1. Study Title and Number

Title: Respiratory Effects of Dose Optimization Under Comprehensive Opioid Management (REDUCE)

Study # 815079

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

This research study is being conducted to understand how different approaches to managing opioid use may affect breathing, sleep quality, and daytime functioning in people who use opioid medications.

You are being invited to participate in this study because you may have sleep-disordered breathing and are currently using opioid medications.

This form explains the research so that you may make an informed decision about participating.

• Research is voluntary - whether or not you participate 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.
• You can say no even if the person inviting you is part of your healthcare team.
• Your decision will not affect your health care or other benefits you may be entitled to.
• Please ask the study doctor or study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.
• You may consult with friends, family, a personal doctor, or anyone else before deciding whether or

not to be in the study.
• You will be given a copy of this consent form and the Participant's Bill of Rights.

The purpose of this research study is to determine whether Comprehensive Opioid Management improves breathing stability during sleep in individuals with chronic opioid use and sleep-disordered breathing. The study will compare usual care (your current medical management) to Comprehensive Opioid Management delivered under the supervision of the participant's treating clinician and/or designated opioid management provider. A designated opioid management provider is a healthcare provider who specializes in helping manage opioid medications and pain treatment and who may take responsibility for managing your opioid prescriptions while you are receiving care through the UC San Diego Opioid Management Program.

People who join this study will complete several research activities, including overnight sleep studies (polysomnography [PSG]), questionnaires, psychomotor vigilance testing (PVT), blood draws for opioid levels, and follow-up safety monitoring to evaluate how opioid management approaches affect breathing during sleep.

The study includes overnight sleep studies and other research procedures to evaluate how opioid management approaches affect breathing during sleep. After eligibility is confirmed, participants will be assigned by chance to either the Usual Care group or the Comprehensive Opioid Management group. Participants assigned to the Usual Care group will continue receiving opioid and pain-management care from their regular healthcare providers. Participants assigned to the Comprehensive Opioid Management group will participate in the existing UC San Diego Opioid Management Program as a result of their random study assignment.

The UC San Diego Opioid Management Program provides individualized assessment and management of opioid therapy and pain. Treatment decisions, including whether to change opioid medications, adjust an opioid dose, or use other pain-management strategies, will be made by the participant's treating clinician or designated opioid management provider based on the participant's individual clinical needs. The research team will not prescribe opioids or direct opioid dose adjustments, and participation in the study does not require changes to opioid therapy.

Your total participation in this study will last approximately 26 weeks. During this time, you will complete study visits, questionnaires, cognitive testing, blood sample collection, safety monitoring activities, and one or more overnight sleep studies to evaluate how changes in opioid use affect breathing during sleep, sleep quality, and daytime functioning.

The risks and possible discomforts of this study include trouble sleeping or discomfort during overnight sleep studies, mild skin irritation from monitoring sensors, feeling sleepy or less alert the morning after an overnight study, discomfort or bruising from blood draws, and feeling uncomfortable answering some questionnaires.

This study does not require your opioid dose to be reduced. However, your regular healthcare provider or designated opioid management provider may recommend changes to your opioid or pain treatment if they believe it is medically appropriate. These changes are part of your medical care and may occur whether you are assigned to the Usual Care group or the Comprehensive Opioid Management group. If your opioid treatment changes, you could experience withdrawal symptoms, increased pain, mood

changes, difficulty sleeping, nausea, diarrhea, reduced ability to do your usual activities, breathing problems, or an increased risk of overdose. In some cases, these symptoms may require medical care or hospitalization. The research team will not prescribe opioids or make decisions about your opioid treatment.

A complete listing of possible risks and discomforts associated with this study can be found in Section 9 of this document.

We cannot promise any benefit to you or to others from participating in this research. However, possible benefits include gaining additional information about your sleep-disordered breathing and how opioid use may affect your breathing and sleep. In addition, the information learned from this study may help researchers better understand sleep-disordered breathing and improve treatment approaches for future patients.

Alternatives to participating in this research include continuing to receive your usual medical care from your healthcare providers without participating in this study. The UC San Diego Opioid Management Program is an existing clinical treatment option and is not available only through this research study. If you choose not to participate in this study, you may still discuss referral to or treatment through the UC San Diego Opioid Management Program with your healthcare provider, subject to the program's usual clinical eligibility, referral, insurance, and scheduling requirements. Other alternatives may include continuing your current opioid management and treatment for sleep-disordered breathing, such as positive airway pressure (PAP) therapy, oral appliances, or other treatments recommended by your healthcare providers.

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?

We plan to study approximately 68 participants at UC San Diego.

