UNIVERSITY OF CALIFORNIA
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

UC Reliance #2471: A Phase 2, Proof-of-Concept, Double-Blind-Randomized, Placebo-Controlled Adaptive Design Trial of Nicotinamide in MCI due to AD and Mild AD Dementia

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

RESEARCH TEAM

Lead Researcher

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Other Researchers

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Sarah Kremen, MD
Clinical Physician of Neurology
University of California Los Angeles*
Co-Director, Katherine and Benjamin Kagan AD Treatment Development Program
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(310) 825-6301

STUDY LOCATION(S):

UCI

1100 Gottschalk Medical Plaza
University of California, Irvine
Irvine, CA 92697-4285

Institute for Clinical and Translational Science (ICTS)
Hewitt Hall Clinic 843 Health Sciences Rd
Irvine, CA 92697

Newport Diagnostic Center
1605 Avocado Avenue,
Newport Beach, CA 92660

UCLA:

Center for Neurotherapeutics
UCLA Medical Center
300 Medical Plaza, Westwood Blvd

Los Angeles, CA

STUDY SPONSOR(S):
UC Cures Initiative, University of California Office of the President

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to test whether nicotinamide, also known as vitamin B3 or niacinamide, taken in high doses, can reduce phosphorylation of tau (the protein that accumulates in neurofibrillary tangles) in people with Mild Cognitive Impairment or mild Alzheimer's disease (AD) dementia.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 100 participants will take part in the research across two study sites. UCI and UCLA* will enroll approximately 50 participants at each site.

**As of March 2021, UCLA is no longer open to enrollment.*

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if you

- are age 50 or older
- have been diagnosed with Mild Cognitive Impairment or mild dementia due to Alzheimer's disease
- are willing and able to undergo lumbar punctures (also known as spinal tap)
- have a study partner that you see at least 3 times a week, who can provide accurate information about your health and can attend required study visits with you
- are able to swallow oral tablets

Exclusion Requirements
You cannot participate in this study if you

- have a history of cancer within 3 years prior to screening
- have a history of alcohol or substance abuse within 5 years of screening
- live in a skilled nursing facility
- are unable to have an MRI scan
- are unable to have a lumbar puncture procedure
- are participating in or have recently (in the last 6 months) participated in any other clinical trial for AD
- are pregnant, lactating or of child bearing potential

HOW LONG WILL THE STUDY GO ON?
This study consists of a screening phase and treatment phase and is expected to last about 54 weeks total.

The screening phase will take up to 60 days and will include 3 visits to our clinic. The treatment phase includes up to 6 trips to the clinic and at least 3 telephone interviews over a 48-week period.

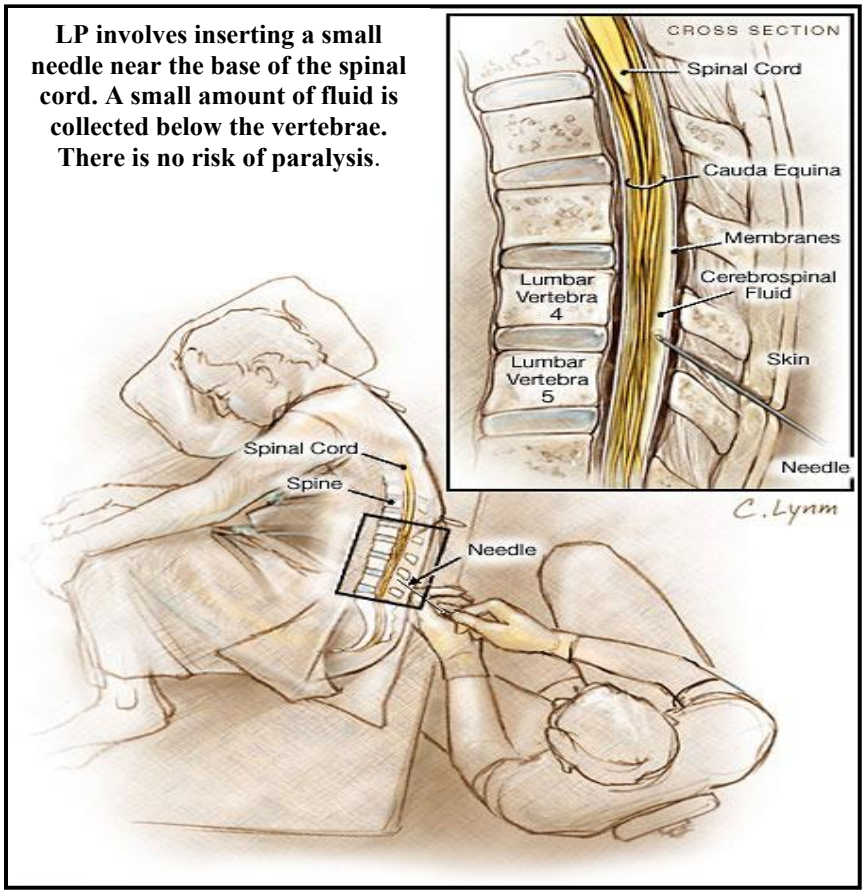
WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?

