

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

**Study Title: Examining the Impact of Photobiomodulation (PBM) on Behavior, and Biomarkers of Alzheimer’s Disease**

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Co-Principal Investigator:	Julio Rojas-Martinez, M.D., Ph.D., Assistant Professor of Neurology, UCSF Phone: 415.502.7341 email: julio.rojas-martinez@ucsf.edu

This is a clinical research study. Your study doctors Linda Chao, Ph.D. from the UCSF Department of Radiology & Biomedical Imaging and Psychiatry and the San Francisco VA, and Julio Rojas-Martinez, M.D., Ph.D. from the UCSF Department of Neurology will explain the study to you.

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

You are being asked to take part in this study because you have been diagnosed with probable Alzheimer's Disease.

**Why is this research study being done?**

- Photobiomodulation (PBM) describes the use of near-infrared light (which is not visible to the naked eye) to heal and protect tissue that has either been injured, is degenerating, or else is at risk of dying.
- Research suggests that the light delivered during PBM enhances the body’s biochemical ability to store and use energy and increase blood flow, which triggers the body’s natural healing processes.
- We are conducting this study to determine if PBM with the Vielight Neuro Rx gamma device administered through the scalp and skull (i.e., transcranially) and through the nose (i.e., intranasally) influences cognitive function and behavioral symptoms in people with Alzheimer’s disease (AD).
- The study will also examine whether PBM influences biomarkers of AD in the blood and spinal fluid of patients with AD. A biomarker is a specific physical trait used to measure the progress of a disease or condition.

**Who is paying for this study?**

- University of California, San Francisco

**How many people will take part in this study?**

- Approximately 16 patients with AD and their study partners will take part in this study.

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

If you are eligible and agree to participate in this study, the following things will happen:

1. I will describe the study to you and your legally authorized representative (LAR), if you have one, so that you and your LAR can decide if you want to participate in the study. This will take about 1 hour.
2. If you decide to participate in the study, you will need to have an individual (e.g., spouse or relative), called a “**Study Partner**”, who is willing to:
  - Accompany you to the study visits.
  - Answer questions about your memory and daily function.
  - Tell the study doctors about all medications you are taking
  - Check with the study doctors before you start to take any new medications.
  - Help you use the Vielight Neuro Rx gamma device every other day for 20 minutes for 16 weeks.
  - Answer questions about your experience with the Vielight Neuro Rx Gamma device every two weeks for 16 weeks while you are using the device.
  - Tell the study staff about any changes in your health and/or medication.
3. If you decide to participate in the study, you will be scheduled for a Screening Visit to determine if you meet the requirements to be in the study and to make sure it is safe for you to undergo the procedures. If you meet the requirements to be in the study, you and your study partner will be enrolled in the study and scheduled for the following appointments/procedures:

**If you do not have biomarker confirmation of your AD diagnosis**, you will have a blood draw to collect 5 mL (about 1 teaspoon) of blood so that we may assay your plasma for biomarkers of AD. This procedure can take place at the San Francisco VA, for which you will sign a separate VA consent form. If the biomarker analysis suggests that you have AD biomarkers, you will undergo the following **baseline procedures**:

**Baseline Cognitive Assessment:** The purpose of this appointment is to obtain information about your cognitive function. This procedure can take place at the San Francisco VA or a quiet, private location of your choice (such as your home). This procedure will take approximately 1 hour and your study partner will not be present while you are taking the tests.

**Baseline Blood Coagulation Tests:** The purpose of this procedure is to collect about 7 mL (about 1.5 measuring teaspoons) of blood so that we can assess your blood clotting function. This procedure can take place at the San Francisco VA Medical Center or the UCSF Neurosciences Clinical Research Unit (NCRU). You will be asked to sign a separate VA consent form for this procedure if it takes place at the SF VA. This appointment will take approximately 1 hour.

