UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: First-in-human evaluation of an astrocytic glutamate transporter (EAAT2) PET tracer in healthy and Alzheimer's diseased brain

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This is a clinical research study. Your study doctor, David Wilson, M.D., Ph.D from the UCSF Department of Radiology and Biomedical Imaging, or one of their associates will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are between the ages of 40 and 75 and have mild Alzheimer's Disease or no cognitive impairment.

STUDY SUMMARY

Introduction: The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: In this study we will be testing a substance named [18F]Fluoro-fluorenylasparaginate methyl ester ([18F]RP-115) as a contrast material for Positron Emission Tomography (PET) imaging. The researchers want to find a contrast material that will help identify Alzheimer disease. This study will test the spread and accumulation of this contrast material in your body.

Study Procedures: If you choose to be in this study, the study investigator will determine which you will participate in:

1) [Cohort 1] Healthy Volunteers recruited via Flyer with interest in participating

2) [Cohort 2 - Part A] Subjects without cognitive impairment referred to the study team by providers in the UCSF Memory and Aging Clinic

3) [Cohort 2 - Part B] Subjects with cognitive impairment or mild Alzheimer's Disease referred to the study team by providers in the UCSF Memory and Aging Clinic

You will be asked to complete the following procedures.

If you are in Cohort 1:

- You will have [^{18}F]RP-115 administration and PET/MRI imaging after enrolling in this study.
- Your study participation will end after the [^{18}F]RP-115 injection and PET/MRI imaging and all follow-up procedures are completed.

If you are in Cohort 2:

- You may have an arterial line placed and blood drawn by qualified personnel with experience in arterial catheterization.
    - For this part of the study you may have a small piece of tubing called a catheter placed in one of your arteries. Arteries, like veins carry blood throughout your body and can be located by feeling for a pulse. The catheter allows blood to be drawn out of, and fluid to be put into, the body without needing to use additional needles.
- You will have [^{18}F]RP-115 administration and PET/MRI imaging after enrolling in this study.
- If you are a healthy volunteer in Cohort 2 – Part A of this study, you have the option of participating in a second [18F]RP-115 injection and PET/MRI scan within 30 days of your first scan. If you agree, you may repeat the same scanning procedures as explained later in this consent form, including receiving a second [18F]RP-115 injection and PET/MRI scan.
- Your study participation will end after the [^{18}F]RP-115 injection and PET/MRI imaging and all follow-up procedures are completed.

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

- **Radiation risks:** This research study involves exposure to radiation. Not all this radiation exposure is necessary for your medical care and is for research purposes only. Typically, persons in the U.S. receive an annual background dose of radiation of about 3 mSv (a mSv, or millisievert, is a measurement of radiation) from the environment. The additional amount of radiation that you will receive in any 12 month period as a result of participating in this study will be a maximum of 3 mSv, or approximately 1 time the yearly natural background. It is unclear whether this amount of radiation may result in a very small increased risk of future cancer. If you have had a lot of x-rays or other procedures involving radiation, you should discuss this with the principal investigator for this study or your regular doctor and consider whether as a result of total radiation exposure, participation in this study is appropriate for you. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

- **Optional Research with repeated scan (Cohort 2 Part A Only):** If you choose to take part in the optional repeat scan, you will receive additional radiation exposure from the second [18F]RP-115 injection. The total amount of radiation that you will receive in any 12 month period as a result of participating in this study and this optional repeat scan will be a maximum of 6 mSv, or approximately 2 times the yearly natural background. It is unclear whether this amount of radiation may result in a very small increased risk of future cancer. If you have had a lot of x-rays or other procedures involving radiation, you should discuss this with the principal investigator for this study or your regular doctor and consider whether as a result of total radiation exposure, participation in this study is appropriate for you. If you are pregnant or breast feeding, you SHOULD NOT participate in this study.
- **Cohort 2 Part B patients (including □-amyloid and/ or tau PET scans within 12 months of the RP-115 injection):** This research study involves exposure to radiation. Not all this radiation exposure is necessary for your medical care and is for research purposes only. Typically, persons in the U.S. receive an annual background dose of radiation of about 3 mSv (a mSv, or millisievert, is a measurement of radiation) from the environment. The total amount of radiation that you will receive in any 12-month period as a result of participating in this study will be a maximum of 19 mSv, or approximately 6 times the yearly natural background. It is unclear whether this amount of radiation may result in a very small increased risk of future cancer. If you have had a lot of x-rays or other procedures involving radiation, you should discuss this with the principal investigator for this study or your regular doctor and consider whether as a result of total radiation exposure, participation in this study is appropriate for you. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

In the case you are participating in other research studies involving a Positron Emission Tomography (PET) scan, the radiation exposure you will receive from this study will be additional to that of any other investigational PET imaging agent (e.g. amyloid, tau).