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

Study Procedures

If you agree to participate in this study, you will complete several study visits and procedures over approximately 26 weeks. Depending on your prior sleep testing and eligibility status, you may complete one or two overnight sleep studies as part of the study. Screening, consent, eligibility review, questionnaires, physical assessments, and blood sample collection may occur during a daytime visit or may be completed in conjunction with an overnight study visit. Participation may include overnight and daytime visits at the UC San Diego Sleep Research Laboratory, home monitoring, questionnaires, psychomotor vigilance testing (PVT), blood sample collection, and safety monitoring activities.

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, in accordance with HIPAA regulations and IRB approval.

If you do not have a qualifying sleep study completed within the prior 8 weeks, 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

Blood samples will be collected at the Baseline and Week 26 visits by trained ACTRI research nurses using standard phlebotomy procedures. Approximately 10 mL of blood will be collected at each visit, for a total planned collection of approximately 20 mL over the course of the study. Samples will be used to measure opioid levels, characterize participant opioid exposure, and assess potential relationships between opioid use and study outcomes.

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, become pregnant during the study, 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 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 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 the study confirms that you meet eligibility criteria, you will be randomized to one of two study groups.

Randomization Visit (if needed)

You may return to the research center for a separate daytime visit. During this visit, study staff will review your results and confirm your eligibility. If a separate visit is not needed, randomization procedures may occur in conjunction with another study visit.

You will be randomized to one of two study groups. Randomization means that you are assigned to a study group by chance, like flipping a coin. You will have an equal chance of being assigned to either group.

You will be assigned to one of the following groups:

Usual Care: You will continue receiving opioid and pain-management care from your regular healthcare providers. Your providers may make any treatment or medication changes they believe are medically appropriate. These decisions will be based on your clinical needs and will not be directed by the research team.

Comprehensive Opioid Management: As a result of your random study assignment, you will participate in the existing UC San Diego Opioid Management Program. Your treating clinician or designated opioid management provider will provide individualized opioid and pain-management care and will decide whether any treatment changes are medically appropriate. The research team will not prescribe opioids or direct opioid dose changes.

Study staff will review the study procedures, answer your questions, and provide instructions about participating during the treatment period.

Treatment Period (Weeks 0–26)

You will participate in a 26-week treatment period.

Participants assigned to the Usual Care group will continue receiving opioid and pain-management care from their regular healthcare providers according to usual clinical practice. Treatment decisions will be made by those providers based on each participant's clinical needs and will not be directed by the research team. Participants in this group will not be prevented from receiving any medically appropriate treatment.

Participants assigned to the Comprehensive Opioid Management group will participate in the UC San Diego Opioid Management Program. Opioid prescribing and other treatment decisions, including any opioid dose adjustments, will remain under the direction of the participant's treating clinician or

designated opioid management provider. The research team will not prescribe opioids or independently direct opioid dose changes.

The study does not require an opioid dose reduction in either group. Changes to opioid or pain-management treatment may occur in either group if a treating clinician determines that a change is medically appropriate.

During the treatment period:

• You will remain in your assigned study group.

• You will receive twice weekly text-message safety check-ins.

• You will receive twice-monthly telephone outreach from study staff.

• Study contacts may also occur if concerning, absent, or worsening responses are identified.

These contacts will assess opioid use, medication changes, withdrawal symptoms, pain control, mood symptoms including suicidal thoughts, respiratory symptoms, emergency medical care use, adverse events, and study participation.

Some participants may also use an under-mattress monitoring device during sleep. The device is placed underneath the mattress and is designed to monitor breathing patterns, heart rate, movement, and other physiologic signals during sleep. The device does not record audio or video.

12-week Interim Visit

Approximately halfway through the study, you will complete a study visit that may include review of your medical history, current medications, opioid use, questionnaires, and other study assessments.

End-of-Study Visit (Week 26 Overnight Sleep Study)

At the end of the 26-week treatment period, you will return to the UC San Diego Sleep Research Laboratory for a final overnight sleep study.

If you are able to become pregnant, a urine pregnancy test will be performed before the overnight sleep study.

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 $TcCO_2$).

The sleep study will end in the morning, when all sensors will be removed. You will then complete morning questionnaires, a 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.

A blood sample may also be collected during this visit to measure opioid levels.

Questionnaires and Testing

Throughout the study, you will complete questionnaires about your sleep, symptoms, pain, opioid use, mood, and overall well-being. You will also complete cognitive testing (PVT) to assess alertness and attention. Blood samples will be collected at select study visits to measure opioid levels and help assess how opioid use relates to breathing and sleep outcomes.

