CONSENT FORM FOR RESEARCH

Study title: Evaluating the efficacy and tolerability of the Oxygenating Bite Block (OBB)

Study support provided by: Anesthesiology Department, Cedars-Sinai Medical Center

Cedars-Sinai Principal Investigator:
Robert Wong, MD. Principal Investigador

Study contact phone number at Cedars-Sinai:
Robert Wong M.D. 310-423-1682
Ofelia Loani Elvir-Lazo, MD. Co-Investigator

After-hours emergency contact (24 hours): Robert Wong, M.D. 310-423-1682

1. Key Information

We are asking for your consent to take part in this research study. This section provides key information about the study. The rest of this form has more detailed information.

- **Voluntary:** Taking part in this research study is your choice. You can also stop taking part at any time. You will not lose any services, benefits or rights you would normally have if you choose not to take part or stop taking part.

- **Purpose:** To evaluate a bite block prototype to see if the device increases oxygenation by reducing the anatomic dead space required to reach the lungs for safer sedation in patients undergoing endoscopy. We think this this device will create a significant improvement of the current standard of care.

- **Procedures:** The main procedure that will happen in this research study is that the Oxygenating Bite Block will be placed in your mouth instead of the standard and customary bite block during your endoscopy procedure.
  A short questionnaire will be administered following the scheduled procedure.

- **Duration:** Taking part in this study will last one day.

- **Risks:** All research studies involve some risk. Risks or discomforts from this study are the same risks you are exposed to while undergoing a standard endoscopy procedure. This OBB

simply has an improvement on the existing oxygen delivery and monitoring for sedated patients in the GI lab.

- **Benefits:** A potential benefit from taking part in this research study is that the device might increase the oxygenation delivery you will receive during your sedation. The information learned from this study will contribute to the safety of future patients who undergo endoscopy and sedation.

- **Alternatives:** You can choose not to take part. There may be other choices for you. Some other choices may be to use the standard Oxygenating Bite Block routinely applied. Please talk about these choices with the study team.

Please take time to read this entire form. You should ask questions before deciding whether to take part in this study. You can talk with family, friends and/or healthcare providers before you decide.

During the study, we may find out new information about this research study. We will tell you about any important changes or new findings that may impact whether you want to continue taking part in the study.

2. Purpose of the Study

We are doing this study to test an investigational bite block, which is a device placed inside the mouth to protect the teeth and used to keep the endoscope (a long, flexible tube that is placed down the throat and into the esophagus that contains a light and camera used to provide a visual of the area) in place. This Oxygenating bite block has been modified to allow the convenient use of an oral nasal cannula for administration of oxygen and sampling of end-tidal carbon dioxide (measurement of the amount of carbon dioxide exhaled at the end of a breath) during endoscopic procedures.

The primary objective of this study is to evaluate the tolerability and efficacy of the device. We will be testing how this device improves the flow of oxygen and provides safer sedation.

This device has not been approved by the U.S. Food and Drug Administration (FDA). Bite blocks indicated for use as an endoscopy accessory are classified as exempt from premarket notification.

You are being asked to take part in this research study because you are scheduled for an upper endoscopy, esophageal-gastro duodenoscopy (EGD), endoscopic ultrasound (EUS), or endoscopic retrograde cholangiopancreatography (ERCP) procedure.

The study will include up to 10 people in total.

3. Main Study Procedures

This section talks about what will happen in this study. When you read this section, also read the flowchart of procedures. The flowchart is given with this consent form.

The flowchart of procedures shows a timeline of the study. It shows which study procedures are research-related and which are standard of care (routine). **Research-related procedures** are procedures done only for the research study. They would not be performed for your routine care outside of the study. **Standard of care (routine) procedures** would be performed as part of your routine care even if you did not take part in this study.

Section 4 in this form describes the common medical procedures that will be done or repeated only for this research study.

Description of main research procedures:
The Oxygenating Bite Block prototype will be used instead of the standard bite block. This device is placed inside the mouth to protect the teeth and used to keep the endoscope in place, additionally administrate oxygen and measure your carbon dioxide during the procedure.

This study has 1 study group:

- All participants are scheduled for an upper endoscopy and will be using the Oxygenating Bite Block prototype instead of the standard bite block.

How long will you be in the study?
We think you will be in this study for one day. After your procedure, you will be asked to fill out a short questionnaire about the tolerability of the device.

