INFORMED CONSENT FORM
Is Obstructive Sleep Apnea Important in the Development of Alzheimer's Disease?

ClinicalTrials.gov ID NCT05094271

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March 04 2024

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The faculty and staff of the University of California, San Diego wish you to know:
Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of a signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

If you have questions regarding a research study, the researcher or his/her assistant will be glad to answer them. You may seek information from the Human Research Protections Program - established for the protection of volunteers in research projects - by calling (858) 246-4777 from 7:30 AM to 4:00 PM, Monday through Friday, or by writing to the above address.

University of California, San Diego
Consent to Act as a Research Subject

Is Obstructive Sleep Apnea Important in the Development of Alzheimer's Disease?

Introduction

Atul Malhotra, MD and associates are conducting this research and asking for your consent to participate. This study is funded by the National Institute of Health (NIH). This section provides a summary of important information. The rest of the form provides additional details.

- Research is voluntary - whether or not you join is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes but change your mind later.
- If you say no, we will not hold your decision against you.
- Your decision will not affect your health care or any other benefits you may be entitled to.
- You can say no even if the person inviting you is part of your healthcare team.
- Please ask questions or mention concerns before, during or after the research.

We would like to examine how obstructive sleep apnea (OSA) may contribute to the potential risk of Alzheimer's disease. Participation in the study may or may not benefit you directly, and may result in new knowledge that may help others. We will ask that you waive the right to information about your risk of developing Alzheimer's disease since the information can be quite concerning to some people and there is no current approach to treatment or prevention.

If you agree to be in this study, the following will happen to you:

1) You will have a basic health exam and report on your health status. You will complete questionnaires and a genetic assessment (cheek swab). Additionally, a researcher will ask you a set of questions to test aspects of your brain function such as memory and your language ability. (Day Visit).
2) A standard overnight sleep study (Overnight Visit #1) to assess OSA severity will be completed. If you are unable to come in person for Overnight Visit #1, a Home Sleep Test will be given during your daytime visit. You will also complete a blood draw, heart function assessment, assessments of your brain function, a reaction test completed on a computer screen, and a sleep questionnaire.
3) An MRI and PET scan of the brain (Imaging Visit #1).
4) If your sleep study results were suggestive of OSA, you will complete two overnight sleep studies (Overnight Visit #2 and #3). While sleeping, you will be given either a therapeutic level of supplemental oxygen or pressurized room air. If you receive room air during your second overnight, you will be given supplemental oxygen during your third visit and vice versa. You will also complete a heart function assessment, assessments of

your brain function, a reaction test completed on a computer screen, and a sleep questionnaire.

If the results of your overnight sleep study suggested that you have OSA and may benefit from nightly supplemental oxygen, you will either receive treatment for OSA (positive airway pressure therapy) or be given nightly supplemental oxygen to use for 12 weeks at home. You will then be invited to complete a final visit:

5) At your final visit, you will be asked to complete a blood draw, a heart function assessment, assessments of your brain function, a reaction test completed on a computer screen, and a sleep questionnaire (Morning Visit).

The most commonly expected risks of the study are feeling sleepy the next morning after your overnight sleep studies, having nasal dryness from use of supplemental oxygen/pressurized room air during the overnight sleep studies, and having temporary discomfort after your blood draw.

The most serious risks of the study may include claustrophobia in the MRI, allergic skin reactions from placement of the sensors and electrodes, infection from venipuncture (blood draw), and exposure to radiation during the PET scan.

Additional detailed information about this research is provided below. Please feel free to ask questions before signing this consent.

Why have you been asked to participate, how you were selected, and what is the approximate number of participants in the study?

You have been asked to participate in this study because you are a person 65-85 years old who is receiving care through a UCSD clinic or living in the area. There will be approximately 260 participants in this study, which is being conducted only at UCSD.

What will happen to you in this study and which procedures are standard of care and which are experimental?