**Baseline Clinic Visit:** The purpose of this appointment is to collect blood and cerebrospinal fluid (CSF) from you for biomarker testing. This procedure will take place at the UCSF NCRU and will take about 2 hours. The following things will happen at the

### Baseline Clinic Visit:

- a. You will be asked **not** to eat food or drink beverages such as coffee, tea, milk or juice (water is OK) for at least of 6 hours prior to the Baseline Clinic Visit.
- b. 10 mL of blood (about 2 measuring teaspoons) of blood will be drawn from a vein in your arm for biomarker testing.
- c. A lumbar puncture (LP) will be performed to collect 10 mL (about 2 measuring teaspoons) of the fluid that washes around the brain and spinal cord for biomarker testing. This procedure involves inserting a needle into your lower back, below the spinal cord, to

collect a small amount of the spinal fluid. Your body will replace the spinal fluid collected within 2 hours.

- d. During the lumbar puncture, you will either lie on your side, curled up into a ball or you will sit on the edge of a bed or chair and be asked to lean forward.
- e. The lower part of your back will be cleaned with antiseptic. A local anesthetic will be injected into the skin of your lower back at the area of the lumbar puncture. When the area in your back is numb, a very thin needle will be inserted into the spinal canal in the lower back, well below the level where the spinal cord ends.
- f. After the lumbar puncture is completed, you will remain in the clinic for about 30 minutes. You will be given something to eat and drink before you leave.
- g. You should avoid any strenuous physical activity 24 hours after the Baseline Clinic Visit. This includes lifting, bending, doing housework and gardening, or doing exercise such as jogging or bicycle riding.
- h. A study staff will call you and your study partner the day after the clinic visit to check on your well-being.

**Randomization:** After you complete the baseline cognitive assessment and clinic visits, you will be randomly assigned to one of two groups by a computer program. You have a 50-50 chance of being in either group (like flipping a coin). Neither you, your study partner, nor the study doctors can choose the group you will be in.

- Both groups will use the **Vielight NeuroRx Gamma device** (see picture below) once every other day (e.g., Mon, Wed, and Fri) for 16 weeks.
- Individuals assigned to the **Active PBM** group will receive active PBM treatments for 16 weeks. Individuals assigned to the **Sham group** will **not** receive active PBM treatments.
- Although Active and Sham Vielight Neuro RxGamma device look the same, the Sham device will **not** deliver active PBM.

### What is the Vielight Gamma device?

- The Vielight Gamma device (see Figure 1) is a headset engineered to deliver near- infrared light to parts of the brain that are important for memory about personal experiences associated with a certain time and place (i.e., autobiographical memory).
- The device has 4 main parts: the headset which has support pads, the nasal applicator, the controller, and the charging adaptor (which is not shown in Figure 1).
- The transcranial headset is worn on the head with the single cluster in the front (about where the hair line would be). The band with the three clusters is worn on the back of the head. The support pads, which are labeled right and left, sit around the ears (see Figure 2).
- The nasal applicator is clipped into the right or left nostril with the clip on the outside of the nostril (see Figure 2).
- The Vielight Gamma device is activated by pressing the “on” button on the controller (see Figure 1). The device will automatically shut itself off after 20 minutes.
- The Vielight Gamma is not currently FDA- approved for

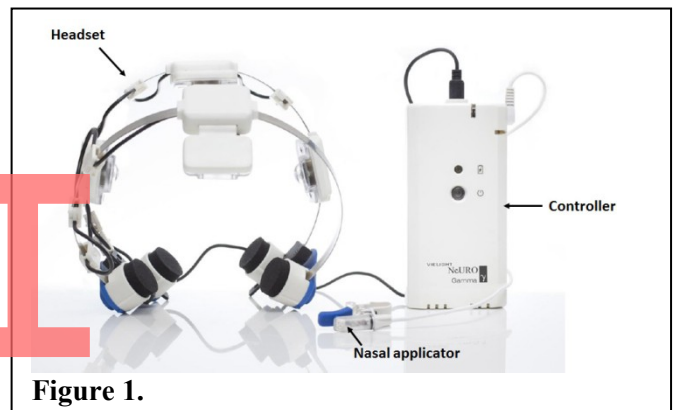


Figure 1.