At-Home Responsibilities

While participating in this study, you will be responsible for:

• Following study instructions

• Reporting any symptoms, medication changes, adverse events, or concerns to the study team

Standard Care vs Research Procedures

Some procedures in this study, such as review of your medical history, medication management, and overnight sleep studies, may be part of standard clinical care. However, the assignment to a study group (usual care or Comprehensive Opioid Management), additional study-related monitoring, blood sample collection for opioid levels, questionnaires, and the frequency and timing of study visits are being done specifically for research purposes and are not part of routine medical care.

Repeat Visits

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

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.

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 activities that may cause discomfort or involve risks.

The risks and possible discomforts of this study include trouble sleeping or discomfort during overnight sleep studies, mild skin irritation from the monitoring sensors, feeling sleepy or less alert the morning after an overnight study, discomfort or bruising from blood draws, and feeling uncomfortable

answering some questionnaires. There is also a small risk that your personal information could be accidentally shared, although we take steps to protect your privacy.

This study does not require your opioid dose to be reduced. However, your regular healthcare provider or designated opioid management provider may recommend changes to your opioid or pain treatment if they believe it is medically appropriate. These changes are part of your medical care, not required by the study, and may occur whether you are assigned to the Usual Care group or the Comprehensive Opioid Management group. If your opioid treatment changes, you could experience withdrawal symptoms, increased pain, changes in mood, including depression or suicidal thoughts, difficulty sleeping, nausea, diarrhea, or reduced ability to do your usual activities. In some cases, these symptoms may require medical care or hospitalization. Changes in opioid use may also affect your breathing or increase the risk of overdose. The research team will not prescribe opioids or make decisions about your opioid treatment.

There may also be risks that are unknown at this time. If we learn new information that may affect your willingness to stay in the study, we will tell you.

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 measurement of carbon dioxide levels through the skin (transcutaneous carbon dioxide monitoring, or $TcCO_2$).

Risks Related to Blood Collection

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 Changes in Opioid or Pain Treatment

Your treating clinician or designated opioid management provider may recommend changes to your opioid or pain treatment if they believe it is medically appropriate. These decisions are part of your medical care and may occur whether you are assigned to the Usual Care group or the Comprehensive Opioid Management group. Participants assigned to the Comprehensive Opioid Management group will receive these recommendations through the UC San Diego Opioid Management Program. Clinically supervised changes to opioid therapy may lead to withdrawal symptoms such as anxiety, sweating, irritability, trouble sleeping, nausea, diarrhea, increased pain, or other symptoms. Opioid dose reduction may also cause worsening pain, mood changes, functional decline, or other clinical destabilization. Any changes to opioid therapy will be determined by your treating clinician or designated opioid management provider and may be modified, paused, or adjusted if clinically appropriate. Opioid prescribing and dose-adjustment decisions will remain under the direction of your treating clinician or designated opioid management provider.

Risks Related to Pregnancy

The effects of study participation on pregnancy are not fully known. For this reason, participants who are pregnant, become pregnant during the study, or have a positive pregnancy test will not be eligible to continue participation. If you become pregnant during the study, you should notify the study team as soon as possible.

Risks Related to Questionnaires and Testing

You will be asked to complete questionnaires about your sleep, symptoms, mood, pain, 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. To help minimize this risk, we will use secure institutional systems, coded study identifiers, and limited-access research records to protect your information. Information collected during the study may include medical information, medication and opioid-use information, sleep study results, physiologic monitoring data, blood test results, and questionnaire responses.

Risks of Incidental Findings

Although the testing you will have in this study is being performed for research purposes and should not be considered a substitute for normal medical care, it is possible that the study team may notice something that could affect your health, such as sleep apnea, abnormal heart rhythm, seizure-like activity, REM sleep without atonia, depression, suicidal thoughts, or concerns related to opioid use. If this occurs, we will inform you and, if appropriate, your personal doctor or another appropriate clinical provider. Any follow-up care will be your responsibility or that of your insurance.

Possible Unknown Risks

In addition, there may be risks that we cannot predict at this time. These unknown risks may be mild or serious. You will be informed of any new findings that may affect your willingness to continue in the study.

We will closely monitor you during the study and will address any discomforts or side effects as best as possible. If any side effects are severe or if continued participation is no longer considered safe, study procedures may be slowed, paused, or stopped for your safety.

Protection Against Risks

To minimize potential risks, the study will be conducted by experienced investigators and monitored by trained personnel. All data will be kept confidential, and protective measures will be taken to ensure your safety during the study.

10. How will information about me be protected?

While we cannot guarantee complete confidentiality, we will limit access to information about you. Only people who have a need to review your information, documents, or specimens will have access. These people may include:

- Members of the research team and other staff or representatives of UC San Diego whose work is related to the research or to protecting your rights and safety.
- Representatives of the National Institutes of Health (NIH), which is funding this study.
- Representatives of the UC San Diego Institutional Review Board (IRB).
- Representatives of federal or other regulatory agencies that make sure the study is done properly and that your rights and safety are protected.

