COMIRB
APPROVED
For Use
21-Nov-2025
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Initial Screening Informed Consent and Authorization Form

STUDY TITLE:	**Phase II Trial to Evaluate Safety and Efficacy of GM-CSF/Sargramostim in Alzheimer's Disease (SESAD)**
PROTOCOL NUMBER:	**COMIRB #19-2727**
FDA IND:	**152023**
STUDY DRUG:	**Sargramostim (also referred to as "study drug")**
SPONSOR/PRINCIPAL INVESTIGATOR:	**Huntington Potter, PhD** **University of Colorado** **Alzheimer's and Cognition Center** **Mail Stop 8680** **12700 E. 19th Ave.** **Aurora, CO 80045**
STUDY SITE INFORMATION:	**University of Colorado** **Anschutz Medical Campus** **Aurora, CO 80045**

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

You are being asked to undergo some initial tests and procedures to see if you are eligible to participate in the clinical research study Phase II Trial to Evaluate Safety and Efficacy of GM-CSF/Sargramostim in Alzheimer's Disease (SESAD). This form provides you with information about these procedures. A member of the research team will describe the procedures 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. Information about the rest of the clinical research study will be provided in a separate consent form, which can be provided to you now for your review.

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.

WHAT IS THE PURPOSE OF THIS INITIAL SCREENING VISIT

This initial screening visit (also known as Tier 0.5) is meant to determine, if needed in the judgement of the study doctor, whether plasma levels of the beta amyloid protein OR pTau protein are present in your blood at a level that clinical guidelines have determined show evidence of the pathological presence of Alzheimer's disease. As well, it is to gather information about your activities of daily living and functioning, via questionnaires, to determine if they fall within a range that would suggest the presence of these pathological changes are impacting your cognition. This will allow the study team to have an initial determination of broad study eligibility without asking you to submit to more invasive and extensive testing needed for full study eligibility.

The finding from these initial results will be confirmed if you are deemed eligible to move forward in screening, with the Alzheimer's pathology confirmed by either a lumbar puncture or amyloid PET scan.

WHAT IS THE PURPOSE OF THE OVERALL STUDY?

Alzheimer's disease is a major medical problem in the elderly, affecting 12% of those over age 65 and 40-50% of those over age 85. Current treatments offer minor benefits in slowing the development of memory problems but do not stop or reverse the damage from the disease.

The purpose of this study is to determine if injections of a medicine called sargramostim in people with Alzheimer's disease is safe and effective in improving cognitive function and memory and to evaluate its safety (side effects). Sargramostim has not been FDA approved as a safe or effective treatment for people with Alzheimer's Disease. That is why sargramostim will be referred to as a "study drug" or "study medication" throughout this document. This study is also being performed to find out more about how sargramostim works within the body over a longer time period than previously studied. You are being asked to be in this research study because you have been diagnosed with mild-to-moderate Alzheimer's disease and are between the ages of 60 and 85 years.

OTHER PEOPLE IN THIS STUDY

Up to 300 people (including participants and their study partners) from your area may be invited to participate in the study.

WHAT HAPPENS IF I JOIN THIS STUDY?

If you agree to join this initial screening for the study, you will potentially undergo a blood test (based upon the judgement of the study doctor) and will complete some questionnaires to see if you are eligible to fully screen for participation in this study. Details of the full study are contained in the Participant Informed Consent document, which you can review now and, if you are eligible, will review in detail with the study team before that portion of screening starts.

SCREENING TIER 0.5

For this potential initial blood test and set of questionnaires, the study team is looking to determine if you meet basic criteria to continue screening by:

- Setting up an appointment with a central laboratory (QUEST Diagnostics, LabCorp, or other qualified laboratory for you where they will draw some of your blood to test for a protein called Beta amyloid or a protein called pTau. The results of this test will help determine your eligibility. There are 26 QUEST laboratory and 27 LabCorp locations across the Front Range, and the draw for the pTau test would occur at CU Anschutz or at a LabCorp location.

- Sending you an email with a link that will ask you to fill out several questionnaires on your computer/tablet. These questionnaires can take up to about 30 minutes to complete.