The overnight sleep studies, MRI and PET scans, and trial of supplemental oxygen or PAP therapy are voluntary study activities and separate from your standard of care.

Daytime Visit 1

We will get a saliva sample as well as have you complete a number of questionnaires. The saliva sample will be sent and processed by a clinical laboratory. The laboratory will perform a genetic test intended to determine your potential risk of developing Alzheimer's disease. After the result of your genetic test is acquired, the original saliva sample will be destroyed. Your samples will not be shared with any other researchers or institutions. All study data (including the results of the saliva sample) will be summarized in a report for the study sponsor, NIH, and journal articles. No identifiable information (name, date of information, address, etc.) will be presented alongside your study data.

We will also do a basic history and physical examination to make sure you are otherwise healthy. The length of your visit is dependent on how quickly you complete the questionnaires, but it should not take more than 1 to 2 hours. During this visit, you will complete memory and language related activities. Because scoring your verbal responses while guiding you through the activities may be difficult, we are asking for your permission to take an audio recording. Please note that the audio recording will only be done over the 30-45 minute memory activities and not during your entire visit. As stated previously, we ask that you waive the right to information about your potential risk of developing Alzheimer's disease since the information can be quite concerning to some people and we do not have an approach to treatment or prevention that works. The information we acquire will be used for research purposes only.

Can we obtain an audio recording for administration of the memory and language related activities you will complete? You can say yes and change your mind later.

Yes ☐ No ☐ Initials _____

The next visit is an overnight sleep study. If you are unable to come in for Overnight Visit 1 , you will be given the option to complete a Home Sleep Test (HST) instead. An HST device is used to evaluate for sleep apnea at home. The HST will include a strap to measure chest movement, tubing in the nose to measure breathing, and a finger probe to measure blood oxygen saturation. You will use the device for one night and return the equipment. If the results of the Home Sleep Test are inconclusive, you may be asked to repeat the test for additional compensation outlined below.

Are you willing to repeat the Home Sleep Test, if data is inconclusive? You can say yes and change your mind later.

Yes ☐ No ☐ Initials _____

After you complete the test, you will either schedule an appointment to return the equipment to our study site or mail the device through the postal service. If you select the mail option, we will provide you mailing supplies and a mailing label.

Overnight Visit 1

The following procedures will be performed at the Altman Clinical Translational Research Institute Clinic, 9452 Medical Center Dr, La Jolla, CA 92037. All overnight sleep studies will be hosted at this location. You will be asked to arrive at the UCSD Sleep Laboratory at approximately 8pm in order to start the procedures of the sleep study.

Before sleep, you will complete assessments of your brain function. These tasks include but are not limited to organizing lists of numbers or words and matching similar words together. You

will also complete a 10-minute reaction assessment on the computer. For every instance a red circle appears on the screen, you will tap the spacebar as quickly as possible.

To prepare you for the sleep study, you will have sensors pasted on your scalp, face, chest, and legs that will help determine when you are asleep or awake. A microphone will be placed on your neck to monitor snoring. A small vital sign monitor will be taped to your finger to read additional vital signs. An adhesive body position sensor will be placed on your body to monitor what position you are sleeping in, and the volume of your chest while breathing. Almost all of this equipment is standard for a diagnostic sleep study and should not be uncomfortable.

In some instances, you will complete the overnight sleep study at home after being set up on site by a night technician. You will be asked to wear the equipment the entire night while sleeping on your back. In the morning, you will return to our study site and have the equipment removed before beginning additional testing as outlined below.
The sleep study will end at approximately 6AM and all the monitoring equipment will be removed. You will then complete morning neurocognitive assessments and a sleep questionnaire. You will also complete a non-invasive measure of blood vessel function, which involves lying down for 15-minutes with a blood pressure cuff on your arm. This non-invasive heart function test is intended to look at cardiac health by observing how well blood is able to flow after blood vessels are tightened and then relaxed.