Screening:

Before you can participate in the main part of the study, you will need to have "screening" exams, tests or procedures performed. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include

- Informed consent: You and your study partner will need to read, confirm understanding, and sign this informed consent.
- Medical history: A complete medical history will be taken
- Medication review
- Physical exam & vital signs:
- Efficacy and safety assessments. Tests will be done to assess how well you are thinking, how well you are performing your daily activities, and how well you are feeling.
- Brain magnetic resonance imaging (MRI) scan. MRI scans produce detailed pictures of the brain by using a magnetic field and radio waves. You will have one MRI scan of the brain during Screening to determine if there are any abnormalities present in your brain (such as stroke or hemorrhage) which would prevent your continuation in the study.
- Electrocardiogram (ECG): ECGs measure electrical activity of your heart by putting small sticky patches on certain areas of your body.
- Concomitant medication monitoring: The study doctor will record all the medications you take during the study.
- You will have the following blood and urine tests:
    - Standard safety and health assessments
    - A blood test at the Screening visit to see if you carry a particular variant of a gene called apolipoprotein E (ApoE) that has been linked to AD.
    - Some of your blood will be stored for future research use.

- A total of 50 milliliters (approximately 3.5 tablespoons) of blood will be taken during the Screening period of the study.



- Cerebral spinal fluid (CSF) collection: During lumbar puncture procedure, you will lie on your side with your knees drawn up to your chest; or you will sit in a bent forward position, depending on your doctor's instructions. A long, thin needle will be put in the spinal canal in the area of your lower spine and up to approximately 1.5 tablespoons (20 milliliters [mL]) of CSF will be removed. Before the doctor inserts the needle you will be given medicine to make the area numb. The entire procedure takes about 30 minutes. Because CSF is continually being made, the small amount of fluid that is removed will be quickly replaced. Some of your collected CSF will be tested for sugar level, protein, and cell count. The tests will be used to monitor each patient for any unusual results.
- In some cases, it may be necessary for the doctor to perform the lumbar puncture with the help of an imaging tool called fluoroscopy. Fluoroscopy is a type of x-ray that allows the doctor to see your spine in order to determine where to insert the needle.

Screening Phase			
Visit Number	**SC1**	**SC2**	**SC3**
Approximate Length of Visit (hours)	**3**	**2**	**2**
Sign Informed Consent	✓		
Review of Inclusion/Exclusion Criteria	✓		
Medical History	✓		
Memory & Thinking Skills Tests	✓		
Review Concurrent Medications	✓		
Behavioral and Functional Rating Scales	✓		
Vital Signs	✓		
Physical/Neurological Exams	✓		
Electrocardiogram (ECG)	✓		
Blood draw	✓	✓	
Urine collected	✓		
Fasting Lumbar Puncture*		✓	
MRI Scan*			✓

*The visit order of the lumbar puncture and the MRI may be reversed

During the main part of the study

If the screening tests show that you can continue to be in the study, and you choose to take part, you will participate in some additional "baseline" testing before you will be randomized to receive either the active study drug or the placebo. You have a 50/50 chance of receiving the study drug. Neither you nor the study personnel will know who is receiving the nicotinamide or the placebo

Group	Dose	Dosing Schedule
Nicotinamide	3000 mg/day	2 oral tablets taken twice a day
Placebo	[no active drug]	2 oral tablets taken twice a day

Once you have been assigned to a treatment group, you will be asked to come to the clinic up to 5 more times for testing and to receive more medication. Additionally, we will call you on the telephone routinely to ask you about any adverse events.

