1. Study Title and Number

Title: Opioid Physiology and Individual Outcomes with Supplemental O_2 (OPIO2)

Study # 814959

2. Principal Investigator

Dr. Jeremy Orr, MD / Associate Professor of Medicine
Department of Pulmonary, Critical Care, and Sleep Medicine, UC San Diego

3. Principal Investigator Phone Number, Research Team Number, and Emergency Contact Number

Principal Investigator (PI): (858) 692-6556
Research Team Number: (858) 246-2154
Emergency Contact Number: (858)692-6556

4. Study Sponsor

National Institutes of Health (NIH), the study sponsor, is paying UC San Diego to conduct this research study.

5. Study Overview

You are being invited to participate in this research study because you have been prescribed opioid medications. The purpose of this research study is to determine whether using supplemental oxygen while sleeping improves breathing in adults with sleep-disordered breathing who have chronic opioid use. For this study, chronic opioid use means taking prescribed opioid medications for chronic pain or opioid use disorder (OUD) under medical supervision for at least 3 months. This form explains the research so that you can decide whether you want to participate.

- Taking part in this research is voluntary. Whether or not you participate is your choice.
- You may choose to participate now and change your mind later.
- If you decide not to participate, we will not hold your decision against you.
- You may choose not to participate even if the person inviting you is part of your healthcare team.
- Your decision will not affect your health care or any benefits you may be entitled to.
- Please ask the study doctor or study team questions about anything that is not clear. Feel free to ask questions or share concerns before, during, or after the study.
- You may discuss this study with your family, friends, your personal doctor, or anyone else before deciding whether to participate.
- You will receive a copy of this consent form and the Participant's Bill of Rights.

What will happen if I participate?

If you decide to participate, we will first determine whether you qualify for the study. This may include reviewing your medical history, sleep history, medications, previous sleep studies, questionnaires, height, weight, vital signs (such as blood pressure and heart rate), a physical exam, and other relevant medical information. Some screening activities may take place before you sign this consent form using information already available in your medical record.

If you qualify, your participation will last about 6 to 10 weeks.

During the study, you will:

- Attend approximately 3 to 4 overnight visits at the sleep center. You will complete 3 overnight sleep studies as part of the study. You may complete an additional baseline overnight sleep study if you have not had a qualifying sleep study within the past 6 months or if your medical or sleep-related condition has changed.
- Use study equipment at home while you sleep for two separate 7-night treatment periods, with about 2 weeks between treatment periods.
- Be assigned by chance (like flipping a coin) to receive supplemental oxygen first or a placebo device (which is regular room air delivered through the same type of equipment but without extra oxygen).
- Neither you nor most of the study staff will know which treatment you are receiving during each treatment period.
- Complete questionnaires and a simple test of attention and reaction time.
- Provide one blood sample at the beginning of the study.
- You will receive daily automated text-messages and a weekly telephone check-in during each home treatment period so the study team can answer your questions, check on your safety, and make sure the study equipment is working properly.
- You will be asked to use a small monitor placed under the mattress to help measure breathing, heart rate, breathing rate, movement, and other body signals during sleep.

During your overnight sleep studies, we will monitor your sleep and breathing. One overnight study will also be used to determine the oxygen level that is safest and most appropriate for you to use at home. More detailed information about each study procedure is provided later in this consent form.

What are the possible risks?

The most common risks or discomforts include:

- Discomfort or poor sleep during overnight sleep studies or other study testing.
- Mild skin irritation from the monitoring sensors.
- Dryness or irritation of the nose from wearing the oxygen tubing.
- Feeling sleepy or less alert the morning after an overnight sleep study.
- Discomfort when answering questionnaires or completing study assessments.
- Temporary discomfort, bruising, or bleeding from the blood draw.
- Inconvenience or tiredness related to overnight research visits.