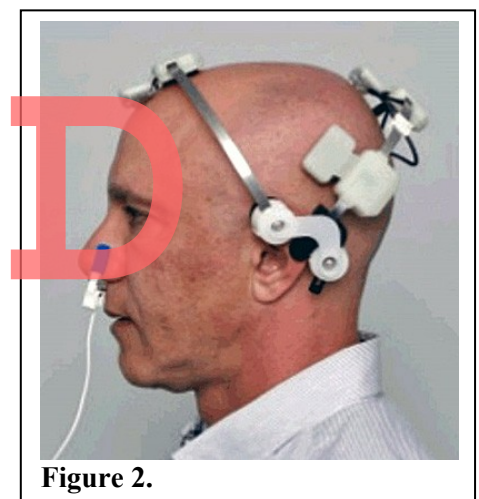


Figure 2.

treating dementia symptoms.

- Your study partner will be trained to position the Vielight Gamma device on you. You will be present at training session, which will last about 30 minutes.
- Your study partner will help you to use the Vielight Gamma device once every other day (e.g., Mon, Wed, and Fri) for 16weeks.

#### **Confirmation Visit:**

- One week after you have been using the Vielight Gamma device, a study staff member will check in with you and your study partner (either in person or via video conferencing) to make sure that your study partner has been positioning the device correctly on your head. You will be present during this visit, which may last up to 30 minutes.
- A study staff will speak with you during the **Confirmation Visit**, separate from your study partner, to see how things are going and to make sure you still want to participate in the study.
- After the **Confirmation Visit**, a study staff will call your study partner every two weeks to see how things are going. The study staff will ask to speak with you during these calls, separate from your study partner, to make sure that you still want to participate in the study.

#### **16-Week Blood Coagulation Tests:**

- You will have 7 mL (about 1.5 measuring teaspoons) of blood drawn again at the San Francisco VA Medical Center or the UCSF NCRU so that we can assess your blood clotting function. This procedure will be identical to the baseline blood coagulation test.

#### **16- Week Clinic Visit:**

- You will have a blood draw and lumbar puncture after you have finished using the Vielight Gamma device for 16 weeks. The procedures will be identical to the procedures at the Baseline Clinic Visit and will take place at the UCSF NCRU.

#### **Will I find out the group to which I was assigned?**

- Yes, we will inform you and your study partner of the group to which you were assigned after you complete all of the 16-Week procedures.
- If you were assigned to the Sham group, you will have the opportunity to receive a full series (16-weeks) of Active PBM treatments at that time.
- If you opt to receive Active PBM treatments, you will not undergo additional blood draws or lumbar punctures. You will only undergo cognitive assessment after completing 16 weeks of Active PBM.
- Like before, your study partner will help you to use the Vielight Gamma device once every other day (e.g., Mon, Wed, and Fri) for 16 weeks.

#### **Are any of the procedures experimental?**

- The Vielight Gamma device is experimental. It has not been approved by the Food and Drug Administration (FDA) for treating dementia symptoms.
- Although the goal of this study is to determine if PBM has an effect on cognition, dementia symptoms, and blood and CSF biomarkers of AD, it is not known if use of the Vielight Gamma device will improve cognition, dementia symptoms, or affect blood and CSF biomarkers of AD.

#### **How long will I be in this research study?**

- If you are in the Active PBM group, you will be in the research study for approximately 18 weeks. If you are assigned to the Sham PBM group, you will also be in the research study for approximately 18 weeks unless you chose to receive active PBM after the 16-week follow-up visits. If so, then you will be in the research study for approximately 36 weeks. The table below summarizes the amount of time you will spend in the study.