- You will be given memory and thinking skills tests and you and your study partner will be asked questions about your daily functioning. (occurs at visits 1, 3, 4)
- You will return unused medication (occurs at visits 2-4)
- You will be issued new medication (occurs at visits 1-3)
- Your height, weight and vital signs (blood pressure, heart rate, breathing rate and temperature) will be recorded) (occurs at visits 1-4)
- Physical and neurological exam will be performed. (occurs at visits 1, 3, 4)
- Your medical history will be reviewed. (occurs at visits 1-4 and all telephone interviews)
- A list of medications you are currently taking will be collected. During the study, your reactions to the study drug will be carefully monitored. The study doctor must be informed of any medications, vitamins and herbal substances that you take or any medication that you may plan to start taking

during the study. (occurs at visits 1-4 and all telephone interviews)

- Blood will be drawn from a vein in your arm and you will be asked for a urine sample. These samples are for routine laboratory tests and to measure the levels of nicotinamide and its metabolites in your body. Some of your blood will be stored for future research use. The total amount of blood drawn for this study will be approximately 170 mL of blood (roughly 11.5 tablespoons). The routine laboratory tests ensure that there are no medical conditions that might interfere with your participation in the study or that could be responsible for any changes in your well-being throughout the study period. (occurs at visits 1, 3, 4)
- You will be asked about any adverse events (changes in health, any side effects/ reactions to medications, injuries or illnesses) that you may have experienced since your last visit. (occurs at visits 1-4 and all telephone interviews)
- MRI (occurs at visit 4)
- CSF sampling (occurs at visit 4)

Study Timeline

Treatment Phase							
*Visit Number**	1	Telephone	Telephone	2	3	Telephone	4
week	0	2	4	12	24	36	48
Answer Questionnaires	✓	✓	✓	✓	✓	✓	✓
Return unused study medication	✓			✓	✓		✓
Memory & Thinking Skills Tests	✓				✓		✓
Physical & Neurological Exam	✓			✓	✓		✓
Vital Signs	✓			✓	✓		✓
ECG	✓				✓		✓
Blood collected	✓			✓	✓		✓
Urine collected	✓				✓		✓
MRI Scan							✓
Fasting Lumbar Puncture							✓
Receive study medication	✓			✓	✓		

*visits may occur over multiple days

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. The researchers may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the drug. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to the research team about any side effects you experience while taking part in the study.

In large controlled studies, no risks or side effects related to nicotinamide that occurred more frequently than placebo have been reported for doses of 3000mg or lower. At higher doses than are being used in this study, the following side effects have reported:

- Nausea
- Headache

- Lightheadedness
- Vomiting
- Diarrhea

To avoid overdosing, do not take any over-the-counter products during the study that contain niacin and niacinamide, which are both forms of Vitamin B3. Overdosing may result in abnormal results from liver function tests which may signal liver toxicity.

Randomization: You will be assigned to a study group by chance (like a coin flip) rather than by a medical decision made by the researchers. The treatment you receive may prove to be less effective or to have more side effects than the other study group(s), or than standard treatments available for your condition.

Placebo: A placebo is an inert substance that is indistinguishable from the active study treatment. In this study, the placebo is a tablet that does not contain nicotinamide. During this study there is a 50% chance that you will receive a placebo. During this time you may experience worsening of your condition, such as cognitive decline. The researchers will carefully monitor your condition. If your symptoms worsen and make you uncomfortable, you can withdraw from the study.

Blood draw: Removing blood by a needle may cause temporary pain, bruising, bleeding, swelling, dizziness, and on rare instances fainting or infection.

Psychological discomforts: Some of the procedures may cause anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop.

MRI
The MRI procedure uses a powerful magnetic field to generate detailed images of the body. The magnet could move objects within your body that contain metal, such as implants, clips and pacemakers. Tell the doctor if you have any metal items within your body.