Less common but more serious risks include worsening breathing during sleep, breathing that becomes too slow or too shallow, higher-than-normal carbon dioxide levels, low oxygen levels, or other

breathing problems that may require medical attention. These risks are uncommon. Your breathing will be closely monitored during the overnight sleep studies, and the study team will regularly check on you throughout the study to help reduce these risks.

A complete description of the possible risks and discomforts associated with this study can be found in Section 9 of this consent form.

Will I benefit from participating?

We cannot promise that you or others will receive a direct benefit from participating in this research. Possible benefits include identifying breathing problems during sleep or other important health findings that were not previously known, learning more about how your breathing responds during sleep, and possible short-term improvement in breathing for some participants. The information learned from this study may help researchers better understand how opioid medications affect breathing during sleep and may help improve future treatment options for people with sleep-disordered breathing.

Other options instead of participation in this study include receiving standard clinical care for sleep-disordered breathing, such as positive airway pressure (PAP) therapy, oral appliances, supplemental oxygen prescribed outside of research, medication adjustments, or other treatments recommended by your doctor. You may also choose not to participate in this study.

More detailed information about this research study is provided below.

6. Whom can I talk to if I have questions?

If during your participation in the study you have questions or concerns, or if you think the research has hurt you, contact the research team at the numbers listed in Section 3 on the first page of this form. You should not agree to participate in this study until the research team has answered any questions you have about the study, including information contained in this form.

If before or during your participation in the study you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:

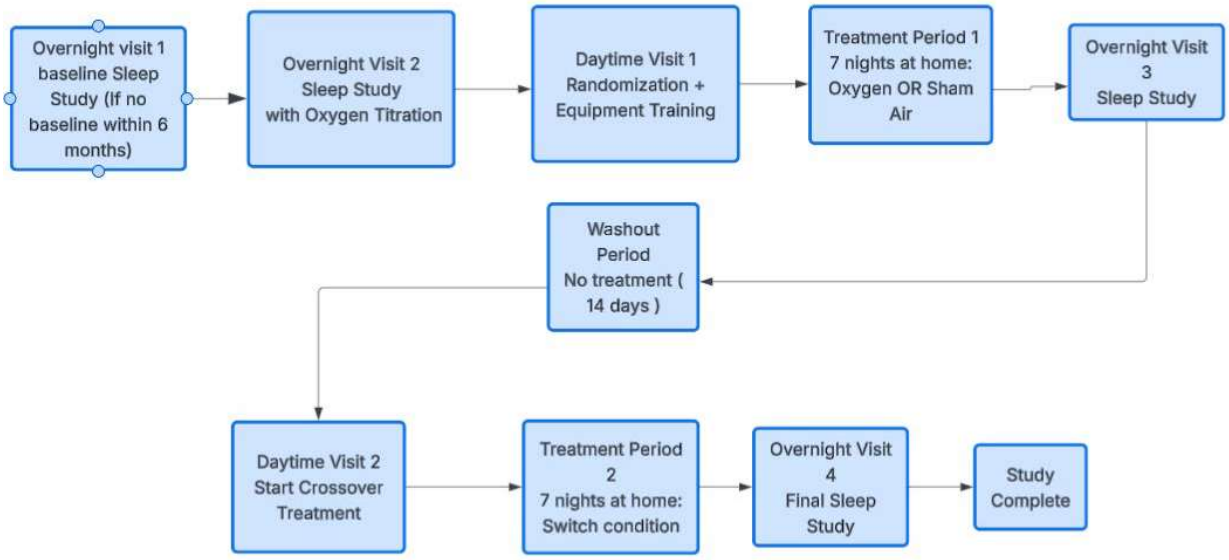
- UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

7. How many people will take part?

Approximately 62 participants will take part in this research study at UC San Diego.

8. What happens if I take part in the research?

If you agree to participate in this study, you will complete several study visits and procedures over approximately 6–10 weeks. Depending on your prior sleep testing and eligibility status, you may complete approximately 3 to 4 overnight sleep studies as part of the study. Participation may include overnight and daytime visits at the UC San Diego Sleep Research Laboratory, as well as study-related activities performed at home.



