# Optional Amyloid PET Informed Consent and Authorization

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| **STUDY TITLE:** | **Phase II Trial to Evaluate Safety and Efficacy of GM-CSF/Sargramostim in Alzheimer's Disease (SESAD)** |
| **PROTOCOL NUMBER:** | **COMIRB #19-2727** |
| **STUDY DRUG:** | **Sargramostim (also referred to as "study drug")** |
| **SPONSOR/PRINCIPAL INVESTIGATOR:** | **Huntington Potter, PhD**<br>**University of Colorado**<br>**Alzheimer's and Cognition Center Mail Stop 8680**<br>**12700 E. 19th Ave.**<br>**Aurora, CO 80045** |
| **STUDY SITE INFORMATION:** | **University of Colorado**<br>**Anschutz Medical Campus**<br>**Aurora, CO 80045** |

Alzheimer's and Cognition Center
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

## INTRODUCTION

You are being asked to have two optional amyloid Positron Emission Tomography (PET) scans as part of the clinical research study Phase II Trial to Evaluate Safety and Efficacy of GM-CSF/Sargramostim in Alzheimer's Disease (SESAD). To help you decide, you should understand the procedure and what it will involve to participate. This form provides you with information about the procedure. A member of the research team will describe this procedure to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Some people in this study may have a medical condition or a disability that does not allow them to make important decisions for themselves. If you have been asked to decide for someone else whether they should be in this study, please read this consent form carefully. In this form, we use the words "you" and "your." If you are reading this form and deciding for someone else, the words 'you' and 'your' refer to that other person, not to you.

## WHY IS THIS OPTIONAL AMYLOID PET SCAN BEING DONE?

You are being asked to have optional amyloid Positron Emission Tomography (PET) scans because you have been diagnosed with mild-to-moderate Alzheimer's Disease (AD) and have agreed to take part in the Phase II Trial to Evaluate Safety and Efficacy of GM-CSF/Sargramostim in Alzheimer's Disease (SESAD). While **it is not necessary** to have these amyloid PET scans to

participate in the main study, as you have chosen to have the lumbar puncture for study entry criteria, the PET scans are very valuable for research into the deposition of amyloid beta proteins within the brain, and to give further information to study researchers on what impact, if any, sargramostim has on that amyloid deposition within the brain.

## WHAT WILL HAPPEN IF I HAVE AMYLOID PET SCANS?

If you consent to participate in the optional amyloid PET scan research part of the study, you will receive 2 amyloid PET scans in total in the study (1 in the screening portion of the study after the lumbar puncture visit, and 1 at follow-up visit). It is expected that approximately one-half of participants will take part in the optional amyloid PET scanning research part of the study. Each amyloid PET scan visit should take approximately 2 hours, while the scan itself should take approximately 25 minutes.

Before the PET scan, an intravenous catheter (IV) will be placed in your arm or hand. This IV is placed so that the radiopharmaceutical (the imaging agent that binds to the amyloid protein) can be given for the scan. A skinny needle is used to guide a small skinny flexible plastic catheter into a vein. The needle is then removed, and the catheter is temporarily left in the vein.

You will lie down on the scanner bed for the scan. The first part of the PET scan will be a quick (< 2 minute) computed tomography scan (CT scan, CAT scan) of your brain. This CT scan is done to help set up the PET scanner and to help with interpretation of the images of your brain obtained from the PET scan. Immediately after the CT scan, the radiopharmaceutical will be injected into your vein using the IV. It is important to not move your head position between the CT scan and the PET scan.

The instrument produces cross-sectional images of the body including the head. Using the CT information combined with the PET radiotracer, we are able to construct 3 dimensional images of your brain allowing for this research to be conducted.

You will continue to lay on the scanner bed quietly without sleeping for the PET scan portion of the exam. The scan will last approximately 25 minutes. During the entire scan, you will be able to communicate with the scanner staff at all times. You can ask to end the scan at any time. The staff will try to make you as comfortable as possible by providing padding, pillows, and blankets. After the PET scan, you are encouraged to drink water to urinate and help remove the imaging agent from your body. The study team will request that you urinate before leaving the facility where you receive the PET scan.

As the results of the optional amyloid PET are for research purposes, you will NOT be informed of the results of the scan.

## WHAT ARE THE POSSIBLE DISCOMFORTS OR RISKS?

*Possible risks of amyloid PET scan*

As part of this optional study we will perform an amyloid PET scan of your head by using a radioactive tracer such as flutemetamol $F^{18}$, also known as Vizamyl. This tracer binds with the amyloid beta depositions within the brain. Vizamyl has been approved for research and commercial use in the United States for imaging amyloid plaques in the brains of people with AD.

*Radiation Exposure*

The Vizamyl radioactive tracer is estimated to give you a dose of 5.92 mSv, roughly equivalent to 1-2 years of natural background radiation dose. This is an estimate - the amount of radiation dose you receive could be higher or lower, depending on how much tracer is injected into your body, and your body size in relation to the dose. The radioactive drug is eliminated from the body quickly, and should be gone from your body within 24 hours. Most of the drug will be eliminated through urination.

As part of the optional amyloid PET we will also perform a CT scan (Computed Tomography) of your head. The CT scan for this particular study has been estimated to be 0.6 mSv. Total estimated radiation dose for the combined amyloid PET/CT imaging is 6.5 mSv. This dose is well below the research participant single dose limit of 30 mSv and annual dose limit of 50 mSv.

Although not everyone is exposed to radiation from medical imaging scans, everyone is exposed to natural background radiation. There is natural background radiation in the soil, in water that we drink, in vegetables that we eat, in the air, from the sun, and within small amounts of radioactive atoms in our own bodies. However, increased radiation sources are associated with some increased risk of cancer over a person's lifetime.