MRI scanning is painless but you might experience discomfort in the machine. You may be bothered by feelings of claustrophobia when placed inside the MRI, or by lying in one position for a long time. In addition, loud noises occur during the study when the scanner is collecting measurements. These noises are beeping and hammering sounds and may bother you. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear ear plugs.

Lumbar Punctures
There are 2 lumbar punctures in this study - one at the beginning of the trial, during the screening phase and one at the end of the trial. A total of up to 40 mls (less than 3 tablespoons) of cerebrospinal spinal fluid (CSF) may be taken during this entire study and your body will make up for this loss.

For most people, a lumbar puncture does not cause any serious problems. The most common problem is a headache. For example, in one study, only 7% of people having a lumbar puncture experienced a mild, moderate, or severe headache. The frequency of severe headache in this study was less than 1%. If you experience a headache that does not go away after 1 or 2 days, it may be due to a leak of the spinal fluid. A leak can be treated with a blood “patch”. A blood “patch” is made with a small amount of your blood. Your blood is injected into the area where the leak is and typically resolves post-lumbar puncture headaches.

Some people also complain about back pain or stiffness, pain at the place where the needle was placed, and neck or shoulder pain. These complaints are not as common as a headache and can be treated.

Rare or very uncommon complaints include low blood pressure and dizziness, bleeding into the spinal canal, or an infection of the spinal fluid (known as meningitis). These rare complaints could be serious. They could require you to be put in the hospital.

During this study you may have up to 2 fluoroscopy x-ray scans of your spine. These scans are solely for the purpose of this research and you would not have these scan(s) if you decide not to participate in this research study. A fluoroscopy x-ray scan uses radiation to create pictures of the structures inside the body. The total radiation dose that you will receive from 2 scan(s) of this type is about 400mrem. A millirem is a unit used to quantify radiation dose. Typically persons in the U.S. receive a radiation dose of about 310 millirem per year from natural sources of radiation, including from the sun, air, water and soils. Therefore your total radiation dose will be about the same as approximately 15 months of natural background radiation.

There is no known health effects associated with this amount of radiation exposure, and no radiation remains in the body after the scan. If you are especially concerned about radiation exposure, you should discuss this with the researcher listed at the top of this form.

Incidental finding:
There is a risk of an unexpected finding from your MRI scans. The results will be shared with you and if necessary, you will be referred to your primary care physician or other specialist for additional consultation.

Unknown risks:
There may be risks related to the research that we don't know about yet. However, you will be informed of any additional risks to which you may be exposed, and any changes that are made to the study, as a result of any newly-identified risks.

ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY?
Participant Benefits
Taking part in this study may or may not make your health better. While researchers hope the study drug will be more effective than the standard (usual) treatment, there is no proof of this yet.

If you are in the group that receives nicotinamide and it proves to treat your condition more effectively, you may benefit from participating in the study, but this cannot be guaranteed

Benefits to Others or Society
This study will help researchers learn more about nicotinamide, and it is hoped that this information will help in the future treatment of patients with Mild Cognitive Impairment and mild Alzheimer's disease.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?
If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:

- Getting no treatment
- Getting standard treatment for your condition without being in a study.
- Getting a different experimental treatment/taking part in another study.

As an alternative to being in the study, you may ask your doctor about Aduhelm (an antibody also known as Aducanumab). Aduhelm received accelerated approval by the FDA for the treatment of Alzheimer's disease in June of 2021. There is evidence that Aduhelm can reduce amyloid levels in the brain, but it is not clear whether it slows the clinical progression of Alzheimer's disease. People taking Aduhelm cannot participate in this study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

You are eligible to receive the following compensation in cash during the course of this study:
Visit 1 completion: $50
Visit 2 completion: $50
Visit 3 completion: $50
Visit 4 completion: $100

The grand total compensation for this study is a maximum of $250 in cash at UCI or by check at UCLA.

You will also receive a handmade quilt.

If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits and/or procedures that you have completed.

Reimbursement

You will not be reimbursed for any out of pocket expenses, such as transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you or your insurer/third party payer for study procedures. The study drug will be provided at no cost to you.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY AT UCI?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY AT UCLA?