Screening Procedures

Screening procedures will be performed to determine your eligibility for this study. Screening activities may include review of your medical history, sleep history, medications, prior sleep studies, questionnaires, vital signs, height, weight, body mass index (BMI), physical examination, and other relevant medical information. Screening procedures may also include review of existing medical records and prior diagnostic studies.

Some screening procedures may occur before informed consent using available medical records.

If you do not have a qualifying sleep study completed within the prior 6 months, or if there has been a clinically significant change in your medical or sleep-related condition, you may be asked to complete a baseline overnight sleep study to confirm eligibility.

Blood Sample Collection

At the baseline study visit, one blood sample (approximately 10 mL, or about 2 teaspoons) will be collected from a vein in your arm by trained study personnel using standard procedures. The blood sample will be used to measure opioid levels and other study-related laboratory measures that may help researchers better understand the relationship between opioid use, breathing during sleep, and study outcomes. No genetic testing or genetic analyses will be performed on your blood sample.

Overnight Visit 1 (Baseline Sleep Study – if needed)

You will complete an overnight sleep study at the UC San Diego Sleep Research Laboratory. If you are able to become pregnant, a urine pregnancy test will be performed before the overnight sleep study and repeated prior to each in-laboratory polysomnography (PSG) visit. Participants who are pregnant or have a positive pregnancy test will not be eligible to continue participation because the effects of study procedures on pregnancy are not fully known.

Before going to sleep, you will complete study questionnaires. These questionnaires ask about topics such as your sleep, daytime sleepiness, medical history, medications, mood, quality of life, and any symptoms you may be experiencing. Some questions may be personal or sensitive. You may skip any questions you do not wish to answer. During the overnight sleep study, sensors will be placed on your scalp, face, chest, and legs to monitor your sleep stages, breathing, heart rate, oxygen levels, and

body movements. Additional sensors may be used to monitor airflow, chest movement, sleep position, and carbon dioxide levels through the skin (transcutaneous carbon dioxide monitoring, or $TcCO_2$). This equipment is standard for sleep studies and is designed to be as comfortable as possible.

The sleep study will end in the morning, when all sensors will be removed. You will then complete morning questionnaires, a 10-minute computerized psychomotor vigilance test (PVT), which measures alertness and reaction time, and any other study assessments. Morning safety assessments may also be performed before you leave the research center to help ensure it is safe for you to drive following overnight testing.

Overnight Visit 2 (Oxygen Titration Sleep Study)

You will complete an overnight oxygen titration sleep study at the UC San Diego Sleep Research Laboratory before beginning study treatment.

During the oxygen titration study, oxygen will be delivered through a small tube placed under your nose (nasal cannula). The oxygen level may be adjusted (titrated) during the night based on your oxygen levels and breathing patterns to evaluate your response and help determine an appropriate oxygen setting for home use. The oxygen flow rate will not exceed 4 liters per minute (L/min).

Before going to sleep, you will complete questionnaires. During the overnight sleep study, sensors will be placed on your scalp, face, chest, and legs to monitor your sleep stages, breathing, heart rate, oxygen levels, and body movements. Additional sensors may be used to monitor airflow, chest movement, sleep position, and carbon dioxide levels through the skin (transcutaneous carbon dioxide monitoring, or $TcCO_2$). This equipment is standard for sleep studies and is designed to be as comfortable as possible.

The sleep study will end in the morning, when all sensors will be removed. You will then complete morning questionnaires, a 10-minute computerized psychomotor vigilance test (PVT), which measures alertness and reaction time, and any other study assessments. Morning safety assessments may also be performed before you leave the research center to help ensure it is safe for you to drive following overnight testing.

If you qualify for the study, you will return for a daytime study visit before starting the study treatment. At this visit, you will be assigned by chance (like flipping a coin) to one of the study groups.

