Study Partner Informed Consent and Authorization Forı

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** **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

INTRODUCTION

A person you know very well is being considered for participation in a clinical research study of an investigational drug called sargramostim compared to placebo (a drug that looks like sargramostim but has no drug in it) for Mild to Moderate Alzheimer's disease. For the purposes of this form, this person is referred to as the "study participant". The study doctor wants to know if you agree to support the study participant in the research study. Your decision to act as a study partner to the study participant is voluntary. This form is called an "informed consent form". It describes your role as a study partner in the study so that you can decide whether or not you want to take on this role.

If you have any questions about being a study partner in this study, you should ask the study doctor. If you do not understand something in this form, you should ask the study doctor. You should talk about taking on the study partner role in the study with anyone you choose. You can also ask to read the consent form the study participant has to read and sign. (That form has more detailed information about the study.) Do not sign this form unless your questions have been answered, and you decide that you want to be a study partner in this study. You will get copy of the signed form to keep.

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.

WHY AM I BEING ASKED TO BE A STUDY PARTNER IN THIS STUDY?

Each study participant needs a study partner to support him or her throughout the full duration of this study. In order to be a study partner in this study you need to spend sufficient time with the study participant so that you can provide certain information about the participant to the study doctor and staff during the course of the study. You do not need to be living with the study participant. If you do not live with the study participant the study doctor needs to be sure that the study participant can contact you easily at all times. You have been asked to take on this role because the study participant has identified you as a good candidate to be his/her study partner. If you agree to take part, information you provide to the study doctor or study staff will be used for the study. Some of the information you provide will be in the form of interviews, some of which will be audio recorded. The audio recordings are done to confirm the scoring of the tests and for quality control. You cannot be a study partner for the study participant if you do not want the study doctor or study staff to record the interviews. Additionally, if you agree to take part, you agree to participate in the regular injection of the study drug and helping monitor the participant for the presences of any adverse events.

How long does the study last and how many visits do I need to participate in?

As a study partner, you can expect to be in the study for approximately 10.5 months.

The first 3 months of this will involve the study participant participating in various tests and procedures that will determine whether s/he is eligible to participate in the treatment portion of the study. You will need to directly participate briefly in 1 visit during these 2 months, but depending on your relationship with the study participant, you may come to all the visits, as necessary. If needed, it may be acceptable for another friend/family member of the participant to accompany them to some of the study visits.

If the study participant is eligible to receive study drug they will then receive study drug for 6 months. You will need to participate in 3 visits during these 6 months to answer questions about the participant. Additionally, as you will be involved in the regular injection of the study drug, you will participate in the 4 in-clinic visit for injection site review and review of the study drug injection log that is to be filled out at home, injection training as needed, and at all other in-home visits, weekly tracking of possible adverse events.

During the final 1.5 months of the study, the participant will not take any study drug but will still be assessed to see how they are doing after they have stopped taking study drug. You will need to participate in 1 visit during this time.

WHAT IF I DECIDE NOT TO BE A STUDY PARTNER IN THIS STUDY OR CHANGE MY MIND LATER?

Being a study partner to a study participant in this research study is voluntary. You may choose not to take on this role. Or you may decide to take on this role but then change your mind. If you do not want to be a study partner in the study or decide to stop being the study partner, there will be no penalty to you or to the study participant and no loss of benefits. However, the participant will need to identify a replacement study partner in order to stay in the study. If there is no suitable replacement

study partner, the study participant will have to leave the study. If you decide that you no longer want to be a study partner in this research study, you can withdraw your consent and you will not be allowed to continue being a study partner in the study. If you revoke this consent, the study doctor, researchers and the Sponsor may continue to use and disclose the information they have already collected to protect the integrity of the research.

The study participant's decision to be in the study is also voluntary. S/he can stop being in the study at any time, without penalty or loss of benefits. If the study participant leaves the study, your role as study partner will also stop. The study participant may have to leave the study early even if s/he wants to stay in the study. This could happen if:

- The study doctor or sponsor thinks it is in the study participant's best interest to leave the study
- The participant does not follow study instructions
- You, as the study partner, do not follow the instructions of the study doctor
- There is a change in the study participant's medical condition
- The study is stopped by the sponsor, the Institutional Review Board (IRB) or any regulatory authority (for example, FDA) for any reason

If you or the participant wants to leave the study early for any reason, please tell the study doctor or study staff. You will not have to give a reason for leaving the study early. If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected.