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor, UC Irvine or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision

may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return for a final close-out evaluation and return unused study medication.

If you elect to withdraw or are withdrawn from this FDA-regulated research study, the data collected from your participation in this study must remain in the trial database in order for the study to be scientifically valid.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.

Data Storage

Research data will be maintained in paper format in a secure location at UCI and UCLA. Only authorized individuals will have access to it. Data will also be stored electronically on a secure network in an encrypted file with password protection.

Data Retention

The researchers intend to keep the research data in a repository indefinitely. Other researchers may have access to the data for future research. Any data shared with other researchers, will not include your name or other personal identifying information.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized UC personnel, the study sponsor, the coordinating site at UC San Diego and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

ClinicalTrials.gov is a Web site that provides information about clinical trials. 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.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?

Use of Specimens

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

Genetics

In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. In California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a

decision to hire, promote, or fire you or when setting the terms of your employment. However, these laws do not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you would like more information about the federal GINA law go to: http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf or CalGINA: http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_0551-0600/sb_559_bill_20110906_chaptered.pdf

Investigator Financial Conflict of Interest
No one on the study team has a disclosable financial interest related to this research project.

Future Recruitment Opportunities
You may be approached by the study team for permission to use your images and information related to your research participation for promotional purposes.

Request for Donation of Specimens and/or Data for Future Use
This is a request for donation of your blood, CSF, urine, DNA, and data for medical research. Please read each sentence below and think about your choice. After reading each sentence, check either the "Yes" or "No" box and provide your initials. If you have any questions about this request for donation, please talk to the researchers. If you choose not to donate your specimens, any leftover tissue or blood that is not needed for diagnosis or the discussed study outcomes will be thrown away and/or no additional normal tissue or blood will be removed for research purposes. Checking "YES" permits researchers to perform additional analyses with your tissue and data, beyond those immediately described in this consent form.

You may keep my blood, CSF, urine, DNA, and data for future research to learn about, prevent, or treat any health problem such as Alzheimer's disease, diabetes, genetic research, heart disease, or be kept for general research purposes. My blood, CSF, urine, DNA, and data will be stored in a way that does not directly identify me.

☐ YES ☐ NO _____ Subject Initials

If you were referred to this study by the Brain Health Registry (BHR), are you willing to have your screening data shared back to the BHR organizers?

☐ YES ☐ NO ☐ Not Applicable _____ Subject Initials

Optional Research Opportunities:

Study Extension

☐ Yes, I would be interested in learning more about participating in a 12-month extension of the treatment phase of this study if it becomes available.

☐ No, I would not be interested in learning more about participating in a 12-month extension of the treatment phase of this study

Future Contact:

☐ Yes, UCI or UCLA researchers may contact me in the future to ask me to take part in other research studies.

☐ No, I do not want to be contacted in the future to take part in other research studies.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

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 suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 160 Aldrich Hall, Irvine, CA 92697.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

Participant Signature	**Date**
Printed Name of Subject	
Legally Authorized Representative/Guardian Signature	***Date***
Printed Name of Legally Authorized Representative/Guardian	***Relationship to Subject***
Signature of Physician Obtaining Informed Consent	**Date**
Printed Name of Person Obtaining Informed Consent	

A witness signature is required on this consent form only if: ***(Researchers: check which one applies)***

☐Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____

Witness Signature **Date**

(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____

Printed Name of Witness

Study Partner/Caregiver Information

As the subject'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:

1) You must have direct in person contact with the subject at least three days per week.

2) You must be able to accompany the subject to all of the clinic visits.

3) You are an important source of information about the subject. You must agree to be asked questions about the subject's health, memory, thinking, functioning and emotional well-being.

4) You must be willing to help the subject take the study medication as prescribed.

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

You have read all the preceding information which describes both the subject's participation in the study and your involvement as the subject's study partner. The study has been explained to you in detail. All your questions have been answered to your satisfaction.

Study Partner's Name (print)	**Signature**	**Date**

Person Obtaining Consent (print)	**Signature**	**Date**

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 160 Aldrich Hall, Irvine, CA 92697.