After the study team has reviewed this information, you will be contacted to let you know if you are eligible to continue with the full screening process for the clinical trial, details of which are contained in the full participant informed consent document.

Possible risks of having blood drawn
For this screening study, if the study doctor determines you need the blood test, we will need to get about 0.5 teaspoons of blood from you. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle went under the skin.

Other:
There is a risk that you may feel some discomfort answering the questionnaires about your heath and functional abilities. Additionally, there is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

This study is designed for the researcher to learn more about the effect of the study drug on Alzheimer's disease. However, there is no guarantee that your health will improve if you join this study. Also, there could be risks to being in this study. If there are risks, these are described in the section describing the discomforts or risks.

ARE THERE ALTERNATIVE TREATMENTS?

There may be other ways of treating your Alzheimer's disease. These other ways include medications such as donepezil, rivastigmine, galantamine, memantine, lecanemab, and donanemab. You may also choose to get no treatment at all.

You should talk to your doctor about your choices to be certain that you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other medications available to you. During this study, you may also take the Alzheimer's medications listed above, except for lecanemab and donanemab.

You should inform your doctor about previous participation in this study before beginning lecanemab or donanemab therapy.

WHO IS PAYING FOR THIS STUDY?

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

WILL I BE PAID FOR BEING IN THE STUDY?

To help defray your cost of participation for items such as travel costs, if randomized, you will receive a $75.00 payment at the end of the 24-week treatment period even if you cannot or choose not to complete the study, and you will receive a $25 payment after the follow up visits. Additionally, you

will receive a $75.00 payment after each lumbar puncture, and a $125.00 payment after each amyloid PET procedure, for a total maximum of $500.00.

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

FINANCIAL DISCLOSURE
Dr. Huntington Potter (the principal investigator on this study) is a co- inventor of certain methods evaluated in this study, which are owned by the University of South Florida. A plan to manage any potential conflict of interest has been approved by the University of Colorado. Dr. Potter has relinquished any and all personal rights to shared royalties from USF patents and has instructed the USF Technology Transfer Office to transfer any such income that might come in the future to the University of Colorado Foundation to support research by the Potter Alzheimer Dementia Fund. Please feel free to ask any additional questions that you may have about these matters.

WILL I HAVE TO PAY FOR ANYTHING?
It will not cost you anything to be in the study.

IS MY PARTICIPATION VOLUNTARY?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. 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.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

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. 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 trial and 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. 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, document or biospecimen 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, 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, 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 Principal Investigator (PI), 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.
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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, and the Office of Human Research Protections (OHRP) that protect research subjects 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 Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* of the following health information about you collected in this study available to:

- Quest Labs (for blood testing for Tier 0.5) for beta amyloid testing
- LabCorp central lab (for blood testing for Tier 0.5) for pTau testing

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.)

- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to diagnosis(es), medical history and physical examination, laboratory or tissue studies, radiology studies, procedure results
- Research visit and research test records
- Psychological and mental health tests
- Alcoholism, alcohol or drug abuse

WHAT HAPPENS TO DATA (INCLUDING IMAGING DATA) AND BIOLOGICAL SAMPLES (INCLUDING BLOOD, CEREBROSPINAL FLUID) THAT ARE COLLECTED IN THIS STUDY?
Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data and biological samples collected from you during this study are important to this study and to future research. If you join this study:

- The data and biological samples given by you to the investigators for this research no longer belong to you.
- The Sponsor or Investigator of this study may examine your data or biological samples collected during the study.
- If data or biological samples 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 STUDY AND USE MY DATA
I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. 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 understand that I will get a signed and dated copy of this consent form.

PARTICIPANT

Signature:_____ Date:_____

Print Name:_____

Signature Line For Legally Authorized Representative and/or Proxy Decision Maker, if applicable

_____ Date_____
Legally Authorized Representative/
Proxy Decision Maker Signature

Print Name: _____

Participant Assent(If consenting via proxy/LAR): _____

Print name: _____

Date: _____

Consent form explained by:_____ Date:_____

Print Name: _____