We will take 2-3 teaspoons of blood. Please note that this blood will be separated into serum and plasma for analysis to find links between other diseases. We will not be using this blood sample for DNA analysis.

If you consent to giving blood or tissue specimens as part of this study, these specimens will become the property of the University of California. The blood samples will not be shared with other researchers/institutions outside of University of California, San Diego.

A member of the research team will assess your level of sleepiness before you leave. We want to make sure it is safe for you to drive, or we recommend you have a responsible adult drive you home.

In some cases, the quality of your sleep may not allow us to get all the data we need. In these cases, you may be invited back for an additional overnight stay. However, you are under no obligation to participate in the extra overnight study.

Are you willing to be contacted for the extra overnight visits, if needed? You will be compensated for the additional study night ($200).

☐ Yes ☐ No Initials _____

The results of your sleep study will be reviewed to determine your participation in overnight visits 2-3.

Imaging Visit 1

We will try to schedule your imaging after your sleep study has been completed. We will obtain imaging of your brain through Magnetic resonance imaging and Positive Emission Tomography. Magnetic resonance imaging scans (MRIs) are pictures that can be obtained by the use of magnetic field and radio frequencies around your head. Your vital signs will be taken before the MRI scan. For the MRI scan, you will lie down inside the center of a large, doughnut shaped magnet for approximately 30 minutes.

Immediately after this, you will complete a Positron Emission Tomography (PET) scan to detect specific protein deposits in your brain. A small catheter (plastic tubing with a needle on the end) will be inserted into a vein of your arm. A tracer, radioactive substance dissolved in 5-10 milliliters of saline, will be injected into the catheter. Once administered it will take approximately 45 minutes for the tracer to travel through your body and accumulate to identify the brain proteins. During this time, you will be asked to rest quietly and avoid significant movement or talking. You will then be placed in the PET scanner, where you will stay for about 30 minutes. You will be asked to remain still for the duration of the examination. When the scan is completed, you will be able to get up and stretch or relax as you wish.

The tracer used in this study is called MK-6240. This is an injectable radioactive compound that binds to the protein called tau, allowing researchers to see where this protein is in the brain. MK-6240 is not used routinely, and its safety is not known for certain; however, it has been approved for use in research studies by the Food and Drug Administration (FDA). If any new risks become known in the future, you will be informed of them.

After the scan is completed you will be asked to empty your bladder and drink plenty of fluids to flush the radioactive substance from your body. We will also retake your vital signs. Otherwise, there are no restrictions on daily routine after the test. The scanners can feel closed in and can cause some claustrophobia but are generally well tolerated. We will try to schedule imaging around the time of your sleep test. The visit for scanning should take about 1-2 hours.

Your participation in the study will conclude with the imaging visit, if your first overnight sleep study results were not suggestive of sleep apnea. If your first overnight sleep study results were suggestive of sleep apnea, you will be invited to complete two overnight visits.

You will complete the imaging visit at California Protons center in Sorrento Valley at 9730 Summers Ridge Rd, San Diego, CA 92121.

Overnight Visit 2

We will repeat the sleep test similar to the one you had before but this time we will give you either regular air (room air) or supplemental oxygen to breathe while you sleep. You will not be told which of the two treatments you are receiving. Supplemental oxygen or pressurized room air will be delivered through a nasal cannula. We will also repeat the neurocognitive testing including questionnaires and the reaction time test as we did for the first visit.

Overnight Visit 3

We will repeat the sleep test similar to the one you had before but this time we will give you either regular air (room air) or supplemental oxygen to breathe while you sleep. Depending on what you received on visit 2, we will decide on what to give you to breathe for visit 3. You will not be told which of the two treatments you are receiving. We will also repeat the neurocognitive testing including questionnaires and the reaction test as we did for the first visit.

3-Month Trial Therapy with Start and End of Treatment Sleep Studies

Participants who were determined to have sleep apnea based on overnight visit 1 may participate in this part of the study. At the start and end of the treatment phase, you will be scheduled for an evening visit followed by either an in-lab or at home overnight sleep study based on laboratory availability and participant preference.