Daytime Visit 1 (Randomization Visit)

You will return to the research center for a daytime visit. During this visit, study staff will review your results and confirm your eligibility. You will be randomized to one of two study sequences: supplemental oxygen followed by placebo device (which is regular room air delivered through the same type of equipment but without extra oxygen), or placebo device followed by supplemental oxygen. Randomization means that you are assigned to a study group by chance, like flipping a coin. You will have an equal chance of starting with either condition.

Neither you nor most study staff will know which condition you are receiving during each study period. You will receive study equipment and training on how to use it during sleep at home. Study staff will review instructions with you and answer any questions before you begin the first treatment period.

Study Conditions

You will receive both of the following study conditions during the study:

• Supplemental Oxygen – oxygen delivered through a nasal cannula during sleep

• Sham Air – air delivered through the same equipment without additional oxygen

The use of supplemental oxygen and sham air in this study, as well as the comparison between these conditions, is being performed for research purposes. The timing and combination of these procedures are not part of standard medical care.

Treatment Period 1 (Home Use)

You will use the assigned study condition at home during sleep for 7 consecutive nights. You will be trained on how to use the equipment and asked to use it each night while sleeping.

During each treatment week, study staff will send you daily automated text-message safety check-ins and will call you once per week to ask about any symptoms or side effects, review your use of

the study equipment, answer questions, and help resolve any equipment problems. If there are concerns about your safety or the equipment, the study doctor may be notified. During the at-home treatment period, you will be asked to use an under-mattress monitoring device while you sleep. The device is placed underneath your mattress and does not require any sensors to be attached to your body. The device is designed to monitor breathing patterns, heart rate, respiratory rate, movement, and other body signals during sleep. Information collected by the device may be reviewed by study staff to help monitor study safety and evaluate study outcomes.

Overnight Visit 3

You will return to our research laboratory to complete an in-lab overnight sleep study while using the assigned study condition.

Before going to sleep, you will complete questionnaires described above. During the overnight sleep study, sensors will be placed on your scalp, face, chest, and legs to monitor your sleep stages, breathing, heart rate, oxygen levels, and body movements. Additional sensors may be used to monitor airflow, chest movement, sleep position, and carbon dioxide levels through the skin (transcutaneous carbon dioxide monitoring, or $TcCO_2$). This equipment is standard for sleep studies and is designed to be as comfortable as possible.

The sleep study will end in the morning, when all sensors will be removed. You will then complete morning questionnaires, a 10-minute computerized psychomotor vigilance test (PVT), which measures alertness and reaction time, and any other study assessments. Morning safety assessments may also be performed before you leave the research center to help ensure it is safe for you to drive following overnight testing.

Washout Period

After completing Treatment Period 1, you will have a washout period of approximately 2 weeks during which you will not use oxygen or sham air. You may notice changes in your sleep quality, breathing patterns, or symptoms during this time.

Daytime Visit 2 (Start of Treatment Period 2 – Crossover)

You will return to the research center before starting the second treatment period. During this visit, study staff will review your experience during the first treatment period, answer any questions, and provide instructions and equipment for the second study condition.

You will switch to the other study condition (oxygen or sham air) and use the assigned condition at home during sleep for 7 consecutive nights.

During each treatment week, study staff will send you daily automated text-message safety check-ins and will call you once per week to ask about any symptoms or side effects, review your use of the study equipment, answer questions, and help resolve any equipment problems. If there are concerns about your safety or the equipment, the study doctor may be notified.

During the at-home treatment period, you will be asked to use an under-mattress monitoring device while you sleep. The device is placed underneath your mattress and does not require any sensors to be attached to your body. The device is designed to monitor breathing patterns, heart rate, respiratory rate, movement, and other measurements during sleep. Information collected by the device may be reviewed by study staff to help monitor study safety and evaluate study outcomes.

Overnight Visit 4

You will return to our research laboratory to complete a final in-lab overnight sleep study while using the assigned study condition.