- **Arterial Catheterization risks:** The following risks are likely as a result of this procedure. Additional risks are listed later in this consent form.
  - Local pain and swelling
  - Bleeding or hematoma formation
  - Temporary occlusion of the artery (reversible)

- **PET/MRI risks:** Because the MRI machine that is part of the PET/MRI scanner acts like a large magnet, it could move iron-containing objects in the room during your examination, which in the process could possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains, are not allowed in the PET/MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the PET/MRI room and cannot have a PET/MRI.

Having a PET/MRI may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear earplugs. At times during the test, you may be asked to not swallow for a while, which can be uncomfortable.

Because the risks to a fetus from PET/MRI are unknown, pregnant women must not participate in this study.

Possible Benefits: There will be no direct benefit to you from participating in this study.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Taking part in another study
- Not participating in any study

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Why is this study being done?

In this study we will be testing a substance named [18F]Fluoro-fluorenylasparaginate methyl ester ([18F]RP-115) as a contrast material for Positron Emission Tomography (PET) imaging. The researchers want to find a contrast material that will help identify Alzheimer disease. This study will test the spread and accumulation of this contrast material in your body.

[^{18}F]RP-115 binds very specifically to a protein called the Excitatory Amino Acid Transporter (EAAT2) which is expressed abundantly by cells in the brain. The compound sticks to these proteins and emits a low level of energy, which can be detected by a PET camera. A PET camera detects energy given off from radioactive material to make detailed pictures of areas where the F-18 accumulates in the body. The PET scan is often combined with a MRI scan, which helps to more accurately map the location of where in the body the radioactive material has collected.

In this study, we will use a combined PET/MRI scanner to map radioactive [^{18}F]RP-115 binding in living subjects. We believe that this approach will give us better insight into the role of inflammation in early Alzheimer's Disease as well as an early and sensitive measure of Alzheimer's Disease onset and progression.

[^{18}F]RP-115 is an experimental compound that is not yet approved by the United States Food and Drug Administration (FDA), and its use in this study is for research purposes only. This is called a "first in human" study because it is the first time this drug will be given to humans. This means that the safety and risk information we have is based on how animals have reacted to [^{18}F]RP-115. We want to find out what effects, good and/or bad, it has on you and your Alzheimer's Disease.

This study is being funded by an award from the Alzheimer's Drug Discovery Foundation.

How many people will take part in this study?

A total of 68 people between the ages of 40 and 75 will take part in this study. There are two groups of participants in this study. The first cohort will consist of 8 healthy volunteers (**Cohort 1**). Additionally, the study will begin enrollment for its second group. There will be 60 patients in this group, which will consist of 30 healthy volunteers (**Cohort 2 – Part A**) and 30 patients with mild Alzheimer's Disease (**Cohort 2 – Part B**).

What will happen if I take part in this research study?

If you are in Cohort 2 Part B (Alzheimer's Disease): You must have a study partner (informant) who spends a minimum average of 5 hours per week with you (e.g. family member, significant other, friend, caregiver), is generally aware of your daily activities, can provide information about your cognitive and functional performance, and will accompany you in all study procedures.

Before you begin the main part of the study...

You will need to have the following exams, tests or procedures to find out if you can be in the main part of the study.

- **MRI Screening:** Before you receive a PET/MRI scan you will be screened via telephone for the presence of metal or any other materials on or within your body that are not compatible with the PET/MRI machine.
- **Medical Chart Review:** The study doctors will review your medical chart.

During the main part of the study...

If the exams, tests and procedures show that you can be in the main part of the study, and you choose to take part, then you will need the following tests and procedures.

- **Pregnancy Test** (*Women of Child-bearing Potential ONLY*): If there is any chance you can be pregnant, a urine pregnancy test will be performed prior to the imaging study.
- **Vital Signs:** Your vital signs (respiratory rate, heart rate, blood pressure) will be assessed before and approximately 60 minutes after your scan.
- **Electrocardiogram exam (ECG):** a recording of the electrical signal of your heart will be assessed before and approximately 60 minutes after your scan.
- **Physical Exam:** A routine physical exam will be conducted by a healthcare professional.

- **Arterial Line Placement**–*Cohort 2 (If applicable)*: qualified personnel will insert an arterial catheter.
- **Venipuncture**: A venous catheter will be placed by inserting a needle into a vein in your arm.
- **[^{18}F]RP-115 Administration:** The [^{18}F]RP-115 agent will be given by intravenous (IV) injection. Your infusion will take about 1-2 minutes.
- **Dosimetry Blood Sample Collection:** For patients requiring the arterial catheter:
    - **Cohort 2** *(If applicable)***:** up to 10 arterial blood samples will be collected within 120 minutes after [^{18}F]RP-115 administration.
- **PET/MRI Imaging:** *PET Imaging will be combined with an MRI (PET/MRI)*
    - After the injection of the [^{18}F]RP-115, you will be asked to lie flat on a narrow bed that will then be placed in a tunnel that is 6 feet long by 22 inches wide and open at each end. You will be asked to lie still while the PET cameras detect the radioactivity in your body, and the MRI takes pictures of the structure and function of your body.

      The imaging will begin either immediately after injection or 30-90 minutes after injection. The pictures obtained from this PET/MRI scan will allow researchers to look for cells that may take up the imaging agent. A physician or technologist will be with you in the control room for the scanner, and you will be able to communicate with them at any time. Some people may find the scanner to be constricting or claustrophobic. If at any time you wish to stop the scan, this will be done immediately upon your request.

      You will be inside the scanner for approximately 120 minutes. Prior to the PET/MRI scan you will be asked to remove all metal from your clothing, pockets, shoes, and person. You will be asked to wear clothing compatible with the PET/MRI environment. You will be provided with earplugs or headphones that you must wear during the entire scan. Protective padding will be placed between your body and the inner walls of the scanner. During the scan you will hear loud sounds that are a normal part of the scan.

Study location: All study procedures will take place at UCSF China Basin Imaging Center.
When you are finished with your scan…

A follow-up telehealth observational questionnaire will be completed and documented 24-48hours post-scan *(if you are in Cohort 2 Part B: you will be accompanied by your study partner)*.

How long will I be in the study?

Screening will take place within 90 days of the study. The imaging day will take roughly 3-5 hours to complete. After your scan, a follow-up telehealth observational questionnaire will be completed 24-48 hours post-scan. If you are a healthy volunteer for Cohort 2 of this study, you have the option of participating in a second [18F]RP-115 injection and PET/MRI scan within 30 days of your first scan. If you agree, you may repeat the same scanning procedures as explained

earlier in this consent form, including receiving a second [18F]RP-115 injection and PET/MRI scan.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely. The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors do not know all the side effects that may happen. Side effects may be mild or very serious. In some cases, side effects can be serious, long lasting, or may never go away. There is also a risk of death.

Risks and side effects related to [^{18}F]RP-115 administration include:

- **Radiation risks:** This research study involves exposure to radiation. Not all this radiation exposure is necessary for your medical care and is for research purposes only. Typically, persons in the U.S. receive an annual background dose of radiation of about 3 mSv (a mSv, or millisievert, is a measurement of radiation) from the environment. The additional amount of radiation that you will receive in any 12 month period as a result of participating in this study will be a maximum of 3 mSv, or approximately 1 time the yearly natural background. It is unclear whether this amount of radiation may result in a very small increased risk of future cancer. If you have had a lot of x-rays or other procedures involving radiation, you should discuss this with the principal investigator for this study or your regular doctor and consider whether as a result of total radiation exposure, participation in this study is appropriate for you. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.
    - **Optional Research with repeated scan (Cohort 2 Part A Only):** If you choose to take part in the optional repeat scan, you will receive additional radiation exposure from the second [18F]RP-115 injection. The total amount of radiation that you will receive in any 12 month period as a result of participating in this study and this optional repeat scan will be a maximum of 6 mSv, or approximately 2 times the yearly natural background. It is unclear whether this amount of radiation may result in a very small increased risk of future cancer. If you have had a lot of x-rays or other procedures involving radiation, you should discuss this with the principal investigator for this study or your regular doctor and consider whether as a result of total radiation exposure, participation in this study is appropriate for you. If you are pregnant or breast feeding, you SHOULD NOT participate in this study.
    - **Cohort 2 Part B patients (including □-amyloid and/ or tau PET scans within 12 months of the RP-115 injection):** This research study involves exposure to

radiation. Not all this radiation exposure is necessary for your medical care and is for research purposes only. Typically, persons in the U.S. receive an annual background dose of radiation of about 3 mSv (a mSv, or millisievert, is a measurement of radiation) from the environment. The total amount of radiation that you will receive in any 12-month period as a result of participating in this study will be a maximum of 19 mSv, or approximately 6 times the yearly natural background. It is unclear whether this amount of radiation may result in a very small increased risk of future cancer. If you have had a lot of x-rays or other procedures involving radiation, you should discuss this with the principal investigator for this study or your regular doctor and consider whether as a result of total radiation exposure, participation in this study is appropriate for you. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

In the case you are participating in other research studies involving a Positron Emission Tomography (PET) scan, the radiation exposure you will receive from this study will be additional to that of any other investigational PET imaging agent (e.g. amyloid, tau).

- **Blood drawing (venipuncture) risks:** Drawing blood may cause temporary discomfort or pain from the needle stick, bruising, infection, and fainting from placement of an IV catheter. It may also be associated with a risk of bleeding.
- **Arterial Catheterization risks:**

Likely
- Local pain and swelling
- Bleeding or hematoma formation
- Temporary occlusion of the artery (reversible)

Less Likely
- Infection
- Blood clot

Rare but serious
- Hand ischemia
- Nerve damage
- Pseudoaneurysm or dissection
- Arteriovenous fistula formation
- Air embolism
- Compartment syndrome: a condition in which increased pressure within a limited space, usually caused by bleeding or tissue swelling, compromises the blood flow to the area and may lead to significant organ damage or even death.

Risks and side effects related to the imaging procedures:

- **PET/MRI risks:** Because the MRI machine that is part of the PET/MRI scanner acts like a large magnet, it could move iron-containing objects in the room during your examination, which in the process could possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains, are not allowed in the PET/MRI room. If you have a piece of metal in your body,

such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the PET/MRI room and cannot have a PET/MRI.

Having a PET/MRI may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear earplugs. At times during the test, you may be asked to not swallow for a while, which can be uncomfortable.

Because the risks to a fetus from PET/MRI are unknown, pregnant women must not participate in this study.

Reproductive risks: You should not become pregnant or father a baby while on this study because the procedures in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important to understand that you need to use birth control while on this study. The [^{18}F]RP-115 agent will be excreted from the body over 24 hours. After 24 hours from injection, it is safe for patients to become pregnant or father a baby. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

Electrocardiogram (ECG): The Electrocardiogram involves placing electrodes on the skin. You may experience an allergic reaction to the adhesive used to attach the electrodes to the skin. These symptoms are generally mild and clear up on their own. Please let your doctor know if you are aware of any allergies.

Incidental Findings: There is a possibility that while reviewing your scans, we may see an unexpected abnormality. This is called an incidental finding. If we note that your scan looks unusual, we will send it to a radiologist who will determine if the finding is concerning and whether you should be referred to your doctor.

Breach of Confidentiality: Although we take several precautions to protect your identity, there is a chance that confidentiality could be compromised. To minimize this risk, we will not put your name on any study forms or materials (including PET/MRI scans). Instead we will use a unique number. Your name and contact information will be stored in a secure database in our lab.

Unknown Risks: The experimental imaging agent, [^{18}F]RP-115, may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

- For more information about risks and side effects, ask your study doctor

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study will help doctors learn more about the novel [^{18}F]RP-115 agent, and it is hoped that this information will help to develop an impactful clinical biomarker for Alzheimer's disease.

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

This is not a treatment study. [^{18}F]RP-115 is not a therapy. It will not help treat any Alzheimer's Disease. The alternative to participating in this study is not to participate and to undergo standard MRI imaging.

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will my information be used?

Researchers will use the information collected from your scan to conduct this study. Rio Pharmaceuticals Inc., a company focused on diagnostic imaging that collaborates with UCSF on this study, might assist with analyzing de-identified information from your study. Once the study is completed, we may share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records and may be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of Rio Pharmaceuticals
- Representatives of the Food and Drug Administration (FDA)
- Representatives of the University of California

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

No. The sponsor has agreed to pay for all items associated with this research study; you or your

insurer will not be billed.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be paid $150 for taking part in this study. You will be paid by check, and you should receive the check four to six weeks after your study visit. You must give researchers your address and Social Security number so the check can be processed. If any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. David Wilson, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 415-514-6229.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact Dr. David Wilson at 415-514-6229.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

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OPTIONAL RESEARCH

Please note: This section of the informed consent form is about optional research studies that are being done with people who are taking part in the main study. You may take part in these optional studies if you want to. You can still be a part of the main study even if you say "no" to taking part in any of these optional studies.

1) Optional repeat scan *(Cohort 2 – Part A [Healthy Volunteers] Only)*

If you are a healthy volunteer for Cohort 2 of this study, you have the option of participating in a second [18F]RP-115 injection and PET/MRI scan within 30 days of your first scan. If you agree, you may repeat the same scanning procedures as explained earlier in this consent form, including receiving a second [18F]RP-115 injection and PET/MRI scan.

The purpose of repeat imaging is to evaluate the reproducibility of the results with the [18F]RP-115 imaging agent. The choice to have the second scan is up to you. No matter what you decide to do, it will not affect your care.

Benefits
There will be no direct benefit to you for receiving repeat [^{18}F]RP-115 injection and imaging. Information from repeat scans will be used to better evaluate the use of this imaging method for future patients.

Risks
See 'Risks and side effects related to [^{18}F]RP-115 administration' and 'Risks and side effects related to the imaging procedures' described earlier in this consent form. The greatest risk to you is the additional radiation from the [^{18}F]RP-115 PET. If you choose to take part in the optional repeat scan, you will receive additional radiation exposure from the second [18F]RP-115 injection. The total amount of radiation that you will receive in any 12 month period as a result of participating in this study and this optional repeat scan will be a maximum of 6 mSv, or approximately 2 times the yearly natural background. It is unclear whether this amount of radiation may result in a very small increased risk of future cancer. If you have had a lot of x-rays or other procedures involving radiation, you should discuss this with the principal investigator for this study or your regular doctor and consider whether as a result of total radiation exposure, participation in this study is appropriate for you. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult your study doctor.

In the case you are participating in other research studies involving a Positron Emission Tomography (PET) scan, the radiation exposure you will receive from this study will be additional to that of any other investigational PET imaging agent (e.g. amyloid, tau).

2) Optional dosimetry analysis

If you are a participant in Cohort 2, you have the option of participating in the dosimetry analysis procedures. If you agree, before you begin your scan during your visit day qualified personnel with experience in arterial catheterization will insert an arterial catheter. Afterwards, up to 10 blood samples will be collected within 120 minutes after injection. You will be monitored by qualified personnel and study team for any adverse effects for the remainder of your visit.

The purpose of this is to allow the study doctor to learn more about the imaging agent behavior in different individuals.. The choice to participant in the optional dosimetry analysis is up to you. No matter what you decide to do, it will not affect your care.

Benefits

There will be no direct benefit to you for participating in optional dosimetry analysis. Information from your participation will be used to better evaluate the use of this imaging method for future patients.

Risks

Additionally, the risks to you involve those listed under “Arterial Catherization Risks” described earlier in the consent form. If you have any questions regarding the risks involved, please consult your study doctor.

MAKING YOUR CHOICE

Please read each sentence below and mark your choices by putting your initials in the "Yes", "No", or "N/A" box. If you have any questions, please talk to your doctor or nurse, or call our research review board at 415-476-1814.

No matter what you decide to do, it will not affect your care or participation in the main study.

1. *I choose to take part in the optional second [^{18}F]RP-115 injection and PET/MRI scan within 30 days of the first scan.*

YES	*NO*	*N/A – I am not in Cohort 2 - Part A*

2. *I choose to take part in the optional dosimetry analysis on the day of my scan.*

YES	*NO*	*N/A – I am not in Cohort 2*

CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep. You will also be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you

If you wish to participate in this study, you should sign below.

_____	_____
Date	Participant's Signature for Consent
_____	_____
Date	Signature of Person Conducting Consent Discussion
_____	_____
Date	Witness – Only required if the participant is a non-English speaker

OR

The person being considered for this study is unable to consent for him or herself because he or she is cognitively impaired or is not capable of reading or signing the consent form. I have been asked to give my permission to include this person in this study. I know of no reason why he or she would refuse were it possible to do so. I agree to sign a self-certification of surrogate decision maker form (by signing the surrogate form I am stating I am the best person to make decisions regarding research participation for the person and will state my relationship to the person and provide my contact information).

_____	_____ / _____
Date	Signature of Legally Authorized Representative / Relationship
_____	_____
Date	Signature of Person Conducting Consent Discussion
_____	_____
Date	Witness – Only required if the participant is a non-English speaker