If you would like more information regarding radiation, please ask the study coordinator or investigator for a copy of “The University of Colorado Radiology Adult Dose-Risk Smartcard.”

Please inform your doctor if you have had any radiation exposure in the past year, from research studies or standard clinical procedures. This is suggested to limit your radiation exposure and minimize risk. Radiation exposure includes x-rays, cardiac catheterization, fluoroscopy, as well as any scans that included the injection of radioactive materials.

*Side Effects*
Possible side effects include:

- Injection site reactions including irritation or pain.
- Nausea
- More rarely, it is possible that you may have an allergic reaction to the radioactive tracer including swelling of face or lips, feeling short of breath, tightness in chest and irritation in throat.

*Reproductive Risk:*
In order to reduce the risk of pregnancy, if you are a woman who is able to have a child or you are a man who is able to father a child and your partner is of child-bearing potential, you must not have sexual intercourse or you must agree to use an effective method of birth control around the time of the optional amyloid PET study. As you need to be using a method of birth control in order to participate in the main study, the study doctor or study staff will confirm with you whether the method of birth control you are using for the main study is acceptable for use during this study. You must tell your study doctor immediately if you/your partner becomes pregnant during the study. Your study doctor may ask you about the outcome of you/your partner’s pregnancy.

*Unforeseen Risks*
Since the radioactive tracer is investigational when used in combination with other medications, 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.

You will be monitored carefully from injection until the conclusion of the imaging study. The study doctor or other qualified study physician(s) available if any questions arise during the PET scan. The research coordinator and Nuclear Medicine Technologist will be present through the entire duration of the PET scan, consistent with CU Anschutz imaging center guidelines. You will be contacted by phone approximately 2 (+/- 1) business days after you were injected with the specific PET tracer to confirm your well-being and asked about any new adverse events.

## WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct benefits to participating in this optional PET study. However, the information may lead to better understanding of Alzheimer's disease, how the main study drug, sargramostim, interacts with amyloid beta in the brain, and how the brain responds to treatment with the study drug, sargramostim.

## WHO IS PAYING FOR THIS STUDY?

The study is being paid for by grants from the Alzheimer's Association and National Institutes of Health, and with funds from the University of Colorado Alzheimer's and Cognition Center.

## WILL I BE PAID FOR BEING IN THE STUDY?

To help defray you cost of participation for items such as travel costs, you will receive a $125.00 payment after each (optional) amyloid PET procedure, for a total maximum of $250.00.

It is important to know that payments for participation in a study are taxable income.

## WILL I HAVE TO PAY FOR ANYTHING?

It will not cost you anything to be in the optional amyloid PET study.

## IS MY PARTICIPATION VOLUNTARY?

Taking part in this optional procedure is voluntary. You have the right to choose not to take part in this optional procedure. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. You can choose not to take part in this optional procedure, and still participate in the main study.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

## CAN I BE REMOVED FROM THIS STUDY?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

## WHAT HAPPENS IF I AM INJURED OR HURT DURING THE STUDY?

If you have an injury while you are in this study, you should call Dr. Huntington Potter (303-724-7385) immediately. If you consider an event to be an emergency, please call 911 for emergency services.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

## WHO DO I CALL IF I HAVE QUESTIONS?

The researcher carrying out this study is Dr. Huntington Potter (Sponsor). You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Huntington Potter at 303-724-7385. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call the study doctors with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

### What happens to data collected in this study?

The data we collect will be used for this study but may also be important for future research. With your consent on this form, your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

### Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, documents or biospecimens from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:
To those connected with the research,
If required by Federal, State or local laws,
If necessary for your medical treatment, with your consent,
For other scientific research conducted in compliance with Federal regulations,
To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

## WHO WILL SEE MY RESEARCH INFORMATION?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the

Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not give us this permission, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information t, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Sponsor, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

*Huntington Potter, Ph.D.*
*Kurt N. and Edith von Kaulla Memorial Professor of Neurology*
*Director, University of Colorado Alzheimer's and Cognition Center*
*Research Complex #2, Rm. 4010*
*Anschutz Medical Campus*
*University of Colorado, Denver MS 8608*
*12700 E. 19th Ave.*
*Aurora CO 80045*

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA), the National Institutes of Health (NIH) and the Office of Human Research Protections (OHRP) that protect research participants like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- The Data Safety Monitoring Board (the committee that reviews the safety of the study).

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names and any other personally identifiable information of the research participants, like you, private.

You have the right to request access to your personal health information from the Principal Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

**INFORMATION ABOUT YOU THAT WILL BE SEEN, COLLECTED, USED AND DISCLOSED IN THIS STUDY:**

- Name and demographic information (age, sex, ethnicity, address, phone number, etc.)
- Research scan results

**WHAT HAPPENS TO DATA (INCLUDING IMAGING DATA) THAT ARE COLLECTED IN THIS STUDY?**

Scientists at the University of Colorado Anschutz Medical Campus and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The imaging data given by you to the investigators for this research no longer belongs to you.
- The Sponsor or Investigators involved in this research may study your imaging data collected from you.
- If imaging data are in a form that identifies you, CU Anschutz or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

## AGREEMENT TO BE IN THIS OPTIONAL AMYLOID PET STUDY AND USE MY DATA

I have read this paper about the optional amyloid PET study or it was read to me. I understand the possible risks and benefits of the procedure. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

## PARTICIPANT

Signature:_____ Date:_____

Print Name:_____

Signature Line For Legally Authorized Representative, if applicable

_____ Date_____
Legally Authorized Representative

Print Name: _____

Participant Assent (if consenting via LAR):_____

Print Name:_____

Date:_____

Consent form explained by:_____ Date:_____

Print Name: _____