Before going to sleep, you will complete questionnaires described above. During the overnight sleep study, sensors will be placed on your scalp, face, chest, and legs to monitor your sleep stages, breathing, heart rate, oxygen levels, and body movements. Additional sensors may be used to monitor airflow, chest movement, sleep position, and carbon dioxide levels through the skin (transcutaneous carbon dioxide monitoring, or $TcCO_2$). This equipment is standard for sleep studies and is designed to be as comfortable as possible.

The sleep study will end in the morning, when all sensors will be removed. You will then complete morning questionnaires, a 10-minute computerized psychomotor vigilance test (PVT), which measures alertness and reaction time, and any other study assessments. Morning safety assessments may also be performed before you leave the research center to help ensure it is safe for you to drive following overnight testing.

Questionnaires and Testing

Throughout the study, you will complete questionnaires about your sleep, symptoms, mood, and overall well-being. You will also complete psychomotor vigilance testing (PVT) to assess alertness and attention.

Standard Care vs Research Procedures

Some procedures in this study, such as overnight sleep studies, may overlap with procedures used in standard clinical care. However, the frequency of testing, use of supplemental oxygen compared to sham air, overnight oxygen titration procedures, monitoring of your breathing and other body functions, under-mattress monitoring if used, a blood sample collected at the baseline study visit, and study-related testing are being performed specifically for research purposes.

Repeat Visits

Please note that occasionally not enough data may be obtained during overnight sleep studies. In these instances, you may be asked to repeat the overnight study or day visit. Participation in repeat testing is optional, but not completing repeat testing may affect your ability to continue in the study.

Please write your initials/place a checkmark under “yes” or “no” to indicate if we can contact you to repeat

study visits if additional data collection is needed:

_____ Yes _____ No

9. What are the risks and possible discomforts?

Your participation in this study involves research procedures and interventions that may cause discomfort or have associated risks.

The most common risks or discomforts of this study include discomfort or sleep disruption from overnight sleep studies (polysomnography [PSG). The may include mild skin irritation from monitoring sensors, nasal dryness or irritation from oxygen or airflow delivered through a nasal cannula, morning drowsiness or impaired alertness following overnight testing, discomfort from questionnaires or study-related assessments, and inconvenience or fatigue related to overnight research visits.

Risks Related to Blood Collection

A blood sample will be collected as part of this study, you may experience temporary discomfort when the needle is inserted. Other possible risks include bruising, bleeding, swelling, soreness, lightheadedness, dizziness, fainting, or infection at the blood draw site. In rare cases, participants may develop a small hematoma (collection of blood under the skin) or experience prolonged bleeding. Every effort will be made to minimize these risks by having blood samples collected by trained personnel using standard procedures.

Risks related to overnight sleep studies (polysomnography)

During overnight sleep studies, sensors will be placed on your body to monitor sleep and breathing. These sensors may cause mild skin irritation, redness, or discomfort. Sleeping in a laboratory setting may be uncomfortable and may affect your usual sleep patterns or result in poor sleep quality during study nights.

Additional monitoring may include a small sensor placed on your skin that continuously measures the amount of carbon dioxide in your body while you sleep (called transcutaneous carbon dioxide monitoring, or $TcCO_2$).

Risks related to oxygen and airflow delivery

Rarely, supplemental oxygen may make breathing slower or more shallow in people with certain underlying breathing conditions. This could cause carbon dioxide to build up in the blood. If this occurs, you may feel unusually sleepy, have a headache (especially in the morning), feel confused, have trouble thinking clearly, or feel more short of breath than usual. In rare cases, breathing problems during sleep could last longer or become more unstable, which could result in lower oxygen levels. To reduce these risks, your breathing, oxygen levels, and carbon dioxide levels may be monitored during study visits, and the study doctor will review your safety information.

Risks related to under-mattress sensors

Participants will be asked to use a contactless under-mattress monitoring device (Nightingale device) during home treatment periods. This device is placed underneath the mattress and is designed to monitor breathing patterns, heart rate, movement, and other body signals during sleep. The device does not record audio or video. Although the device is non-invasive, there is a potential risk of loss of confidentiality related to collection and transmission of monitoring data.