Start of Treatment Visit: Home or In-Lab Sleep Test

You will be scheduled for an evening visit where you will either receive positive airway pressure therapy (PAP) or therapeutic nightly oxygen to be used for 3 months (12 weeks) based on randomization. Your chance of being assigned to each group is 1 in 2. Neither you nor the researcher(s) can choose the group to which you will be assigned. Your participation in this intervention is voluntary and separate from your clinical care.

During this visit, you will also complete questionnaires and evening/morning cognitive testing. You will then be asked to complete a baseline sleep study while wearing the sleep therapy you have been randomized to. This is being done to get you acclimated to your treatment therapy and to measure its effect on your cognitive function. Depending on availability, the sleep study will either be conducted in lab or at home with a small portable device called a Home Sleep Apnea Test (HSAT) to use for 6-8 hrs of sleep for 1 night. The HSAT is disposable, which will be worn on your wrist with a probe over one of your fingers to measure oxygen levels and sleep stages. We will be able to download your data remotely, and you can discard your device after it is complete. In the morning, you will complete the remaining morning neurocognitive testing on an electronic device (i.e. iPad or laptop), with support from a research team member as needed. If testing was performed remotely, you will subsequently be scheduled to return the electronic device.

Mid-Treatment: Follow-Up Calls

Following your Start of Treatment Visit, we will contact you every week for a 3–5–minute phone call throughout the 3-month trial to ensure you are using your therapy and answer any questions. Staff will provide encouragement and help you work through any issues that occur with your assigned therapy device. For the study, we ask that you use your therapy at least 4 hours every night during the 12-week period. Compensation will be given based on the number of weeks of successful treatment compliance (at least 4 hours/night every night) and number of weekly phone calls answered. If you do not use your assigned therapy for at least 4 hours/night for a given week, you will not receive the compliance compensation for that week.

End of Treatment Visit: Home or In-Lab Sleep Test

At the end of the 3-month trial, you will return for a final evening visit to complete questionnaires and evening/morning cognitive function testing. You will then complete either a home or in-lab HSAT while wearing the sleep therapy you have been randomized to. In the morning, you will complete the remaining morning cognitive testing on an electronic device, with support from a research team member as needed. You will also return the PAP therapy device or supplemental oxygen equipment, along with the electronic device used for testing. Your participation in the study should conclude after morning testing is finished.

How much time will each study procedure take and how long will the study last?

1) Daytime visit will last approximately 1 hr
2) Overnight Visit 1 will last 10-12 hrs (most of which will be spent sleeping)
3) Imaging Visit 1 will last 1-2hrs.
4) Overnight Visit 2 will last 10-12hrs (most of which will be spent sleeping)
5) Overnight Visit 3 will last 10-12hrs (most of which will be spent sleeping)
6) Start of Treatment Visit (home or in-lab sleep test) will last 10-14 hrs
7) Weekly Phone Calls will last 3-5mins/wk (total: 36-60 mins over the 12 weeks)
8) End of Treatment Visit (home or in-lab sleep test) will last 10-14 hrs

In total, you will be enrolled in the protocol for 16-18 weeks.