Your study information will be labeled with a study code instead of your name or other information that can easily identify you whenever possible. The record linking your name and other identifying information to your study code will be kept separately from the rest of the study information. Research records and electronic study data will be stored in secure, password-protected systems with access limited to authorized study personnel.

Information collected during this study may include your medical history, medication and opioid-use information, sleep study results, breathing and heart-rate monitoring data, questionnaire responses, psychomotor vigilance testing results, blood test results, and other research-related information. Some participants may also use an under-mattress monitoring device that collects information about breathing, heart rate, and movement during sleep. The device does not record audio or video.

This consent form and some details of your study participation will be noted in your UC San Diego Health record. If you do not currently have a UC San Diego Health record, one will be developed for you. People involved with your medical care and insurance may become aware of these details. UC San Diego also participates in Health Information Exchange (HIE) with multiple other health systems. Sharing your electronic health record with other health systems is allowed when they are involved in your medical care. Study details included in your electronic health record may also be shared. For more information about HIE, including how you can opt out of sharing, ask the study team.

Federal and state privacy laws give patients the right to access information about their care and treatment contained in their electronic health record. During this study, you may not be able to access certain information related to this study in your UC San Diego Health record until the study is complete to help ensure that the study remains unbiased. By agreeing to participate in this study, you are also agreeing to this possible temporary withholding of your research records.

The results of this study may be published once the study is completed. However, we will keep your name and other identifying information confidential. We expect this study will be completed in approximately 26 weeks for each participant. The overall study may take longer to complete.

You will be asked to sign a separate UC Health Insurance Portability and Accountability Act (HIPAA) Research Authorization form to allow the use and sharing of health information that identifies you for the purposes of this research study. Please see the separate authorization form for more information. Your permission described in this consent form and the HIPAA Authorization form does not have an automatic expiration date.

Certificate of Confidentiality

Your specimens and information about you are protected by a federal Certificate of Confidentiality. This means that we cannot be forced to release your specimens or information about you for any legal proceeding, even if a court of law asks.

The Certificate allows us to use your specimens and information about you for purposes of this research or to disclose them for other research when allowed by law. The Certificate requires other researchers to also protect specimens and information we share with them.

There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
- You consent to the release of information, such as the uses described in this consent form or if you sign release forms for employment, insurance, or medical care.
- A federal agency audits or evaluates research that it funds.
- Researchers are required to report possible intent to harm yourself or others, suspected child abuse, dependent adult or elder abuse, or certain communicable diseases.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult, or elder, including physical, sexual, emotional, or financial abuse or neglect. In addition, researchers may be required to report certain communicable diseases to the appropriate authorities.

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

There is no cost to you for research procedures performed only for this study. The study will pay for the study-related sleep studies, research blood collection, questionnaires, research testing, and research monitoring described in this consent.

You or your health insurer may be responsible for routine medical care, including opioid management, pain-management visits, medications, or other clinical treatment that you would receive as part of your medical care. You may be responsible for insurance deductibles, copayments, or services not covered by your insurance.

Parking expenses at UC San Diego study sites will be covered by the study. Please ask the study team if you have questions about which costs are paid by the study and which may be billed to you or your insurer.

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?

The information and blood samples collected from you as part of this study may be used to answer other research questions or shared with other researchers for future research only if you give permission below. Before they are used or shared, information that could identify you, such as your name or medical record number, will be removed whenever possible.

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

Please indicate your choice below regarding future use of your remaining blood samples:

☐ **Yes.** My remaining blood samples and associated information may be stored and used for future research.

☐ **No.** My remaining blood samples may not be stored for future research and should be destroyed after the study-required testing has been completed.

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.

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

You will be compensated for completing study procedures as follows:

• Baseline visit without overnight sleep study (PSG): $50
• Baseline overnight sleep study (PSG), if needed: $200
• Randomization visit, if a separate visit is needed: $50
• Safety monitoring contacts (twice-weekly text-message check-ins and twice-monthly telephone outreach): $5 per completed check-in, up to a maximum of $10 per week
• Interim visit (Week 12): $50
• End-of-Study overnight sleep study (Week 26): $200
• Additional daytime study visit, if needed for data collection: $50
• Additional overnight sleep study, if needed because data are inconclusive: $200

Compensation will be provided only for completed study activities. If you withdraw from the study early, you will be compensated for the study activities you have completed.

Compensation may be provided by check, gift card, direct deposit, or another approved payment method in accordance with UC San Diego policies.

If you receive compensation in excess of $2000 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 ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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.

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 studies.

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

Experimental Participant's Bill of Rights

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