Risks related to changes in study conditions (washout period)

During the washout period, you will not use supplemental oxygen or sham air. You may notice changes in your sleep or breathing during this time.

Risks related to questionnaires and testing

You will be asked to complete questionnaires about your sleep, symptoms, mood, opioid use, and overall well-being. Some questions may feel personal or emotionally uncomfortable. You may skip any questions you do not want to answer.

You will also complete computerized psychomotor vigilance testing (PVT) following overnight visits. Some participants may experience temporary frustration, fatigue, or mild discomfort while completing these tasks.

Risks of loss of confidentiality

There is a risk that information about you could be released to an unauthorized party. This includes information about your opioid use disorder (OUD), prescription opioid use, recreational or illicit drug use, or participation in this study. If this information were unintentionally disclosed, it could affect your employment, insurance coverage, driving privileges, or other aspects of your personal life. To help protect your privacy, your study information will be assigned a unique study code rather than being identified by your name whenever possible. Records that link your name to your study code will be stored separately in secure, password-protected UC San Diego systems with access limited to authorized study personnel. Paper records, if any, will be stored in locked research offices. Information you provide about prescription opioid use or recreational/illicit drug use will be kept confidential to the extent permitted by law and will not be shared with your employer, insurance company, or others outside the research team unless required by law or described in this consent form.

Risks associated with reproduction and pregnancy

The procedures and interventions involved in this research may involve unknown risks to pregnant individuals or fetuses. You should not become pregnant or cause a pregnancy while participating in this study. If you are breastfeeding, you should discuss participation with the study team before enrolling.

Risks of incidental findings

Although the testing performed in this study is conducted for research purposes, study doctors may identify medical conditions that were previously unknown. These findings may include sleep apnea, abnormal heart rhythms (arrhythmias), seizures, REM sleep behavior disorder, or other clinically important conditions.

If clinically important findings are identified, you will be informed and encouraged to follow up with your healthcare provider. If you do not have a healthcare provider, the study team will recommend appropriate medical follow-up.

This study is not designed to provide treatment for these conditions. Any medical care or treatment you receive will occur through your usual healthcare providers and not through this research study.

Possible unknown risks

There may be risks that are currently unknown or unforeseeable. These unknown risks may be temporary and mild, or they may be serious or long-lasting. You will be informed of any significant new findings that may affect your health, safety, or willingness to continue participating in the study.

Protection against risks

To help minimize potential risks, the study will be conducted by experienced investigators and monitored by trained study personnel. Participants will be monitored during overnight sleep studies and throughout study participation. Study procedures or participation may be stopped if continued participation is determined to be unsafe.

10. How will information about me be protected?

We will do our best to protect the confidentiality of information collected during this research study. Your research records will be assigned a unique study code rather than your name whenever possible. Research data used for analysis, reporting, and future research activities may be de-identified to the extent permitted by law. The link between your identity and study code will be stored separately in secure, access-restricted systems.

Information collected during this study may include medical history, medication information, sleep study results, monitoring data, questionnaire responses, psychomotor vigilance testing (PVT) results, and other research-related information. Participants will also use an under-mattress monitoring device (Nightingale device) that collects information during sleep. The device does not record audio or video.

Research records and electronic study data will be maintained using secure institutional systems and password-protected servers with access limited to authorized study personnel. Study information may be shared with individuals or organizations involved in the conduct, oversight, monitoring, or regulation of the research, including:

- The research team and authorized UC San Diego personnel
- The UC San Diego Institutional Review Board (IRB)
- The study sponsor, the National Institutes of Health (NIH)
- Government or regulatory agencies responsible for research oversight, if required by law

Representatives of these groups may review study records to ensure the research is being conducted properly and in compliance with applicable regulations.

Results from this study may be presented at scientific meetings or published in medical journals; however, your identity will not be disclosed in any publication or presentation.

Although every reasonable effort will be made to protect your confidentiality, complete confidentiality cannot be guaranteed. There is a small risk that unauthorized individuals could gain access to research information.