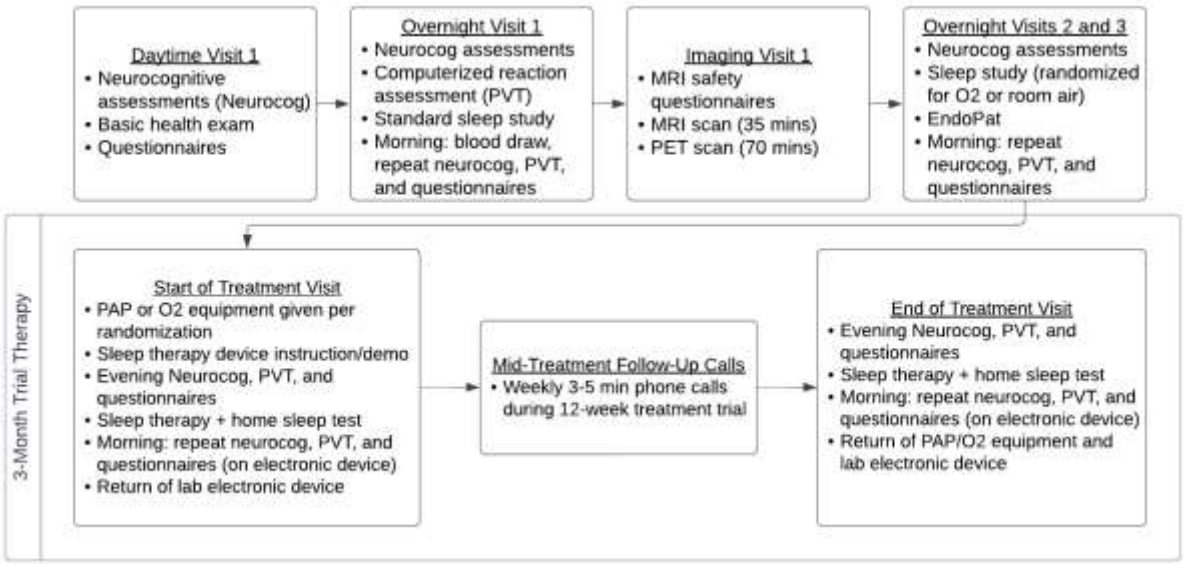

Figure 1. Summary of the Study Activites per Visit.

What risks are associated with this study?
Participation in this study may involve some added risks or discomforts. In addition to the risks described at the beginning of this form,

Risks of Sleep Studies (In Lab or Home Sleep Test): During the sleep studies, there may be discomfort at the electrodes or monitors sites that can develop; a localized skin irritation/allergy can occur due to application of the skin surface electrodes for EEG, EKG, and EMG recordings. Similarly, the nasal cannula and PAP therapy can cause temporary drying of the nose, mouth, or throat, nosebleed, bloating, ear or sinus discomfort, eye irritation, skin rashes.

You might be sleepy the next morning after participating in the study. If you do not feel rested and safe to drive home, you will be provided with a cab voucher. Consider asking someone to drive you to and from the studies.

Risks of a blood draw/blood pressure test: You may have temporary pain or discomfort during the blood draw or non-invasive heart function test.

Risks associated with Intravenous Catheter: Recall that during your imaging visit you will have a small catheter inserted into your vein to receive the tracer. Risks associated with the catheter insertion include infection, vein irritation, and infiltration due to the tracer being delivered into surrounding tissue. The technician performing the catheter insertion is experienced and will use appropriate technique to minimize the risks.

Risks of MRI: The imager makes a loud, banging noise while it is taking pictures. You will be given a set of ear plugs to help with the noise. You may experience feelings of claustrophobia or anxiety. You may also experience some discomfort and tiredness from lying still in a confined space during the imaging. There are no known effects from exposure to magnetic fields (MRI). However, some subjects undergoing this procedure become anxious. If this happens to you, you can stop the procedure at any time. If you have metal clips or plates in your body or a pacemaker, you should tell your doctor about it. MRI may not be appropriate under some of the following conditions: a cardiac pacemaker; metal fragments in eyes, skin, or body; heart valve replacement; brain clips; venous umbrella; being a sheet-metal worker or welder; aneurysm surgery; intracranial bypass; renal or aortic clips; prosthetic devices such as middle ear, eye, joint, or penile implants; joint replacements; hearing aid; neurostimulator; insulin pump; I.U.D.; being pregnant or trying to become pregnant; shunts/stents; metal mesh/coil implants; metal plate/pin/screws/wires, or any other metal implants; and permanent eyeliner and/or eyebrows.