WHAT ARE MY RESPONSIBILITIES IF I DECIDE TO BECOME THE STUDY PARTICIPANT'S STUDY PARTNER IN THIS STUDY?

If you agree to be the study participant's study partner in the study, you must spend sufficient time with the study participant and you must attend the visits described above. Someone else cannot take your place. You must make sure you can do what is required for the study before you agree to participate. If you become unable to do what is required, you must tell the study doctor or study staff promptly so that another study partner can be identified.

You will be asked to provide information about the study participant's memory, cognitive function (mental abilities and thinking processes), how well they are able to perform daily activities, and how they are feeling emotionally including any thoughts or behaviors related to harming themselves.

You will be asked to participate in the at home administration of the study drug to the study participant after appropriate training, using provided prefilled safety needles. The schedule of study drug administration, and the location of each injection, will need to be tracked by you as study partner.

You will also be asked to observe the study participant for possible side effects, and report any changes in health or concerns to the study doctor or study staff immediately. These could include the development of skin rashes or symptoms of infection at the injection site. This is so that the study doctor can investigate potential adverse events (side effects) or health problems promptly.

If you observe the study participant is injured or becomes ill as a result of being in this study, you should seek medical help for the study participant immediately and arrange to notify the study doctor immediately.

WHAT ARE THE RISKS IF I AM IN THIS STUDY?

This study should not involve any physical risk to you. There is a minimal risk of a needle stick if you help the participant administer the study drug. If you have a needle stick injury, there is a small risk of infection through blood borne pathogens from the participant if the needle stick injury is after the study drug injection. There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

Answering the study doctor or study staff's questions could lead you to feel uncomfortable or upset. Please tell the study doctor or study staff if you feel uncomfortable or upset while answering questions. You have the right to refuse to answer any questions.

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. 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.

WHAT ARE THE ALTERNATIVES TO BEING IN THE STUDY?
You do not need to take part in this research study. However, due to the nature of this clinical research, the alternative to being a study partner is not to participate in this study.

WHAT ARE THE POSSIBLE BENEFITS OF BEING A STUDY PARTNER IN THIS STUDY?
As a study partner, you will not receive any direct benefit by taking part in this study. The study drug may or may not help the study participant. However, your taking part may give more scientific information about sargramostim and its effects on Alzheimer's disease. Information from this study may help researchers understand more about how the study drug works. Information from this study may also help researchers come up with new tests or medicines in the future to help people with Alzheimer's disease.

WILL I BE PAID FOR BEING A STUDY PARTNER IN THIS STUDY?
If you agree to be the study partner for this study, there is no reimbursement or compensation.

WILL THERE BE COSTS TO ME AS A STUDY PARTNER IN THIS STUDY?
As a study partner, you may have to pay for costs of getting to and from the study site.

What is the source of funding for this study?
The study is being paid for by the Alzheimer's Association, a National Institute of Health grant, and funds from the Alzheimer's and Cognition Center.

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. Please feel free to ask any additional questions that you may have about these matters.

WHO CAN I CONTACT ABOUT THIS STUDY OR MY RIGHTS AS A STUDY PARTNER RESEARCH PARTICIPANT?

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Your responsibilities as a study partner;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Other questions, concerns, or complaints.

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.

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.
Director of Alzheimer's Disease Programs
Anschutz Medical Campus
University of Colorado 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, 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.

If a medical emergency happens, some information on the study participant may be given to the treating doctor and medical emergency staff. Your contact information may also be provided to the

study participant's doctor and medical emergency staff if this is required for the treatment of the study participant.

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.)
- Questionnaire and interview results

WHAT HAPPENS TO DATA 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 collected from you during this study are important to this study and to future research. If you join this study:

- The data 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 collected during the study.
- If 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 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 will get a signed and dated copy of this consent form.

STUDY PARTNER

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____