Your protected health information collected as part of this research may be used and shared as described in the Authorization to Use and Disclose Protected Health Information for Research that accompanies this consent form.

11. Will I need to pay to participate in the research?

There will be no cost to you for participating in this study. Parking expenses at UCSD study sites will be covered.

12. What if I agree to participate but change my mind later?

Participation is voluntary, and you may withdraw at any time without penalty. If you decide to withdraw, please inform the research team promptly.

In addition, the study doctor or sponsor may stop the study or take you out of the study at any time, even if you would like to continue. This could happen because it is in your best medical interest or you do not follow the instructions given you by the study personnel.

13. What will happen to information and/or biospecimens collected from me?

Information collected during this study may be used for future research after de-identification, to the extent permitted by law. Results from this study may be published, but your identity will remain confidential.

If biospecimens (such as blood, tissue, or saliva) are collected as part of this study or related future research activities, they may be used for future research and shared with other researchers or organizations without additional consent, as permitted by law and IRB requirements.

You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

14. What are my responsibilities if I take part in this research?

You will be expected to attend scheduled visits, comply with study protocols, and report any side effects or issues to the research team.

Oxygen Safety: Oxygen supports combustion and can increase the risk of fire. During the study, while oxygen tanks or oxygen equipment are in use or nearby, you must not smoke or vape and must stay away from smoking, open flames, sparks, or other sources of heat or ignition. Do not allow others to smoke or use open flames near you or the oxygen equipment.

15. Will I be compensated for participating in the research?

You will receive compensation for completing study visits and procedures associated with this research study. Compensation may include:

• Baseline Visit (without PSG): $50.00
• Overnight Baseline Sleep Study (if needed): $200.00
• Overnight Oxygen Titration Sleep Study: $200.00
• Randomization Day Visit (if a separate visit is needed): $50.00
• End of Treatment Period 1 Overnight Sleep Study: $200.00
• End of Treatment Period 2 Overnight Sleep Study: $200.00
• Additional daytime study visits, if needed: $50.00 per visit
• Repeat overnight sleep studies, if needed: $200.00 per overnight visit

Compensation will only be provided for study visits and procedures that are completed. If you withdraw from the study early, you will be compensated for completed study procedures up to the time of withdrawal.

You will receive an additional $200.00 for any repeated overnight visits. If additional daytime study visits are needed for study-related data collection, you will receive an additional $50.00 for completing those visits.

If you receive compensation in excess of $2,000 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.

16. What else is important for me to know?

- You will receive summaries of your sleep study results.
- Any clinically relevant findings will be shared with you for follow-up.
- A description of this clinical trial will be available on www.clinicaltrials.gov.

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 Office of IRB Administration at 858-246-4777 or irb@ucsd.edu for more information about this, to inquire about your rights as a research participant, or to report research-related problems.

We may conduct other research studies in the future that you may be eligible to join.

Please check one:

☐ **Yes.** I give permission for the study team to contact me about future research studies that I may be eligible to participate in. I understand that agreeing to be contacted does not mean I have to participate in any future study.

☐ **No.** I do not want to be contacted about future research studi

Signature Block for Adults Able to Provide Consent

Participant

I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I agree to participate in the research described in this form.

Printed Name of Participant

Signature of Participant Date

Person Obtaining Consent

I document that:

- *I (or another member of the research team) have fully explained this research to the participant.*
- *I have personally evaluated the participant's understanding of the research and obtained their voluntary agreement.*

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Witness (if applicable)

I document that the information in this form (and any other written information) was accurately explained to the participant. The participant appears to have understood and freely given consent to join the research.

Printed Name of Witness

Signature of Witness Date

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.
2. Provided an explanation of 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. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.
5. Informed about 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. Told of the types of medical treatment, if any, available if complications should arise.
7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.
9. Provided a copy of the signed and dated written consent form and a copy of this form.
10. 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 contact the researchers 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 participant, please contact:

- UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777