Risks of PET scan: The PET scan is somewhat uncomfortable because you will be asked to lie still on your back. You will be able to see out of the scanner, but cannot move your head. The PET staff will try to make the PET scan as comfortable as possible by providing padding, pillows, and blankets.

There are risks associated with the MK-6240 compound used in the PET scan. For all clinical trials conducted as of June 2017 using MK-6240, there were no clinically-significant abnormalities noted in physical exams, lab safety tests (chemistry, hematology and urinalysis), vital signs or electrocardiograms. There were no serious adverse events (side effects), deaths, or subject withdrawal from the trial due to a side effect. One participant experienced a frontal headache, but the headache resolved spontaneously.

The injection of either radioactive compound may cause some slight discomfort, however the amount injected is small enough that there is no need for precautions against radioactive exposure. The PET scan uses small doses of radioactivity to measure brain activity. There are no additional pharmacological or drug-related risk associated with the radioactive compound because they are being given in very small (trace) amounts. The radiotracer that is injected will contain a very small amount of alcohol that is 1/1000 of what is allowed for driving a car in most states. We do not expect that you will even recognize any effects from this amount of alcohol.

Allergic reactions to either radioactive compound are rare, but may occur. These can include itching, rash, nausea, vomiting, fast heartbeat, a drop in blood pressure, shortness of breath and/or wheezing.

During your participation in this research study, you will be exposed to radiation from a PET scan. The total exposure resulting from this imaging study is calculated to be approximately 6.5mSv. This amount is more than what you would receive from one year of natural exposure in the San Diego area, which is approximately 1.6 mSv. Cumulative exposure from radiation may increase your risk of developing certain types of cancer in the future. The principal investigators for this research study have determined and verified that the imaging scans prescribed for this study would typically be performed as part of the standard medical care required to adequately monitor a potential illness. If you are especially concerned with radiation exposure, or you have had a lot of x-ray or imaging scans already, you should discuss this with the principal investigator, Dr. Malhotra, for this study or your regular doctor.

Risks of an Incidental Finding: There is a risk of incidental findings that can be identified throughout the study. Examples include, but are not limited to, abnormal heart rhythms that may be observed during the sleep study, abnormal heart function, abnormal MRI scans, etc. Of note, the results of your non-invasive heart function test will not be reviewed in real time. If any significant, unknown findings are seen, the PI will reach out to the subject to provide consultation. The MRI scan protocol has been designed for research purposes, not for clinical diagnostic purposes. All analysis will be done only by research staff for the purposes of our research study only. The scans will not be reviewed by a radiologist. However, it is possible that an abnormality may be identified. In that case, a written report of the abnormality will be shared with you and you may be recommended to seek appropriate evaluation with your primary care doctor.

Risks of Loss of Confidentiality: Even with all of the study procedure precautions that will be taken to protect confidentiality, there is a still a risk of loss of confidentiality associated with this study. Research records will be kept confidential to the extent allowed by law. The study personnel are well trained in securing and safely storing all your data.

Unknown Risks: Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Risks associated with your study group assignment. You will be assigned to a study group at random (by chance). Your assignment is based on chance rather than a medical decision made by

the researchers. The study group you are assigned to might not be the group you would prefer to be in. Your assigned study group might also prove to be less effective or have more side effects than the other study groups(s), or other treatments available for your condition.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Are there risks to the reproductive system or a developing fetus?

The effects of the MRI/PET scan may pose some unforeseeable risks on the reproductive system (sperm, eggs) or the developing fetus.

What are the alternatives to participating in this study?
The alternatives to participation in this study are not to participate in the study.

What benefits can be reasonably expected?
There is no direct benefit to you for participating in this study. Benefits of this study are principally to science and future patients, in that we may be able to identify how obstructive sleep apnea factors into the progression of Alzheimer's Disease. as well as a new and clinically useful treatment methods. This information may be useful to clinicians.