4. Possible Risks and Discomforts of the Main Research Procedures

This section talks about the possible risks and/or discomforts of the study procedures.

Your endoscopy procedure nor anesthesia management will change from current practices. The risks to participants are the same risks you are exposed to while undergoing a standard endoscopy procedure. Side effects and risks of standard care procedures are not described in this consent form.

Study Procedure	Related Risks
Oxygenating Bite Block	Placement of the bite block might cause: • discomfort and/or lead to tooth damage, • tongue swelling, and • oral mucosal and lip injury.
Questionnaire: You will be asked to complete a questionnaire. We will ask you questions to find out your satisfaction with the level of sedation during the procedure, the tolerability of the device, and whether you have a sore throat after the procedure. We think it	Some questions may make you feel uncomfortable or embarrassed. The questionnaire is anonymous. It will have no information that could be used to identify you.

should take about a few minutes to complete the questionnaire.	

Unknown Risks
There may be other risks that we cannot predict. Many complications are minor and do not last long. However, in some cases, they can be serious, long-lasting, permanent and/or fatal.

5. Benefits From Taking Part in the Study

A potential benefit from taking part in this research study is that the device might increase the oxygenation delivery you will receive during your sedation. Participating in this research study will contribute to the safety of future patients who undergo endoscopy and sedation.

6. Reasons Participation May Be Stopped

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.

7. Choosing to Take Part and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

The study team will discuss these options and their risks and benefits with you. You may also choose to discuss these with your treating physician.

8. Confidentiality Protections

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal

information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitors the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

We might share your information and/or research samples collected in this study. It might be shared with other researchers at Cedars-Sinai, other academic institutions or third-party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

A description of this clinical trial will be available on www.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.

9. Research-Related Illness or Injury

Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. As needed, your study doctor will treat you or refer you for treatment. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research-related illness or injury?
A research-related injury or illness is a direct result of either the study device or a procedure performed only as a part of this study and that is not part of your standard clinical medical treatment. Injury or illness related to your underlying medical condition or caused by non-research-related activities (such as treatment provided outside of this study) would not be considered research-related. If you are being treated for a research-related injury or illness, you will not pay for the costs of your appropriate medical care provided at Cedars-Sinai or in any emergency room. Cedars-Sinai may, however, ask for reimbursement, where allowed, from parties such as your health plan. If you choose to obtain non-emergency care elsewhere, you or your health plan may be responsible for the costs of that care. Cedars-Sinai has no plans

to pay for losses such as lost wages or pain or suffering. You do not waive any of your legal rights by signing this form.

10. Financial Considerations

Costs of Participation
Standard of care procedures and implant procedures, and related items, drugs and procedures will be charged to you or your insurance company. You remain responsible for all deductibles, copays and balances under your health benefit plan. But you will not be charged for the cost of the study device (Oxygenating Bite Block).

Payment
You will not be paid for taking part in this research study.

Financial Interest in the Research
The principal investigator and institution have no potential financial conflict of interest with this study.

11. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required 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 utilized.

3. Be given a description of any attendant discomforts and risks to the subject 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 procedure 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 any signed and dated written consent form used in relation to the experiment.

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.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Evaluating the efficacy and tolerability of the Oxygenating Bite Block" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

- ☐ Laboratory tests
- ☐ Pathology reports
- ☐ Imaging reports (e.g., x-rays or scans)
- ☐ Photographs or videos of your image
- ☐ Doctor/clinic records
- ☒ Hospital/medical records
- ☐ Mental health records
- ☐ Billing records
- ☐ Demographics, which may include age, gender identity, race, ethnicity, and/or sexual orientation
- ☐ Other tests or other types of medical information: Click or tap here to enter text.

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.

- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

Flowchart of Visits, Tests and Procedures

Legend
R = Research item/procedure done only for research purposes and their costs are covered by the study. You are not responsible for the costs of these procedures.
S = Standard of care item/procedure that is part of regular care and billed to the patient/insurance. You and your insurance company will be responsible for these costs.
SS = Standard of care item/procedure that is part of regular care but their costs are covered by the study. You are not responsible for the costs of these procedures.

Procedures	Visit #1
Informed Consent	R
Oxygenating Bite Block	R
Questionnaire	R

Footnotes:

Signature Page

Consent Form for Research and Authorization
for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date

Signature by the Investigator
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date