#### **Summary of Visit Activities and Estimated Time per Activity:**

Procedure	Active PBM	Sham PBM
Consent	1 hr.	1 hr.
Blood draw for biomarker screening (if necessary)	1 hr.	1 hr.
Baseline cognitive assessment	1 hr.	1 hr.
Baseline blood coagulation tests	1 hr.	1 hr.
Baseline clinic visit	2 hrs.	2 hrs.
Device training with Study Partner (SP)	30 min.	30 min.
Confirmation of correct device use with SP	Up to 30 min.	Up to 30 min.
Use Vielight Neuro Rx Gamma device	20 min/day, every other day for 16 wks ≈ 19 hrs.	20 min/day, every other day for 16 wks ≈ 19 hrs.
16-week cognitive assessment	1 hr.	1 hr.
16-week blood coagulation tests	1 hr.	1 hr.
16-week clinic visit	2 hrs.	2 hrs.
<b>Total Time</b>	30 hrs.	30 hrs.*

\*individuals who chose to undergo Active PBM treatments will spend more time (up to 53 hours) in the study

### What are the risks or discomforts associated with being in this study?

- **Loss of Privacy:** You may experience a loss of privacy because of participating in this study. While we will do our best to make sure that the personal information gathered for this study is kept private, we cannot guarantee total privacy.
- **Cognitive Assessment:** Some of the questions in the cognitive assessment may be difficult for you to answer. You may find this stressful and/or unpleasant.
- **Blood draw risks:** Removing blood by a needle and syringe poses a small risk of infection, temporary pain, or bruising at the site of the needle stick. Some people may experience fainting or dizziness. To minimize these risks, experienced medical personnel will perform the blood draws in a sterile condition. In total, about 34 mL (about 7 measuring teaspoons) of blood will be taken over the course of the study. If you need a blood draw for biomarker analysis, a total of 39 mL (about 8 teaspoons) will be taken over the course of the study.
- **Lumbar puncture risks:** During the lumbar puncture, 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. If the headache persists, it may require additional treatment. Uncommonly, a blood patch (injection of some of your blood into the lumbar puncture site to patch the CSF leak) may be required to relieve the headache.
  - Although very rare, it is possible that you may have an allergic reaction to the local anesthetic, like lidocaine, used for the lumbar puncture. An allergic reaction would cause swelling and a rash on your skin where the anesthetic was injected. Please alert the staff if you have ever had a reaction to local anesthetic before (especially if this occurred with a dental procedure).
  - Other potential, but rare, risks of lumbar puncture include infection, damage to nerves in your back, and bleeding into the CSF space. The risks of these events occurring is much less than 1%. To minimize these risks, the lumbar puncture will be performed by Dr. Julio Rojas-Martinez or by a specialist specifically trained in the procedure.
  - In total, 20 mL (about 4 measuring teaspoons) of CSF will be collected over the course of the study. Your body will make up for this loss.
- **Other Risks:** Participating in this research study could lead to conflict between you and your study partner and/or LAR if there is disagreement about your and his/her willingness to participate.
- Participation in this research study may involve risks that are not foreseeable.

- There have been no adverse side effects associated with use of the Vielight Neuro Gamma device in Dr. Chao's other clinical trial involving the same device (NCT03160027). However, one study partner, who did not have dementia, reported feeling "tired" after he used the Vielight Neuro Gamma device for a 20-minute treatment session.

### What are the benefits?

- Although we are conducting this study to determine if PBM can help improve cognitive function and behavioral symptoms in people with AD, there is NO GUARANTEE that you will experience improvements in cognition or behavior.
- You will be helping to answer an important research question that may help health professionals better understand whether PBM is beneficial for people with AD.

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

- You may receive treatment or care for your AD symptoms without being in this study.
- If you decide not to take part in this study, you will not be penalized in any way. You can keep participating in activities the way you usually do.
- If you decide not to take part in this study, it will not affect your medical care.

### Where will this study take place?

- Some study procedures (e.g., consent, baseline and 16-week follow-up cognitive assessments, confirmation of correct device use) may take place at your home or a quiet, private location of your choice.
- The biomarker screening blood draw (if you need it), baseline and 16-week blood coagulation tests will take place at the San Francisco VA Medical Center, for which you will sign a separate VA consent form.
- The baseline and 16-week clinic visits will take place at the UCSF NCRU.
- You will use the Vielight Gamma device at your home.

