

## **UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

### **Study Title: Accuracy of cerebral oximeters with hypoxia and methemoglobin or carboxyhemoglobin**

This is a medical research study. One of your study doctors, Philip Bickler, M.D., or John Feiner, 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 21 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, have migraine headaches, or be pregnant to participate.

### **Why is this study being done?**

Pulse oximeters measure the amount of oxygen bound to the protein hemoglobin in the blood by shining light through tissues. 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) and hypoxia combined with either methemoglobin (a form of hemoglobin that forms during exposure to a variety of agents, including the local anesthetic benzocaine, nitrates used in meat treatment, and nitric oxide gas used to treat diseases) or carboxyhemoglobin (formed from breathing air with carbon monoxide as in vehicle exhaust). The studies will help manufacturers design more accurate cerebral oximeters.

### **How many people will take part in this study?**

About 40 volunteer subjects will participate in this study.

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

1. You will lay on a bed and an arterial catheter will be inserted into one of your wrist arteries under local anesthesia.
2. An intravenous catheter will be placed in a vein in one of your hands or arms.
3. A thin plastic tube will be inserted into one of your jugular veins in your neck to enable small samples of blood to be withdrawn. 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.
4. The oximeter probes will be attached to your forehead and to a finger.

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% for less than 30 seconds. Blood will then be sampled from the arterial catheter. This cycle will be repeated a total of 6 times, with a 1 ml blood sample taken each time. A total of less than 1 ounce of blood will be sampled during the study.

6. By toss of a coin, you will be assigned to one of the two following groups:

A. Carbon Monoxide group. While still reclining on a bed, you will re-breathe oxygen to which small quantities of carbon monoxide have been added. Five minutes later, a 1 cc arterial blood sample will be obtained for analysis of hemoglobin compounds. Continuous recordings from the test oximeters will be made during this period of time. When the carbon monoxide level has reached about 10%, you will breathe low oxygen mixtures to produce brief periods of hypoxia, to a level equivalent to a quick ascent to 15,000 foot elevation. Blood samples from the arterial line and jugular line will be taken at each oxygen level.

B. Methemoglobin group. You will receive intravenous sodium nitrite to produce methemoglobinemia. Methemoglobin is a type of hemoglobin that does not carry oxygen; it is normally present in the blood but at levels <2% of total hemoglobin. Blood samples (1 ml) will be taken every five minutes for analysis of methemoglobin levels. Your blood pressure will be checked continuously by watching a monitor. If methemoglobin levels exceed 15%, you will receive oxygen by face mask and intravenous methylene blue, which returns the methemoglobin to the normal type of hemoglobin in your body. The breathing test with the low oxygen will be repeated, and blood samples from the arterial and jugular venous line will be taken at each oxygen level.

The bed you are laying on may be tilted head up or head down during some of the tests. The study will last two to three hours.

The total amount of blood sampled is less than 2 ounces.

### **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 may be done of your heart, lungs, heart rate and blood pressure, height and weight. We may also test if you have good blood flow in your wrist artery by observing the color of your fingers after making a fist.

If you are not sure if you are pregnant, we may ask you to take a pregnancy test before the study.

### **How long will I be in the study?**

Participation in the study will take a total of about 2-3 hours, on a single day.

**Study location:** All study procedures will be done at the UCSF Dept of Anesthesiology, on the Parnassus Campus.

### **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.

### **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 blood clot, infection, damage to a blood vessel, or introduction of air into your bloodstream. You may have a bruise or sore spot on your neck afterwards.

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 the controlled, small amounts of carbon monoxide in oxygen mixtures in this study are remote. The small increases in carbon monoxide that will be induced in this study are comparable to levels present in the blood of cigarette smokers, garage attendants and others who are exposed to carbon monoxide in the environment. The likely side effects of carbon monoxide levels in this range are light-headedness, dizziness, and headache. If the level of carbon monoxide in your blood goes above 15%, oxygen will be administered by face mask until the level drops below 15%. This may be needed for about 30 minutes.

f. The sodium nitrite may decrease your blood pressure for a few minutes. This may make you feel dizzy or light-headed for a few minutes. You may have a mild headache afterwards.

g. The methylene blue that may be given to eliminate methemoglobin will make your urine temporarily green or blue.

- **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 methemoglobin or 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 at any time without penalty.

**Will my medical information be kept private?**

We will do our best to make sure that the personal information in your medical record is kept private. However, 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 the UCSF Committee on Human Research and the FDA. The information on your responses to questions about your health will be kept for 6 months and then destroyed.

**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 you withdraw before the completion of the study you will be reimbursed \$25 for the arterial line, \$50 for the jugular vein line and an amount proportional to the fraction of the study completed. 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 (Bickler or 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/her at (415) 476-1411.

**Treatment and Compensation for Injury.**

If you are injured as a result of being in this study, treatment will be available. The costs of the treatment may be covered by the University of California, depending on a number of factors. The University does 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 about this study. Contact your study doctor(s) Philip Bickler, M.D. or John Feiner, M.D. at (415) 476-8624

**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.

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

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

\_\_\_\_\_  
Date

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Participant's Signature for Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent