Vivoryon Therapeutics N.V.

PROTOCOL: PBD 01187

A Phase 2A Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Varoglutamstat (PQ912) in Patients with Early Alzheimer's Disease with a Stage Gate to Phase 2B (VIVA-MIND)

NCT 03919162

Main Informed Consent Form (ICF)-14Jun2023

ICF Addendum-Compensation for Injury-13Jul2023

Study Partner ICF-21Dec2020

EEG Sub-study ICF-21Dec2020

MRI Qualification ICF-03Sep2021

INFORMED CONSENT FORM

Sponsor / Study Title:	Vivoryon Therapeutics N.V. / "A Phase 2A Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Varoglutamstat (PQ912) in Patients with Early Alzheimer's Disease with a Stage Gate to Phase 2B (VIVA-MIND)"
Protocol Number:	**PBD 01187**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY INFORMATION

You are invited to take part in this research study because you have memory problems that are consistent with early Alzheimer's disease. The purpose of this study is to test an investigational drug called varoglutamstat (PQ912) for this disease evaluating its safety and potential benefit over a study treatment period of up to 18 months. During this time, the study will identify the best dose of this investigational treatment and evaluate whether it benefits the symptoms and the longer-term course of disease. Vivoryon Therapeutics N.V. (Sponsor) and The National Health Institute (NIH) are sponsoring this research study.

Currently, there are several approved drugs (acetylcholinesterase inhibitors and memantine) that have been licensed to treat the symptoms of Alzheimer's disease, however, their effects are symptomatic and limited. There are two new treatment options that target beta-amyloid, which is a protein that accumulates and clumps together between nerve cells in amyloid plaques in Alzheimer's disease. These drugs called aducanumab (Aduhelm™) and lecanumab (Leqembi ™) have received accelerated approval from the Food and Drug Administration (FDA) for their ability to remove these plaques. They may receive full FDA approval in the future. This study you are being asked to participate in is investigating the safety and potential benefits of the study drug varoglutamstat, an alternative approach to these treatments because it prevents formation of a toxic form of the amyloid beta.

If your study doctor determines you meet the requirements to participate in this study, and you choose to do so, then you will be randomly assigned by chance (like the flip of a coin) to receive either varoglutamstat or placebo (inactive substance). You will have a 50% (1 in 2*)* chance of receiving varoglutamstat (with the possibility of receiving 3 different doses) and a 50% (1 in 2*)* chance of receiving placebo. You will receive the study drug in a blister-pack. Neither you nor your study doctor will know to which of these study drug groups

(varoglutamstat or placebo) you are assigned. In case of an emergency, however, your study doctor can get this information as needed for your care.

The study doctors and Sponsor are conducting this study to see what dose is best and to find out if the study drug, varoglutamstat will improve early Alzheimer's disease. Two other studies with varoglutamstat showed that the doses used in this study could be safe. If you participate in this study, you will be monitored closely.

If you choose to participate in this study, you will be asked to come to the clinic for up to 12 study visits. You will be provided with instructions on how to take the assigned study drug and you will be asked to complete several questionnaires about your memory, experiences and feelings. There will be blood tests and Magnetic Resonance Imaging (MRI) brain scans to evaluate how well you are tolerating the study drug.

Research information (data) will be collected as part of this study. This data includes information on the safety of the study drug and any side effects that may occur while you are on study.

Being in a research study is different than attending medical visits that are not part of a research study because the requirements are stricter and will take more time.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to your study doctor and study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

This consent document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes other treatment options that are available to you and it informs you of your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study or whether the study will be of direct medical benefit to you.

Your participation in this study is entirely voluntary. Please take as much time as you need to discuss the study with your doctors, family and friends. The decision to participate or not is yours. If you choose to participate, you have the right to withdraw from the study at any time.

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. When the subject cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the subject rather than the person (legally authorized representative) who is signing and dating this form for the subject. In cases where the subject's representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if

the subject regains the capacity to consent, informed consent will be obtained from the subject and the subject offered the ability to leave the study if desired.

BACKGROUND AND PURPOSE
You are being asked to participate in this research study because you are an adult with early Alzheimer's disease (AD).

The purpose of this study is to learn more about the safety and effectiveness of the study drug called varoglutamstat which may delay or slow the progression of the symptoms of early Alzheimer's disease.

This is a research study that will test the investigational drug varoglutamstat. By investigational we mean it has not been approved by the United States Food and Drug Administration (FDA) and is not available commercially. Some participants in this study will take placebo, which are tablets that look like the study drug but do not contain any active drug in them.

NUMBER OF PARTICIPANTS / LENGTH OF PARTICIPATION
About 414 participants will take part in this study throughout the United States. Neither you nor the study personnel will know whether you are receiving the active study drug or placebo. Your participation in this study will last **up to** twenty and a half months (20 ½) and include approximately 12 study visits to the study center and at least 3 phone calls. You will be asked to bring your study partner to these visits.

This study will use competitive enrollment. This means that when a target number of participants begins the study, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of participants has already begun the study.

WHAT WILL HAPPEN DURING THE STUDY
Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this consent document. The following tests and procedures will be performed to determine if you qualify to take part in this study.

Screening (Visit 1)
The screening activities could take place over several visits at the clinic over a period of up to 6 weeks. You will be asked to bring your study partner with you to these screening visits. Each visit may take several hours to complete.

In order to qualify to take part in this study and go on to receive the study treatment, the following will happen:

- **Demographic Questions:** You will be asked to give personal information about yourself, such as your name, date of birth and education.

- **Health and Medication Questions:** You will be asked to answer questions about your health, your medication history and your current medications.
- **Physical Exam:** You will have a physical exam. You should ask your study doctor about what will happen during the exam.
- **Neurological Exam:** You will have a neurological exam. You should ask your study doctor about what will happen during the exam.
- **Height and Weight:** We will measure how tall you are and how much you weigh.
- **Vital Signs:** Your blood pressure will be checked by putting a cuff around your arm. This will squeeze your arm for about a minute. We will check your pulse, listen to you breathe in and out (respiration rate), and take your temperature. This will be done while you are sitting down.
- **Electrocardiogram (ECG):** ECG stands for electrocardiogram which is a test that measures the electrical signals of your heart.
- **Blood testing:** We will collect between about 3 to 4 tablespoons of blood from your arm.
    - You will have laboratory tests including complete blood count, blood chemistries, blood sugar level, testosterone (sex hormone), thyroid function, vitamin B12, folate (a type of vitamin B that helps produce red blood cells), and infectious disease tests including HIV, Hepatitis B, C, and syphilis. This is to make sure you have no medical conditions that prevent your participation in this study. Your study doctor may be required by law to report the result of infectious disease tests to the local health authority.
    - We will also store a portion of your blood for future research testing.
- **Urine Testing:** A urine sample will be collected to do laboratory tests.
- **Brain MRI:** MRI stands for magnetic resonance imaging. A brain MRI takes pictures of your brain and measures your brain volume and structure. The test takes pictures of some parts of your brain and measures your brain volume and structure. If you have not had an MRI in the past 6 months, you will need to get one.
- **Memory Testing:** You will be asked questions and will do activities to test your memory and thinking. Your study doctor can tell you more about the tests. Some questions may make you feel uncomfortable, and you are free not to answer those questions. You will also be asked about your daily activities, your mood, and your behavior. These are different rating scales that will be done by your study doctor or study staff.
- **Suicidality questionnaire:** We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be referred for appropriate care.
- **Lumbar puncture**: also known as a “spinal tap” is required in order to obtain approximately 3 tablespoons of spinal fluid (that surrounds the brain and spinal cord). Samples will be collected for analysis of markers of Alzheimer’s disease. There will be a telephone call to see how you are, 1 to 3 days after the procedure.

Baseline (Visit 2)

- Health and Medication Questions: We will ask you if you have had any illnesses or changes in your health or medication you are taking since your last visit.
- Physical exam: You should ask your doctor about what will happen during the exam.
- Vital signs (sitting blood pressure, pulse, temperature, respiration rate)
- Weight
- Blood testing: We will collect approximately 3 to 4 tablespoons of blood from your arm.
    - Laboratory tests including complete blood count and blood chemistries, and research testing.
    - A sample of blood will be taken for genetic testing. These results will be used to analyze the study data, but your genetic test results will not be given or shared to you.
    - We will also store a portion of your blood for future research testing.
- A urine sample for laboratory testing
- Suicidality questionnaire: We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be referred for appropriate care.
- Memory Testing
- We will ask you about your experience in your participation in this research study.
- Electroencephalogram (EEG): a test that detects electrical activity in your brain using small discs (electrodes)
    - In preparation for this procedure, please ensure that you have washed your hair thoroughly and that it is dry; do not use hairspray, foam or gel; and do not wear any jewelry (earrings, etc.). You may wear glasses and/or contact lenses.
    - A technician (study staff) will perform the examination. You will lie down on the examination table. You will receive a cap with holes in it (a type of hat), containing about twenty electrodes. The technician will spray a conducting paste in the holes. This paste ensures proper contact between your scalp and the electrodes in the cap. Next, the technician will scrape over the skin under each electrode. This may cause you to feel some discomfort. Sometimes a cap will not be used, and the electrodes will be attached in between your scalp and your hair. The electrodes are connected to an EEG machine with wires. Next, the EEG will be performed. The technician will ask you to perform a number of actions several times during the examination:
        - Open or close your eyes.
        - Breathe in and out deeply for approximately three minutes.
        - Open and close your eyes a number of times in quick succession.
        - Look into a blinking light.
    - Once the EEG has been completed, the technician will remove the cap or the electrodes. The entire examination will take approximately 60 minutes
    - In the first stage of the study, this test will be done in all participants.

- In the second stage of the study, this test will be optional, and will be done only if you chose (consent) to participate in the substudy. You will sign and date a separate consent form for this optional substudy.

At the completion of the baseline visit procedures, you will be assigned randomly (like the flip of the coin) to one of two groups, either to study drug tablets or to matching placebo tablets that do not contain any active drug. You will then receive instructions on how to take the tablets and asked to return to the clinic in 4 weeks.

Week 4 (Visit 3)

- Health and Medication Questions as described in previous visits and from this visit on you will be asked about any adverse events (negative changes in health) you may have experienced since last visit.
- Physical exam: Ask your study doctor about what will happen during the exam.
- Vital signs
- Weight
- Suicidality questionnaire: We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be referred for appropriate care.
- Blood testing: We will collect approximately 2 to 3 tablespoons of blood from your arm.
    - Laboratory tests including complete blood count, blood chemistries, and research testing.
    - You will have additional blood drawn just prior to your morning dose of study drug, and again 2 to 6 hours after taking your morning dose of study drug. This kind of blood test is called pharmacokinetics, and the purpose is to show how your body absorbs, distributes, and gets rid of the study drug.
    - We will also store a portion of your blood for future research testing.

You will then receive more study drug, instructions on how to take the tablets, and asked to return to the clinic in 4 weeks.

The study center will call you to see how you are tolerating the study drug.

Week 8 (Visit 4)

- Health and Medication Questions as described in previous visits and from this visit on you will be asked about any adverse events (negative changes in health) you may have experienced since last visit.
- Physical exam: Ask your study doctor about what will happen during the exam.
- Vital signs
- Weight
- Suicidality questionnaire: We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual

experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be referred for appropriate care.

- Blood testing: We will collect approximately 2 to 3 tablespoons of blood from your arm.
    - Laboratory tests including complete blood count, blood chemistries, and research testing.
    - You will have additional blood drawn just prior to your morning dose of study drug, and again 2 to 6 hours after taking your morning dose of study drug. This kind of blood test is called pharmacokinetics, and the purpose is to show how your body absorbs, distributes, and gets rid of the study drug.
    - We will also store a portion of your blood for future research testing.
- A urine sample for laboratory testing

You will then receive more study drug, instructions on how to take the tablets, and asked to return to the clinic in 4 weeks.

Week 12 (Visit 5)

- Health and Medication Questions as described in previous visits and from this visit on you will be asked about any adverse events (negative changes in health) you may have experienced since last visit.
- Physical exam: Ask your study doctor about what will happen during the exam.
- Vital signs
- Weight
- Memory Testing
- Suicidality questionnaire: We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be referred for appropriate care.
- Blood testing: We will collect approximately 1 to 2 tablespoons of blood from your arm for complete blood count and blood chemistries.

You will then receive more study drug, instructions on how to take the tablets, and asked to return to the clinic in 4 weeks.

Week 16 (Visit 6)

- Health and Medication Questions as described in previous visits and from this visit on you will be asked about any adverse events (negative changes in health) you may have experienced since last visit.
- Physical exam: Ask your doctor about what will happen during the exam.
- Vital signs
- Weight
- Suicidality questionnaire: We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be

referred for appropriate care.

- Blood testing: We will collect approximately 2 to 3 tablespoons of blood from your arm.
    - Laboratory tests including complete blood count, blood chemistries, testosterone (sex hormone), thyroid function tests and blood sugar level, and research testing.
    - You may have additional blood drawn just prior to your morning dose of study drug, and again 2 to 6 hours after taking your morning dose of study drug. This kind of blood test is called pharmacokinetics, and the purpose is to show how your body absorbs, distributes, and gets rid of the study drug.
    - We will also store a portion of your blood for future research testing.
- A urine sample for laboratory testing

You will then receive more study drug, instructions on how to take the tablets, and asked to return to the clinic in 8 weeks.

Week 24 (Visit 7)

- Health and Medication Questions as described in previous visits and from this visit on you will be asked about any adverse events (negative changes in health) you may have experienced since last visit.
- Physical exam: Ask your study doctor about what will happen during the exam.
- Vital signs
- Weight
- ECG: ECG stands for electrocardiogram which is a test that measures the electrical signals of your heart.
- Memory Testing
- Suicidality questionnaire: We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be referred for appropriate care.
- Blood testing: We will collect approximately 2 to 3 tablespoons of blood from your arm.
    - Laboratory tests including complete blood count, blood chemistries, testosterone (sex hormone), thyroid function tests, blood sugar level, and research testing.
    - You may have additional blood drawn just prior to your morning dose of study drug, and again 2 to 6 hours after taking your morning dose of study drug. This kind of blood test is called pharmacokinetics, and the purpose is to show how your body absorbs, distributes, and gets rid of the study drug.
    - We will also store a portion of your blood for future research.
- A urine sample for laboratory testing
- A brain MRI to take pictures of your brain and to measure your brain volume and structure.
- For participants in the first stage of the study, lumbar puncture will be performed: approximately 3 tablespoons of spinal fluid (that surrounds the brain and spinal cord) will be collected for analysis of markers of Alzheimer's disease. There will be a

telephone call to see how you are, 1 to 3 days after the procedure.
- We will ask you about your experience in your participation in this research study.
- EEG
    - In the first stage of the study, this test will be done in all participants.
    - In the second stage of the study, this test will be optional, and will be done only if you chose (consent) to participate in the substudy. You will sign and date a separate consent form for this optional substudy.

You will then receive more study drug, instructions on how to take the tablets, and asked to return to the clinic in 12 weeks.

Week 36 (Visit 8)
- Health and Medication Questions as described in previous visits and from this visit on you will be asked about any adverse events (negative changes in health) you may have experienced since last visit.
- Physical exam: Ask your study doctor about what will happen during the exam.
- Vital signs
- Weight
- Memory Testing
- Suicidality questionnaire: We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be referred for appropriate care.
- Blood testing: We will collect approximately 1 to 2 tablespoons of blood from your arm for complete blood count and blood chemistries.
- A urine sample for laboratory testing

You will then receive more study drug, instructions on how to take the tablets, and asked to return to the clinic in 12 weeks.

Week 48 (Visit 9)
- Health and Medication Questions as described in previous visits and from this visit on you will be asked about any adverse events (negative changes in health) you may have experienced since last visit.
- Physical exam: Ask your study doctor about what will happen during the exam.
- Vital signs
- Weight
- Memory Testing
- Suicidality questionnaire: We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be referred for appropriate care.
- Blood testing: We will collect approximately 2 to 3 tablespoons of blood from your arm.

  - Laboratory tests including complete blood count, blood chemistries, testosterone (sex hormone), thyroid function tests and blood sugar level, and research testing.
  - You will have additional blood drawn just prior to your morning dose of study drug, and again 2 to 6 hours after taking your morning dose of study drug. This kind of blood test is called pharmacokinetics, and the purpose is to show how your body absorbs, distributes, and gets rid of the study drug.
  - We will also store a portion of your blood for future research.
- A urine sample for laboratory testing
- We will ask you about your experience in your participation in this research study.

You will then receive more study drug, instructions on how to take the tablets, and asked to return to the clinic in 12 weeks.

Week 60 (Visit 10)

- Health and Medication Questions as described in previous visits and from this visit on you will be asked about any adverse events (negative changes in health) you may have experienced since last visit.
- Physical exam: Ask your study doctor about what will happen during the exam.
- Vital signs
- Weight
- Memory Testing
- Blood testing: We will collect approximately 1 to 2 tablespoons of blood from your arm for complete blood count and blood chemistries.
- Suicidality questionnaire: We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be referred for appropriate care.

You will then receive your last supply of study drug, instructions on how to take the tablets, and asked to return to the clinic in 12 weeks.

Week 72 (Visit 11) or Early Termination

- Health and Medication Questions as described in previous visits and from this visit on you will be asked about any adverse events (negative changes in health) you may have experienced since last visit.
- Physical exam: Ask your study doctor about what will happen during the exam.
- ECG: Stands for electrocardiogram which is a test that measures the electrical signals of your heart
- Vital signs
- Weight
- Blood testing: We will collect approximately 2 to 3 tablespoons of blood from your arm.
  - Laboratory tests including complete blood count, blood chemistries, testosterone (sex hormone), thyroid function tests, blood sugar level, and research testing.

  - You may have blood samples drawn just prior to your morning dose of study drug, and again 2 to 6 hours after taking your morning dose of study drug. This kind of blood test is called pharmacokinetics, and the purpose is to show how your body absorbs, distributes, and gets rid of the study drug.
  - We will also store a portion of your blood samples for future research.
- A urine sample for laboratory tests
- Suicidality questionnaire: We will ask you if you are feeling irritable or angry, restless, depressed or sad, if you have had problems sleeping, or any strange or unusual experiences, including suicidal thoughts. If you disclose suicidal thoughts, you will be referred for appropriate care.
- Memory Testing
- A brain MRI to take pictures of your brain and to measure your brain volume and structure.
- Lumbar puncture: approximately 3 tablespoons of spinal fluid (that surrounds the brain and spinal cord) will be collected for analysis of markers of Alzheimer's disease. There will be a telephone call to see how you are, 1 to 3 days after the procedure.
- We will ask you about your experience in your participation in this research study.
- EEG
  - In the first stage of the study, this test will be done in all participants
  - In the second stage of the study, this test will be optional, and will be done only if you chose (consent) to participate in the substudy. You will sign and date a separate consent form for this optional substudy.

You will be asked to return to the clinic in 4 weeks.

Week 76 Follow-up (Visit 12)

- Health and Medication Questions as described in previous visits and from this visit on you will be asked about any adverse events (negative changes in health) you may have experienced since last visit.
- Physical exam: You should ask your study doctor about what will happen during the exam.
- Vital signs
- Weight
- Blood testing: We will collect approximately 1 to 2 tablespoons of blood from your arm for complete blood count, blood chemistries, testosterone (sex hormone), thyroid function tests and blood sugar level.
- A urine sample for laboratory tests

If you discontinue study treatment for any reason during the study period, you will be asked to continue participation in the study and attend the remaining clinic visits with your ongoing consent and approval from your study doctor.

<u>After Study Treatment</u>:

Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

EXPECTATIONS
If you participate in this study, you and your study partner will be expected to attend each study visit, take the study product as instructed and follow instructions from your study doctor.

RISKS, SIDE EFFECTS AND/OR DISCOMFORTS OF VAROGLUTAMSTAT:
This study drug is an investigational treatment which means there is limited information about possible side effects and discomfort in humans. Two research studies have been performed to date, 1 study in healthy volunteers and 1 study in participants with early Alzheimer's disease.

The most frequently reported side effects of study treatment were:

- Nausea
- Fatigue (being tired)
- Headache
- Dizziness
- Abdominal pain

These side effects went away after stopping the study drug.

Other less frequent side effects reported by study participants included symptoms related to the digestive system, such as diarrhea, constipation and passing gas. Participants also reported a less common but important side effect of skin rashes which may result from being allergic or intolerant of the study drug. This condition can make your skin very irritated (red and itchy) and could potentially lead to a more serious skin disorder with blisters and fever. You will be asked to report any rashes to your Study Doctor promptly if you experience this problem.

A serious adverse event related to the liver was reported in these previous studies.

<u>Allergic Reaction Risks</u>
As with taking any drug, there is a risk of allergic reaction. 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 doctor and study staff if you have any of these symptoms.

RISKS OF STUDY PROCEDURES

Blood samples: Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

Electrocardiogram (ECG): Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used.

Questionnaires: The questionnaires used in this study may be upsetting. There may be questions about your condition, suicidality, etc. These types of personal questions may make some participants uncomfortable.

Lumbar Puncture:

- During the lumbar puncture procedure, you may have temporary pain and discomfort in your back.
- Headache may occur in about 5% of people who undergo a lumbar puncture. Less commonly, in about 1-4% of participants, a persistent low-pressure headache may develop, probably due to leakage of CSF.
- Uncommonly, a blood patch (injection of some of your blood into the lumbar puncture site to patch the CSF leak) may be required if you experience a persistent headache after the lumbar puncture. This should rapidly relieve the headache.
- Although very rare, it is possible that you may have an allergic reaction to the local anesthetic (lidocaine 1%) used for the lumbar puncture. An allergic reaction would cause swelling and a rash on your skin where the anesthetic was injected. Please tell us if you have ever had a reaction to local anesthetic before (such as when you were visiting the dentist).
- Potential but rare risks of lumbar puncture include infection, damage to nerves in your back, paralysis and bleeding into the CSF space. The risk of these is much less than 1% (1 person in 100).

Magnetic Resonance Imaging (MRI): There are no known biological risks associated with MR imaging but may cause possible anxiety for people due to loud banging made by the machine and the confined space of the testing area. There is also a risk of injury if metal is brought into the imaging room, which might be pulled into the MRI magnet. People with pacemakers, aneurysm clips, artificial heart valves, ear implants or metal/foreign objects in their eyes are not permitted to have an MRI.

Electroencephalogram (EEG)

Placement of the electrodes on your head may be uncomfortable. You are requested to wash your hair on the day of the procedure, but do not use hairspray, gel, or similar. Your hair may be greasy up to an hour after the procedure.

Privacy Risks

If your genetic research data are shared with unauthorized users, you may be at risk of loss of the privacy of your health data. This risk is minimized by protections described in the confidentiality section below.

UNFORESEEN RISKS

Since this is an investigational study, there may be other risks that are unknown. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening.

BIRTH CONTROL RESTRICTIONS

Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. For this reason, female participants must be post-menopausal for at least one year or surgically sterile (bilateral tubal ligation [both tubes tied], hysterectomy [removal of uterus] or bilateral oophorectomy [removal of both ovaries]) for at least 6 months prior to screening.

Male participants with childbearing partners should practice birth control (for example, condoms, abstinence, etc.) during study treatment and until 28 days after the last dose of study drug.

ALTERNATIVES TO PARTICIPATION

You do not have to be in this study to receive treatment for early Alzheimer's disease. Your options may include: donepezil (Aricept®), memantine (Namenda), rivastigmine (Exelon®), galantamine (Razadyne®), aducanumab (Aduhelm™), lecanumab (Leqembi ™) . Taking these drugs may or may not improve your condition. Your study doctor will discuss with you the risks and benefits of the alternative treatments. Please talk to your study doctor about your options before you decide whether taking part in this study.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your decision to continue participation in the study will be provided to you.

BENEFITS

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

If you are in California, ask the study doctor for the estimated recovery time of your participation in this study.

COMPENSATION FOR PARTICIPATION

«Compensation»

[In situations where TOTAL is to be provided]

For your time and inconvenience related to your participation in this study, you will be paid up to a total of $xx.xx if you complete this study. If you do not complete the study, for any reason, you will be paid for the study visits you do complete according to the following schedule: $xx.xx for each completed study visit.

OR

[In situations where the TOTAL is NOT provided]

For your time and inconvenience related to your participation in this study, you will be paid for the study visits you complete according to the following schedule: $xx.00 each for Visits xxx. If you do not complete the study, for any reason, you will be paid for each study visit you do complete according to the schedule below.

[To be included with either paragraph 1 or 2 above]

You will be paid [depending on site submission form – 'after each visit', 'annually', 'bi-weekly', etc.].

If you have any questions regarding your compensation for participation, please contact the study doctor at the telephone number listed on page 1 of this consent document.

OR

You will not receive any monetary compensation for your participation in this study.

CONFIDENTIALITY

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. Your study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

The sponsor may also post this trial on the European registry called "EU Clinical Trials Register". 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.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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.

COMPENSATION FOR INJURY
If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are

participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

All forms of medical findings and treatments – whether routine or investigational – involve some risk of injury. In spite of all safety measures, you might develop medical problems from participating in this study.

You must report any suspected illness or injury to the study doctor immediately. If such problems take place, the study site will provide emergency medical treatment and will assist you in getting proper follow-up medical treatment. There are no plans to provide financial compensation nor reimbursement for such things as pre-existing conditions, illness or disease unrelated to study participation, lost wages, property damage, disability, or discomfort is available.

The National Institute of Health and the Alzheimer's Disease Cooperative Study does not provide compensation for research-related injury. [SITES TO ADD INSTITUTION'S SUBJECT INJURY CLAUSE HERE (you will / will not pay for subject injury, etc)]

By signing this consent form you do not give up any of your legal rights.

COSTS

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

FUTURE RESEARCH STUDIES

Identifiers will be removed from your identifiable private information or identifiable biospecimens (samples taken, such as blood and DNA) collected during this study and could then be used for future research studies or distributed to other qualified researchers for future research studies without additional informed consent.

Your samples will be stored indefinitely. More research may be performed on your sample at a future date. You will not be notified at the time this additional research is conducted, nor will any additional informed consent be obtained. This research will be limited to the health information recorded by your study doctor or generated from any blood samples collected from this study. You will not be contacted in the future to provide any further information.

COMMERCIAL PROFIT

Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and you will not share in this profit.

CLINICALLY RELEVANT RESULTS

Research results which could impact your medical care in the opinion of your study doctor and that are performed in a US licensed laboratory for clinical use will be disclosed to you. You will also have the chance to have these results shared with your primary care physician. You will be asked to agree or disagree to do this. Results from the memory tests administered at the screening visit can be shared with you by your study doctor if you request them. Other research results will not be disclosed until the end of the study, so we avoid influencing results.

GENOME SEQUENCING

With the sample of DNA that you provide researchers will be able to look closely at large amounts of your genetic information by sequencing, or "reading", every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. Potential, future research on your sample may include whole genome sequencing. You will not receive the results of these investigations, but the results will be used in the analysis of the study information.

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, please contact your study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants.

If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, 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: Pro00033891**.**

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please

note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

Your study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, your study doctor may ask you to have some end-of-study tests for your safety.

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant medical findings related to my health (please check yes or no.

❒**YES** (If yes, please complete the information below)
❒**NO**

Name and address of family doctor or primary health care provider:	Name:
	Address:
Telephone and Fax Number:	Tel:
	Fax:

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.

I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Participant's Printed Name

_____ _____

Participant's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Legally Authorized Representative Date

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ

The study participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

_____ _____

Participant's Signature Date

INFORMED CONSENT ADDENDUM
Compensation for Injury

Sponsor / Study Title:	**Vivoryon Therapeutics N.V. / "A Phase 2A Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Varoglutamstat (PQ912) in Patients with Early Alzheimer's Disease with a Stage Gate to Phase 2B (VIVA-MIND)"**
Protocol Number:	**PBD 01187**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This document is an addendum to the Main Informed Consent Form for the study referenced above to inform you that the Compensation for Injury language will change after week 24 of the study schedule. The change will become effective after your week 24 visit. All the elements outlined and described in the Main Informed Consent form you signed and dated before still apply to your participation in this study unless otherwise noted in this form.

Additional Information Regarding Compensation for Injury after the Week 24 study visit:
The study is being funded by The National Health Institute (NIH) and Alzheimer's Disease Cooperative Study (ADCS) from Screening to Week 24. NIH and ADCS do not provide compensation for research-related injury.

The study is being funded by Vivoryon Therapeutics N.V. after Week 24 through the end of the study, Week 76 visit. After Week 24, the Compensation for Injury will become the responsibility of Vivoryon Therapeutics N.V.

<u>The new Compensation for Injury will be as follows:</u>

If you become ill or are injured while you are in the study, you will receive the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

All forms of medical findings and treatments – whether routine or investigational – involve some risk of injury. In spite of all safety measures, you might develop medical problems from participating in this study.

If you are injured as a result of taking the study drug(s) or from procedures done for the purpose of this study after Week 24, the sponsor Vivoryon Therapeutics N.V will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

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

Please contact the study doctor or your study coordinator if you have any comments, concerns or questions.

CONSENT

I have read and understand the information in this Addendum to the informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.

I voluntarily agree to continue participation in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Participant's Printed Name

_____ _____

Participant's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Participant

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ

The study participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date

_____ _____
Participant's Signature Date

STUDY PARTNER/CAREGIVER INFORMATION & CONSENT

Sponsor / Study Title:	Vivoryon Therapeutics */ "A Phase 2A Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Varoglutamstat (PQ912) in Patients with Early Alzheimer's Disease with a Stage Gate to Phase 2B (VIVA-MIND)"*
Protocol Number:	**PBD 01187**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This information sheet is linked to the Main Consent of the study.

As the participant's Study Partner, you have important tasks that need to be carried out in order for the study to be conducted in the safest and best manner possible. These responsibilities include:

- You will participate in the consenting process.
- You must have regular and frequent contact (more than 3-4 times a week) with the study participant.
- You must be able to accompany the study participant to all the clinic visits.
- You will help with the drug supply and bring back all unused study drug and empty or partially full containers.
- You are an important source of information about the study participant. You must agree to be asked questions about the participant's health, memory, thinking, functioning and emotional well-being.
- You can assist to facilitate compliance with the study procedures.

If for some reason you become unable to carry out your responsibilities, please tell the study team immediately. You may be asked to help select a substitute who can take over your duties.

You have read all the preceding information that describes both the study participant's involvement and your role as a study partner.

The study has been explained to you in detail, and all of your questions have been answered to your satisfaction.

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to comply with the responsibilities listed above. All of my questions were answered to my satisfaction. 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.

Study Partner's Name (print)	Signature	Date

Person Obtaining Consent (print)	Signature	Date

CONSENT FOR OPTIONAL ELECTROENCEPHALOGRAM SUB-STUDY IN PHASE 2B

Sponsor / Study Title:	Vivoryon Therapeutics / "A Phase 2A Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Varoglutamstat (PQ912) in Patients with Early Alzheimer's Disease with a Stage Gate to Phase 2B (VIVA-MIND)"
Protocol Number:	**PBD 01187**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This opt in/opt out form is linked to the Main Consent of the study identified above.

You are also being asked to participate in an optional substudy using electroencephalogram, also known as an "EEG" test that will record your electrical activity of your brain.

This is a test that detects electrical activity in your brain using small discs (electrodes).

In the second stage of the study, this procedure will occur only if you consent to participate in the EEG substudy. Participants who consent to the substudy will have an EEG test at the baseline visit, week 24 visit, and at the week 72 visit (end of study treatment).

Preparation

- Please ensure that you have washed your hair thoroughly and that it is dry;
- Do not use hairspray, foam or gel;
- You may wear your glasses and/or contact lenses;
- You should not wear any jewelry (earrings, etc.).

Procedure
A technician (study staff) will perform the examination. You will lie down on the examination table. You will receive a cap with holes in it (a type of hat), containing about twenty electrodes. The technician will spray a conducting paste in the holes. This paste ensures proper contact between your scalp and the electrodes in the cap. Next, the technician will scrape over the skin under each electrode. This may cause you to feel some discomfort. Sometimes a cap will not be used, and the electrodes will be attached in between your scalp and your hair. The electrodes are connected to an EEG machine with wires. Next, the EEG will be performed. The technician will ask you to perform a number of actions several times during the examination:

- Open or close your eyes.
- Breathe in and out deeply for approximately three minutes.
- Open and close your eyes a number of times in quick succession.
- Look into a blinking light.

Once the EEG has been completed, the technician will remove the cap or the electrodes. The entire examination will take approximately 60 minutes.

If you are a participant in the phase 2B of this study, you may decide not to participate in this optional sub-study. If you decide not to participate in the sub-study, your decision will have no impact on your ability to participate in the main study and will have no impact on any other benefits to which you would otherwise be entitled.

The risks of this optional procedure for this study are minimal.

Placement of the electrodes on your head may be uncomfortable. You are requested to wash your hair on the day of the procedure, but do not use hairspray, gel, or similar. Your hair may be greasy up to an hour after the procedure.

Please indicate your preference below:

❒**YES** _____ (initials) I agree to participate in the sub-study described above.

❒**NO** _____ (initials) I do not agree to participate in the sub-study described above.

UNKNOWN RISKS
As with any procedure, it is the possible that there will be unforeseen risks or discomforts. If you have any discomforts, tell the study doctor immediately.

ALTERNATIVES TO BEING IN THE SUB-STUDY
Since the purpose of this sub-study is not to benefit you directly, your alternative is not to participate.

POTENTIAL BENEFITS OF BEING IN THE SUB-STUDY
You will not get any direct benefits by taking part in this sub-study. Test results will not be given to you. However, by taking part in this sub-study you may help other people in the future by helping doctors learn about the relationship between drugs and genes. This sub-study may also help to better understand diseases and help to develop more effective tools that may be used to identify and treat diseases.

COSTS OF BEING IN THE SUB-STUDY
The EEG test for this sub-study will be done at no cost to you.

YOUR PAYMENT FOR BEING IN THE SUB-STUDY
You will not be paid for being in this sub-study.

COMPENSATION FOR INJURY
You are not expected to become ill or hurt as a result of taking part in this sub-study. However, if you become ill or are hurt as a result of giving a sample for this sub-study, get the medical care that you need right away. Any resulting costs of medical care will be covered as described in the consent form that you signed for the main study.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

PROTECTING THE PRIVACY OF YOUR HEALTH DATA
To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

Please refer to the Confidentiality section of the main ICF for additional information.

EMERGENCY CONTACT / IRB CONTACT
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, 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 subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00033891.

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research sub-study for the purposes listed above. All of my questions were answered to my satisfaction. 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 Printed Name

_____ _____
Participant's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ

The study participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

Informed Consent to Act as a Volunteer

Magnetic Resonance Imaging Qualification Scan

Sponsor / Study Title:	**Vivoryon Therapeutics N.V. / "A Phase 2A Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Varoglutamstat (PQ912) in Patients with Early Alzheimer's Disease with a Stage Gate to Phase 2B (VIVA-MIND)"**
Protocol Number:	**PBD 01187**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Why is this qualification study being done?

You are being asked to take part as a healthy volunteer in a quality control test for the Magnetic Resonance Imaging (MRI) scanner here at this study site. This test may include evaluation of image artifacts and any metric related to the performance of the MRI system. Once the scanner is qualified, it will be used in a study that will look at the relationship between clinical, cognitive, imaging, genetic and biomarker tests in order to understand the full spectrum of Alzheimer's disease from its earliest stages.

An MRI scan uses a large magnet and computer equipment to take an electronic picture of your brain. Your MRI scan will be checked to be sure that all technical details required for this study were performed correctly. The scan may have to be repeated. In the event that repeat attempts are needed, repeat scans may or may not be performed on the same volunteer.

What will happen if I take part in this qualification scan?

The MRI will take approximately 45 minutes to complete. You will lie on your back and enter the Magnetic Resonance (MR) machine for the study, during which time you will hear loud knocking noises. People with pacemakers, aneurysm clips, artificial heart valves, cochlear implants, or any metal/foreign objects in their bodies are not permitted to undergo MR studies.

What side effects or risks can I expect from being in this test?

An MRI may cause possible discomfort for people due to the loud banging noises made by the machine and the confined space of the testing area. There is also a risk of injury if metal is brought into the imaging room, which might be pulled into the MRI magnet.

Because the risks to a fetus from MRI are unknown, pregnant women cannot participate.

What are the benefits of taking part in this test?

You will not personally benefit by participating in this quality control test. Your participation in this test will help the investigators prepare for studies to research the future prevention and treatment of Alzheimer's disease. This test will not make your health better.

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

The alternative is not to participate in this MRI Qualification test.

What will happen with my imaging data?

Your MRI images will be sent to the Alzheimer's Disease Cooperative Study (ADCS) at the University of California, San Diego (UCSD). Your imaging data will be labeled with a coded identifier to protect your identity and used to evaluate the performance of the MR system at this site.

What are the costs of taking part in this test?

There is no cost to you for participation in this quality control test. All costs of this procedure are paid by the sponsor of the research study that the MRI scanner will be used for.

Will I be paid for taking part in this test?

«Compensation»

You **[will/will not]** receive payment for taking part in this test.

What happens if I am injured as a result of taking part in this test?

All forms of medical tests and treatments – whether routine or experimental – involve some risk of injury. In spite of all safety measures, you might develop medical problems from participating in this test.

You must report any suspected illness or injury to the study doctor listed on the first page of this form immediately. If such problems take place, the study site will provide emergency medical treatment and will assist you in getting proper follow-up medical treatment. Neither financial compensation nor reimbursement for such things as pre-existing conditions, illness or disease unrelated to test participation, lost wages, property damage, disability, or discomfort is available.

National Institutes of Health and the Alzheimer's Disease Cooperative Study do not provide compensation for injury. Financial compensation for such things as lost wages, disability, or discomfort due to participation is not offered.

By signing and dating this consent form you do not give up any of your legal rights.

Voluntary participation / withdrawal

Your decision to participate in this test is voluntary. You may choose to not participate, or you may withdraw from the test for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

The site/test personnel or study sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the test
- If the study is canceled; or
- For administrative reasons

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, 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 subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Drive, 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: Pro00033891**.**

STATEMENT OF CONSENT

You have read (or have had read to you) the above description of this test. You have been informed of the risks and benefits involved, and all of your questions have been answered to your satisfaction. You understand that your participation is voluntary.

You will receive a copy of this consent form.

You voluntarily agree to participate.

YES **NO** _____ **Volunteer Subject's Initials**

Volunteer Subject's Name (print)	**Signature**	**Date**
Person Obtaining Consent (print)	**Signature**	**Date**