### Will information about me be kept private?

- Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.
- Authorized representatives from the University of California may review your research data for the purpose of monitoring or managing the conduct of this study.
- It is possible that data from the study may be submitted to the Food and Drug Administration (FDA). If this occurs, then authorized representatives from the FDA may also review the research data.

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

- It is important that you tell your study doctor, Linda Chao, Ph.D., and/or Julio Rojas-Martinez, M.D., Ph.D. if you feel that you have been injured because of taking part in this study. You can tell the doctors in person at 415-221-4810, x24386 (Linda Chao) and 415-

502-7341 (Julio Rojas-Martinez).

### **Treatment and Compensation for Injury:**

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

### **Can I stop being in the study?**

- You can stop at any time. You will be given a handout, separate from this consent form, that has the PIs' names and telephone numbers. You can call any of them if you wish to stop being in the study.
- We may ask you to stop taking part in this study if we feel it is in your best interest, if you do not follow the study rules, or if the study is stopped.

### **What will happen if I stop being in the study?**

- If you decide to stop being in the study, you will go back to your usual activities.

### **Are there any costs to taking part in this study?**

- No. The sponsor has agreed to pay for all items associated with this research study; your insurer will not be billed.

### **Will I be paid for taking part in this study?**

- You will be paid \$100 for each Clinic Visit at the UCSF Neurosciences Clinical Research Unit (NCRU).

### **Can I keep the Vielight Neuro Rx Gamma device after the study?**

- No, you will be asked to return the device after the study is over.

### **What will happen if there is any new information that might affect my willingness to participate in this study?**

- If we become aware of any important new findings, we will contact you as soon as possible.

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

- Taking part in this study is completely your choice.
- You may choose either to take part in the study or not take part in the study. If you decide to take part in the study, you may leave the study at any time, for any reason.
- No matter what you choose, you will not be penalized in any way. You will not lose any of your regular benefits, and you can still get your care the way you usually do.
- Your blood and cerebrospinal fluid (CSF) samples collected during this study will be stored in either the San Francisco VA Medical Center Clinical Research Center or the UCSF Neurosciences Research Building, 2<sup>nd</sup> Floor Neurology Laboratory. Access to study samples will be limited to study personnel who are authorized to perform data analyses. Your samples are labeled with your study identification number only. The individual performing the testing will not know your identity. Neither you nor your family will have access to the results of this testing. Additional tests relating to the goals and objectives of this study may be conducted on these samples in case there are proteins we do not know about yet that might help us better understand or develop treatments for AD. While you have the right to withdraw from this study at any time, information and samples that already have been

collected from you may continue to be used. Any future commercial product developed as a result of analysis of blood or CSF samples collected in this study would be from the analysis of all samples collected in the study, not from an individual. You will not be paid or receive money for new discoveries that have potential commercial value.

### **What will happen to my information once the study is over?**

- We will store your blood and CSF samples at the San Francisco VA Clinical Research Center (CRC), for which you will sign a separate consent form.
- We will store demographic information collected about you in this study, your memory test results, and information about your blood and CSF biomarkers in Dr. Linda Chao's laboratory at the San Francisco VA Medical Center in accordance with VHA Records Control Schedule.
- Other researchers may request permission to use data from this study to answer other research questions; however, your personally identifying information (such as your name or contact information) will not be shared.

### **Will I be told the results of the study?**

- Yes, at the end of the study, we will let all study participants know the overall results of the study. However, you will not be given your personal results.

### **Who can answer my questions about the study?**

- A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> (NCT03405662), 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.
- You can talk to the study doctors about any questions, concerns or complaints you may have about this study. Dr. Linda Chao may be reached at 415-221-4810 ext. 24386. Dr. Julio Rojas-Martinez may be reached at 415-502-7341.
- If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the UCSF Institutional Review Board, which is a group of people who review the research to protect your rights. You may contact the UCSF IRB by phone at 415-476-1814 from 8 am to 5 pm, Monday through Friday. The UCSF IRB's address is: UCSF IRB, Box 0962 University of California, San Francisco (UCSF) San Francisco, CA, 94143.

