UCSF University of California San Francisco
IRB NUMBER: 13-12180
IRB APPROVAL DATE: 04/18/2016
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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: **Controlled Desaturation for Cerebral Oximetry**

This is a medical research study. One of your study doctors, Philip Bickler, M.D., John Feiner, M.D., Mark Rollins, M.D., Jeff Sall, M.D., Helge Eilers, M.D., Jennifer Lucero, M.D., Andrew Schober, M.D., or Michael Lipnick, M.D., from the UCSF Department of Anesthesia and their associates will explain this study to you.

Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to participate in this study because you are healthy, between 18 and 49 years of age and willing to participate in breathing studies with blood samples in San Francisco. You must not smoke cigarettes, have any lung problems, or be pregnant to participate.

Why is this study being done?

The aim of this study is to determine the accuracy of cerebral oximeters (devices that detect brain oxygen levels by shining light through the forehead) in the presence of hypoxia (reduced amounts of oxygen) or hypoxia combined with either increases or decreases in carbon dioxide in the air you breathe. The studies will help manufacturers design more accurate cerebral oximeters.

You are being asked to participate in a research study of a monitoring system that includes investigational components. An investigational device is one that is not approved by the U.S. Food and Drug Administration (FDA). The study is paid for by an industry sponsor. The sponsor is also paying some of the study doctors to do the study. There are multiple sponsors that may be funding the study. An attached supplement will inform you of which sponsor is funding the study for your particular study date.

How many people will take part in this study?

Up to 104 volunteer subjects will participate in this study.

What will happen if you take part in this research study?

There will be one or two visits for this study.

Before you begin the main part of the study…
The following will be done:

- You will answer a few brief questions regarding your general medical history and any smoking habits.
- A partial physical examination will be done of your heart, lungs, heart rate and blood pressure, height and weight. We will also test if you have good blood flow in

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your wrist artery by observing the color of your fingers after making a fist.

- For female subjects of child bearing potential, if you are unsure whether you may be pregnant, we will ask you to take a pregnancy test before the study.

During the main part of the study

1. You will lie on a bed and an arterial catheter will be inserted into one of your wrist arteries under local anesthesia (lidocaine).
2. A thin plastic tube will be inserted into one of your jugular veins in your neck to enable small samples of blood to be withdrawn. The superior jugular bulb is the standard site for collecting cerebral mixed venous blood. An ultrasound machine will be used to see the vein during the insertion procedure. You will lay flat or slightly head-down during this procedure. The catheter itself is a soft 20-gauge catheter, much smaller than a typical internal central line catheter used in adult patients. It comes in a kit with an appropriately sized introducer to enable the soft catheter to enter the vein after wire placement. This introducer is quite small in comparison to those used for clinically placed central lines. The introducer is always passed in a direction away from the carotid artery and at an angle much more shallow.
3. The test oximeter sensors will be attached to your forehead; reference oximeter sensors may also be attached to the fingers, forehead, torso, ears or extremities. Some sensors are held in place with an adhesive pad. They work by shining light through tissues. Test sensor placements may be done by a sponsor representative.
4. Electrocardiogram pads will be attached to your chest to monitor your heart.
5. You will then breathe rapidly in and out of a tube through a mouthpiece, with a nose clip on your nose. The gas you breathe will be adjusted to lower your blood oxygen saturation from its normal value of 95-98% to as low as 70% in stepwise fashion. Blood will be sampled from the arterial catheter and the jugular catheter up to two times at each step. This cycle will be repeated several times, with blood samples taken each time. After 5 or 6 steps you will again breathe oxygen. A total of less than 4 ounce of blood will be sampled during the entire study.
6. For some studies, you will then be randomly assigned to one of the two following groups, by toss of a coin:
   A. Elevated carbon dioxide group. While still reclining on the bed, you will re-breathe oxygen to which small quantities of carbon dioxide have been added. In addition, you will breathe low oxygen mixtures to produce brief periods of hypoxia, in steps, as in #5 above. Blood will be sampled from the arterial and jugular catheters
   B. Decreased carbon dioxide group. If you are in this group, you will be asked to hyperventilate so as to reduce the carbon dioxide in your breath. As in the previous part of the study, the air mixture during this hyperventilation will contain reduced amounts of oxygen. Blood will be sampled from the arterial catheter and the jugular catheters, at several steps of decreased oxygen.
7. Throughout the study, standard monitoring equipment will be used to monitor your heart function, pulse rate, blood pressure and respiration rate. Physiological data from any of these devices may be recorded and used for research.

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The above procedures will be done by the doctors and research staff; with only highly experienced attending anesthesiologists conducting the arterial and jugular catheterization procedures.

CT scans of the head
One of the goals for some sponsors of the study is to understand why cerebral oximeters do not read accurately in certain individuals. Depending on the readings obtained, you may be asked to have a head CT scan to examine such factors as the thickness of your skull bones and the anatomy of your sinuses. Some subjects with completely normal readings may be randomly selected to receive a CT scan. Before you undergo the CT scan, you will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you. If selected for your particular study, the CT scan will occur on a day following completion of the study, on a day and time convenient to you.

Photos
In this study we will take photographs of our equipment in use. This will allow us to analyze the data and look at sensor placement for the study. Photos may be taken of your forehead. In most cases, only the equipment site (not your face) will be photographed however, in some circumstances it may be necessary to photograph your face, in this case your face will be de-identified.

In addition to the UCSF research staff, the study sponsor may have representatives present during the study to collect and record electronic data as well as monitoring study procedures.

How long will I be in the study?
Participation in the main part of the study will take a total of about 3 hours, on a single day. If you were asked to have a head CT scan, an additional hour of your time would be needed on another day of your choosing.

Study location: All study procedures will be done at the UCSF Dept. of Anesthesia, on the Parnassus Campus. The CT scan, if needed, will be done in the Department of Radiology at UCSF.

Can you stop being in the study?
Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely. The study doctor may stop you from taking part in this study at any time if he believes it is in your best interest, if you do not follow the study rules, or if the study is stopped. Subjects can choose to withdraw from the study at any time. If the jugular catheter and arterial catheters have already been placed, pressure will have to be applied to these sites after catheter removal before you can leave the study room. If you want to stop during the breathing test portion of the study you may simply spit out the mouthpiece and resume breathing room air.

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What side effects or risks can I expect from being in the study?

a. Risks of the arterial catheter include bleeding, infection, nerve injury and bruising at the site of catheter insertion. There is also a remote risk of arterial spasm or damage to the artery.

b. There is a remote risk of an allergic reaction from the lidocaine given for local anesthesia at the arterial line or central venous line insertion site.

c. Risks of the jugular venous catheter include a bleeding, blood clot, infection, injury to the blood vessels or other structures of the neck, or introduction of air into your bloodstream. You may have a bruise or sore spot on your neck afterwards. In rare cases, jugular catheters may penetrate an artery. If an arterial puncture occurs, you may have a larger hematoma, and there is a rare risk of serious injury or stroke. Since, the ultrasound is used to establish the location and anatomy of the vessels in the neck, this makes hitting the carotid artery a remote possibility. Only highly experienced attending anesthesiologists do the procedure.

d. The risks of the brief exposures to hypoxia include feeling short of breath, and developing a headache or dizziness. Brief loss of consciousness may occur, but is not expected at the levels of oxygen targeted for these tests.

e. Risks of breathing increased amounts of carbon dioxide include feeling short of breath. The risk of hyperventilation is feeling light-headed or dizzy.

f. Risk associated with sensor adhesives is mild skin irritation.

g. If you are asked to complete the CT scan, this research study will involve exposure to radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be less than the yearly natural background radiation in the US, which is 3 mSv (a mSv, or milliSievert, is a measurement of radiation). This amount of radiation involves minimal risk. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

□□ **Unknown Risks:** There may be side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

□□ For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study will help develop a medical device that may help others who have low oxygen levels in their blood.

What other choices do I have if I do not take part in this study?

You are free to choose to not participate in this study or to leave the study

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at any time without penalty.

This is not a treatment study.

Will my medical information be kept private?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include authorized representatives of the study sponsor, UCSF Committee on Human Research and the FDA. Your information and responses to questions about your health will be kept for 2 years after completion of the study and then destroyed.

Once the researchers and their study staff have collected your personal health information that is needed for the study, it is entered onto data forms that are identified only by a code. This means that when it leaves our research office, your health information is no longer linked to your name. In this way, the study sponsor, researchers and their service providers can analyze the health information (data) of all the study participants without having to know your identity.

It is advised that you discuss this in detail with the study doctor or a member of the staff and ask any questions that you may have about the sharing of your health information.

Unless withdrawn, your consent will remain in effect until your personal health information is no longer required by the researchers and the study sponsor for the purposes of this study.

If you decide that you no longer wish to have your personal health information shared:

- You must provide a written request to the study doctor and tell them that you no longer want to share your information.
- The research team can continue to share any of the information that they already have on file.
- You will no longer be a part of this research study.
- Your health information may still be shared if you have a bad reaction to the study device or procedure.

The following privacy information applies in case you are one of the subjects selected to receive a CT scan. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and your scan will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of the results

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of your scan. Your personal information may be given out if required by law.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

What are the costs of taking part in this study?

You will not be charged for any of the study activities.

Will I be paid for taking part in this study?

In return for your time, effort and expenses, you will be reimbursed $300 if you complete the study. If a head CT is requested, you will receive an additional $50. If you withdraw before the completion of the study you will be reimbursed $25 for the arterial line and $75 for the jugular vein line if those procedures were done. You must provide your social security number to the University in order to receive a check. A check will be mailed approximately 4 weeks after your participation in the study has ended.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctors (Dr. Bickler or Dr. Feiner) if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him at (415) 476-1411.

Treatment and Compensation for Injury

If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have

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about this study. Contact your study doctor(s) Philip Bickler, M.D. or John Feiner, M.D. at (415) 476-1411.

For questions about your rights while taking part in this study, call the office of the **Committee on Human Research**, UCSF's Institutional Review Board (a group of people who review the research to protect your rights) at **415-476-1814**.

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CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

____Please initial here to indicate you have reviewed the Experimental Subject's Bill of Rights.

____This study has multiple sponsors. The sponsor for this study date has been provided to you. Please initial to acknowledge.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate in this study or to withdraw at any point without penalty or loss of benefits to which you are otherwise entitled.

You understand that this study and this informed consent form have been reviewed and approved by the UCSF Committee on Human Research.

I agree to share the information obtained in this study to representatives of the UCSF Committee on Human Research, study sponsor representatives, the FDA or other regulatory authorities.

I understand that I have not waived any of my legal rights by signing this form.

You may refuse to sign this document, which will make you ineligible to participate in the study.

If you wish to participate in this study, you should sign below. If you are asked to return

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for a CT scan, you will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

Participant (Print name)

Participant's Signature for Consent **Date (mm-dd-yyyy)** **Time (hh:mm)**

Person Obtaining Consent (Print name)

Person Obtaining Consent Signature **Date (mm-dd-yyyy)** **Time (hh:mm)**