What happens if you change your mind about participating?
If you decide that you no longer wish to continue in this study, you will be requested to reach out to a member of our research team. We will terminate any of your remaining study activities.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons:

- You become ill,
- Become injured and cannot get around without assistance.
- You are no longer able to live independently.

You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?
In compensation for your time and travel, you will receive up to $1,190 for your participation in this research.

- Daytime Visit 1: $25
- Home Sleep Test: $25
- Overnight 1: $200
- Imaging Visit (MRI and PET): $100
- Overnight 2: $200

- Overnight 3: $200
- Start of Treatment Visit (with HSAT): $100
- Weekly Phone Calls (12 weeks): $10 each week (total $120)
- Treatment Compliance (12 weeks): $10 each week (total $120)
- End of Treatment Visit (with HSAT): $100

As stated previously, the Home Sleep Test will be used as a substitute for the overnight sleep study 1 if you are unable to come for the in-lab sleep study, however, you will be allowed to complete overnight 1 if your availability changes. If an additional study night is needed, you will receive an additional $200. If an additional daytime visit/home sleep test is needed, you will receive an additional $25.00.

Personal information about you, including your name, address, and social security number, will be released to the UCSD Accounting Office for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS). If you receive compensation in excess of $600 per calendar year, your name and Social Security number will be collected and released to the UC San Diego Office of Accounting to process the Form 1099-Misc for Internal Revenue Service (IRS) tax-reporting purposes.

Parking will be available free of charge and participants will also be reimbursed for minor out of pocket expenses including meal vouchers, public transportation or taxi vouchers. If the subject terminates the study early, you will receive an amount based on the visits that have been completed. If any of the visits are missed, the subject will not be compensated for those visits.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study. If you are eligible to complete the 3-month trial of nightly supplemental oxygen or PAP therapy, you will receive all equipment and supplies through our research group and asked to return it. Parking expenses at UCSD study sites will be covered.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. To guard your confidentiality, you will be assigned a unique identifying number to label all your data collection sheets. All personal information will be kept strictly confidential by the investigators. All study forms, and data collected will be kept locked in a secure location. All your data forms will only list your unique study ID number. All research staffs are trained in the protection of subject privacy and confidentiality. Research records may be reviewed by the UCSD Institutional Review Board and the NIH.

Whole genome testing will be performed on you DNA, or deoxyribonucleic acid, which carries the genetic instructions for the cells that make up your body. “Whole genome testing” means making a list of the entire order, or sequence, of the DNA in your genome.

Federal and State laws generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: a) Health insurance companies and group health plans may not request your genetic information that we get from this research. b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. c) Employers with 5 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that these laws **do not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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.

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.

Will you receive any results from participating in this study?
Letters summarizing the results of your overnight sleep studies will be provided. If any clinical relevant research results are found during the sleep studies or MRI visits, a written report of the abnormality will be share with you and you may be recommended to seek appropriate evaluation with your primary care doctor.

What are my rights when providing electronic consent?
Under certain circumstances, we will obtain electronic consent via DocuSign in-lieu of obtaining written consent in person.

California law provides specific rights when you are asked to provide electronic consent:

- You have the right to obtain a copy of the consent document in a non-electronic format.
- You have the right to provide consent in a non-electronic format.
- If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however, a copy of your electronic consent will be maintained for regulatory purposes. If you wish to withdraw your electronic consent please tell the study team.

This agreement for electronic consent applies only to your consent to participate in this research study.

Who can you call if you have questions?
This study has been explained to you and your questions have been answered. If you have other questions or research-related problems, you may reach Dr. Atul Malhotra and his research study coordinators at (858) 246-2154. Of note, our research team will utilize text messages and voicemail for important study communication.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent
You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____	_____
Subject Name (Printed)	Date
_____	_____
Subject's signature	Date
_____	_____
Name of the person obtaining consent (Printed)	Date
_____	_____
Signature of the person obtaining consent	Date