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### **Summary of key points of the research study:**



- You will have cognitive tests at baseline and at the 16-week follow-up.
- You will have blood coagulation tests at baseline and at the 16-week follow-up.
- You will have a blood draw and a lumbar puncture baseline and at the 16-week follow-up.
- You will be randomly assigned to an Active PBM group or a Sham PBM group
- Regardless of the group to which you are assigned, your study partner will help you use the Vielight Neuro Rx Gamma device once every other day, 3 days a week (e.g., Mon, Wed, Fri) for 16 weeks.
- You will find out the group that you were assigned to upon completion of the 16-week follow-up procedures.
- If you were in the Sham PBM group, you have the option of receiving 16 weeks of active PBM with the Vielight Neuro Rx Gamma device.

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**CONSENT:**

- You have been given a copy of this consent form to keep.
- You have been given the *Experimental Subjects Bill of Rights*.
- You have been given a handout with the PIs' names and phone numbers.
- Your blood and CSF will be stored, possibly for future analyses.
- You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about yourself.

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

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

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Participant's Signature for Consent**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Person Obtaining Consent**

**OR:**

The person being considered for this study is unable to consent for him or herself because he or she is cognitively impaired or is not capable of reading or signing the consent form. I have been asked to give my permission to include this person in this study. I understand that my obligation is to determine what this person would do if they were able to make an informed decision. If I am not sure what they would do, I will determine what is in their best interests. I agree to sign a self-certification of surrogate decision maker form to state my willingness to serve as a surrogate decision maker, my relationship with the potential participant and my contact information.

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Legally Authorized Representative's Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Person Obtaining Consent**

**OPEN-LABEL STUDY PHASE:**

- If I am in the Sham PBM group, I would like to receive active PBM treatments after I complete the 16-week follow-up procedures. My Study Partner will help me to use an active Vielight Gamma device every other day for 16 weeks. After 16 weeks of active PBM treatments, I will take one final test of my cognitive abilities.
- NO**, I do not want to be the study after I finish the 16-week follow-up assessments.

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Participant's Signature for Consent**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Person Obtaining Consent**

**OR:**

The person being considered for this study is unable to consent for him or herself because he or she is cognitively impaired or is not capable of reading or signing the consent form. I have been asked to give my permission for future contact. I understand that my obligation is to determine what this person would do if they were able to make an informed decision. If I am not sure what they would do, I will determine what is in their best interests. I agree to sign a self-certification of surrogate decision maker form to state my willingness to serve as a surrogate decision maker, my relationship with the potential participant and my contact information.

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Legally Authorized Representative's Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Person Obtaining Consent**

## OPTIONAL RESEARCH

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

**You can say "yes" or "no" to each of the following studies. Please mark your choice for each study.**

*Donating data (i.e., your blood and CSF) may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.*

*There will be no direct benefit to you from allowing your data (i.e., blood and CSF) to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement of science and understanding of health and disease. If the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits. If you decide later that you do not want your information to be used for future research, you can notify the investigator in writing at: Linda Chao, 4150 Clement Street (114M), San Francisco, CA 94121 and any remaining data will be destroyed. However, we cannot retract any data has been shared with other researchers.*

*Please put your initials in the "YES" or "NO" box to indicate your answer.*

*1. My specimens and associated data may be kept for use in research to learn about, prevent, or treat Alzheimer's disease.*

YES	NO
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## MAY WE CONTACT YOU ABOUT FUTURE STUDIES?

- YES, you may contact me about future studies.
- NO, you may not contact me about future studies.

If you are willing to be contacted, please sign below.

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\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Signature for Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent

O

OR:

The person being considered for this study is unable to consent for him or herself because he or she is cognitively impaired or is not capable of reading or signing the consent form. I have been asked to give my permission for future contact. I understand that my obligation is to determine what this person would do if they were able to make an informed decision. If I am not sure what they would do, I will determine what is in their best interests. I agree to sign a self-certification of surrogate decision maker form to state my willingness to serve as a surrogate decision maker, my relationship with the potential participant and my contact information.

I

\_\_\_\_\_  
Date

\_\_\_\_\_  
Legally Authorized Representative's Signature

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\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent