released (for example, name, date of birth, address, telephone number), people may develop ways that would allow someone to link your genetic or medical information back to you. The risks associated with gene studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family

relationships and/or result in paternity suits or stigmatization. The Federal Government passed a law, called the Genetic Information Nondiscrimination Act (GINA), that makes it illegal for health insurance companies and group health plans to use genetic information in making decisions, including decision about providing you with insurance. This helps reduce the risk for disclosures and is further described later in this form.

Risks of MRI Scanning:

MRIs use powerful magnets to make images. There is no radiation that is given during the MRI. People who are anxious or frightened because they are in a small space (claustrophobia) may feel uncomfortable in the narrow tube. Because you must lie with your head and neck inside the scanner, you may become anxious or uncomfortable with having to lie still for a long period of time. If you feel that you cannot remain in the scanner, you will be able to come out of the scanner and rest. Also, you will be able to talk with the study staff at all times during the scan, as they will be able to hear you if you need to stop the scan. There is a risk to people who have metal objects inside their bodies, as the magnet in the MRI scanner can cause these objects to move. Therefore, you will be asked questions about these things before you can go into the scanner room. You cannot have an MRI if you have a pacemaker or any history of heart rhythm concerns, or metal objects located in the eye, ear, brain or blood vessel walls. Dental fillings are not a concern. The MRI can cause some localized warming of the skin; please let us know if you experience any discomfort due to the warming and the procedure will be stopped.

Risks to Women of Child-Bearing Potential and Pregnant Women and Pregnancy Test (only for women of child-bearing age):

The effects of PET imaging and the tracers on fertility or a fetus is not known. Therefore, women who are pregnant should not have an MRI or PET scan. If you are pregnant, or even suspect that you are pregnant, then you will not participate in the scanning. If you could possibly be pregnant, a pregnancy test will be done before scanning procedures are begun. If you are found to be pregnant, or if you are currently breast-feeding an infant, you will not be allowed to take part in the brain scans. If the MRI and PET scans occur on different days, a pregnancy test will need to be done each time.

Risks of PET scan:

The risks from the PET scans include discomfort and claustrophobia. Claustrophobia means you are anxious or frightened because you are in a small space. For the PET scanning session, you will be asked to lie flat with your head and neck inside a narrow scanner tunnel. If you have had claustrophobia before, you should tell your study investigator or study nurse. Should you develop claustrophobic feelings during the study or for any reason feel that you do not want to remain in the scanner, the study will quickly be stopped and you will be removed from the scanner. You will be in voice contact with the study staff at all times during the PET scanning session.

Risks of radiation exposure, including low dose CT scan and the radiotracers: You will have 3 different PET scans at baseline visit and 18 months follow-up:

Procedure	Approximately radiation exposure in rems
Amyloid PET scan	0.3
Tau Flortaucipir scan	0.9
Tau MK-6240 scan	0.54
Total annual whole body radiation dose if all study scans completed	**1.74**

The total amount of exposure you can receive by completing all 3 types of PET scans at one study cycle is approximately 1.74 rems. For comparison, occupational radiation workers are permitted a maximum, annual whole body radiation dose of 5 rems by Federal regulation. Thus, the total 1.74 rems radiation dose that you would receive per year from participation in this study would represent about 35% of the annual whole body radiation exposure permitted to radiation workers.

There is no minimum amount of radiation exposure that is recognized as being totally free of the risk of causing genetic mutations or cancer. However, the risk associated with the total radiation dose is felt to be low in comparison to everyday risks and is very similar to the radiation dose received in similar PET studies performed for research.

Because the study staff assume that your only exposure to radiation has been through your participation in this study, it is important that you inform the study staff of your participation in any other research studies during the past year with also involve exposure to radiation, such as x-rays, PET or CT scans.

Risks of Radiotracers in Addition to Radiation Exposure:
Some PET tracers used in this study (for example, PiB, Flortaucipir and MK-6240) are not currently approved by the United States Food and Drug Administration (FDA).

Risks of Flortaucipir:
- Injection site pain
- Increased blood pressure
- Headache

As with the administration of any drug, there is the rare risk (less than 1 out of 100 people) of an adverse reaction to any of these radiotracers, and you will be monitored for any reactions. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:
- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat, or eyes

- A fast pulse
- Sweating

Please seek treatment immediately and tell the study investigator and study staff if you have any of these symptoms.

Risks of lying immobile for imaging:
There is a common risk that you may experience muscle aches and fatigue (tiredness) from lying still for the PET scans.

Risk of breach of confidentiality:
There is an infrequent risk of a breach of confidentiality during the conduct of this study. The study team will make every attempt to preserve your confidentiality. All of your study information will be labeled with a code and not your name. Access to any identifiable information about you that is contained within your research record will be limited to the investigators associated with this study and their study staff. However, although every reasonable effort has been taken to de-identify your research information, confidentiality cannot be guaranteed and it is possible that re-identification of research data may occur.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the FDA.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure of information required by law to state or local authorities.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

What are possible benefits from taking part in this study?
There are no direct benefits to participation in this study. Participants who are interested in knowing the result of their Amyloid (PiB) PET scan may choose to have this result disclosed to them by a study investigator if they are eligible and may find the scan result helpful. The benefit to society is the increased understanding of the tau and amyloid tracers, of tau and amyloid depositions and their association with cognitive impairment in normal aging and in neurodegenerative diseases (including Alzheimer's disease).

If I agree to take part in this study, will I be told of any new risks that may be found during the course of the study?
You will be promptly notified if we learn any new information during this research study that may cause you to change your mind about participation in this study.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?
None of the services and/or procedures that you receive during this study should be billed to you or your health insurance. If you get a bill or believe your health insurance has been billed for something that is part of the study, notify a member of the study team.

Will I be paid if I take part in this research study?
You will be compensated for the time spent for each procedure during each visit of this study. Listed below is how compensation works for this study site for each procedure during each visit:

Baseline Visit:

Procedure	Payment
1. Cognitive testing	$100.00
2. Blood draw	$50.00
3. MRI scan	$100.00
4. Amyloid PET scan	$100.00
5. Tau MK-6240 PET scan	$100.00
6. Tau Flortaucipir PET scan	$100.00

18 months Follow-up Visit:

Procedure	Payment
1. Cognitive testing	$100.00
2. Blood draw	$50.00
3. MRI scan	$100.00
4. Amyloid PET scan	$100.00
5. Tau MK-6240 PET scan	$100.00
6. Tau Flortaucipir PET scan	$100.00

If you do not complete the study, for any reason, you will be paid for each study procedure you do complete.

You will be paid following each completed study procedure.

If you have any questions regarding your compensation for participation, please contact the study staff.

Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the designated accounting office. All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 26% of the payment be sent by the institution to the IRS for 'backup withholding'; thus you would only receive 74% of the expected payment.

Who will pay if I am injured as a result of taking part in this study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be

responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

To pay medical expenses, the study site will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the study site has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Will this study involve the use or disclosure of my identifiable medical information?
This research study may involve the collection of information about you from your medical records as described in the attached release form. You will be asked to sign the attached release form giving your permission for us to access your medical record information if needed.

Who will have access to identifiable information related to my participation in this study?
In addition to the investigator listed on the first page of this consent form and their authorized study staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

- The staff of the PET Facility will have access to your identifiable research information (which may include your identifiable medical information) for the purpose of performing the PET studies done as part of this protocol.

- Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for purposes of monitoring the conduct of this research study. The National Institutes of Health (NIH)/National Institute on Aging (NIA), FDA and other groups or organizations that have a role in his study will have access to and may inspect and/or copy both your medical and research records due to your participation in this study. This access is necessary to ensure the accuracy of the findings and your safety and welfare. If any publication or presentations result from this study, you will not be identified by name. Results will be reported in a summarized manner such that you cannot be identified.

- Authorized health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this study for the purpose of (1) fulfilling orders, made by the investigators, for services (for example, laboratory tests, diagnostic procedures) associated with study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal study site operations (quality assurance).

- In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

Sharing of De-Identified Data:
Information collected from this study may be shared with other investigators; however, this information will be shared in a de-identified manner (i.e., without identifiers). The de-identified data using the codes but not your name (or any other information that could identify you) gathered in this study will be sent to a database. These data will then be available for use by local investigators and investigators from around the world for the study of aging and dementia. The analysis of these data may result in scientific publications, but you will never be identified in these publications. Your data may be combined with other similar de-identified data gathered in separate local studies or at other research centers in a secure, password-protected database managed by the investigators. These combined, de-identified data may form the basis of scientific publications and may be shared in the future with researchers within or outside of the site. Your data used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, universities, or outside agencies may receive.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of 7 years after final completion and publication of the project and for as long as it may take to complete this research study.

May I have access to my medical information that results from my participation in this study?
This study is being done for research only and, in general, individual results will not be returned to you. If you are interested in learning the results of your research Amyloid (PiB) PET scan, you may be eligible to schedule an additional study visit to discuss the results with the study investigator. You will be asked to sign an addendum to this consent form that will further explain the disclosure process. If it is necessary to perform a urine pregnancy test, you will be informed of the results. You will be asked to give us permission to share this information with your health care provider. Clinically important findings in older study subjects may be returned to the subjects or their physician.

Is my participation in this study voluntary?
Your participation in this research study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing and dating this form. Your decision will not affect your relationship with the investigators nor have any effect on your current or future medical care.

Are there any alternatives to participating in this study?
This research study is for research purposes only. The only alternative is to not participate in this study.

May I withdraw, at a future date, my consent for participation in this study?
You have the right, at any time, to withdraw from this study. You need only provide to the Principal Investigator a written and dated notice of that decision. Withdrawal from the study will not affect your current or future relationship with any affiliated organization. Please note, however, that information obtained from you prior to your withdrawal from this study, will continue to be used by the investigators, also as described above.

If I agree to participate in this study, can I be removed from the study without my consent? It is possible that you may be removed from the research study by the investigators if, for example, you are female and your pregnancy test proves to be positive, or if you are claustrophobic or cannot undergo the PET scan for any reason.

This study may also be stopped at any time by the study investigators, the study Sponsor, and/or the FDA without your consent because:

- Your study investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed of the decision and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study investigator, and/or the FDA have decided to stop the study.

Any identifiable research or medical information recorded for, or resulting from, your participation in this study prior to the date that you were withdrawn from participation may continue to be used and disclosed by the investigators for the purposes described.

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 Investigator's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the Investigator 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: Pro00061365.

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 CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator listed on the first page of this consent document at the telephone number(s) given. I understand that I may contact the study investigator to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the study team is unavailable.

By signing and dating this form, I agree to participate in this research study. A signed and dated copy of this consent form will be given to me.

_____ _____

Participant's Name (Print) Date

_____

Participant's Signature

***USE THE FOLLOWING ONLY WHEN APPLICABLE**

The participant (Name) _____ is unable to consent because:

_____

_____

As the participant's legally authorized representative (LAR), I consent to participation for the participant.

_____ _____

LAR Name (Print) Relationship to Participant

_____ _____

LAR Signature Date

ASSENT

This research has been explained to me, and I agree to participate.

_____ _____

Participant's Name (Print) Date

_____

Participant's Signature

VERIFICATION OF EXPLANATION

I certify that I have carefully explained the purpose and nature of this research study to the above-named participant in appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (assent) to participate in this study.

_____ _____

Investigator's Signature Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the possible risks and potential benefits of participation in this research study. Any questions the individual has about this research study have been answered, and the investigators and study staff associated with this study will be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed and dated.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of the University of Pittsburgh.
- Representatives of the National Institutes of Health (NIH) and the National Institute on Aging (NIA).
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study.

Your health data will be used to conduct and oversee the research, including for instance:

- To compare tau PET radiotracers Flortaucipir and MK-6240 to other PET radiotracers.
- For other research activities related to PET radiotracers and Alzheimer's Disease.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here. Your permission to use and share health data about you will end in 7 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____	_____
Participant's Name (Print)	Date
_____	
Participant's Signature	
_____	_____
LAR Name (Print)	Relationship to Participant
_____	_____
LAR Signature	Date