UCSF University of California San Francisco
IRB NUMBER: 10-03634
IRB APPROVAL DATE: 11/10/2016
IRB EXPIRATION DATE: 11/09/2017

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

Study Title: **Accuracy of detection of carboxyhemoglobin with pulse oximetry**

This is a medical research study. Your study doctors, Philip Bickler, M.D. and John Feiner, M.D. from the UCSF Department of Anesthesiology 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 50 years of age and willing to participate in breathing studies with blood samples in San Francisco

Why is this study being done?

The aim of this study is to determine if new pulse oximeters (devices that measures blood oxygen by shining light through a finger or ear) being developed by several manufacturers accurately detects carbon monoxide when intentionally increased in the blood of volunteers.

How many people will take part in this study?

About 50 volunteer subjects will participate in this study.

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

You will have a small plastic tube placed in a wrist artery under local anesthesia. Standard and test pulse oximeters will be attached to your fingers, forehead, chest, or ears. You will recline on an operating room bed and 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 15%, you will breathe low oxygen mixtures to produce brief periods of hypoxia, to a level equivalent to a quick assent to 15,000 foot elevation.

If the level of carbon monoxide rises above 15% during the tests (heavy smokers can have carbon monoxide levels of 20%), 100% O_2 will be administered by an oxygen mask.

Participation in the study will take a total of about 2 hours. The total amount of blood to be sampled is about 2 oz.

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

- Your medical history will be recorded-we will ask about smoking, and any chronic health problems.
- 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 your wrist artery by observing the color of your fingers after making a fist.

How long will I be in the study?

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

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

Can I 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 arterial cannulation include pain, bleeding, infection, nerve injury and bruising at the site of catheter insertion. There are also remote risks of an allergic reaction from the lidocaine used for local anesthesia, or the development of arterial spasm (tightening of the muscles in the wall of artery), dissection (when a tear forms in the inner wall of an artery) or thrombosis (a blood clot that develops in the artery) that can prevent normal blood flow to the hand or arm, that might require surgical treatment and that, very rarely, can result in permanent damage or loss of limb. The risk of serious damage from a 22 gauge arterial line in a healthy person is much less than 1 in 10,000.

b. 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 for 30-45 minutes until the level drops below 15%.

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

- **Unknown Risks:** The experimental treatments may have 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 carbon monoxide poisoning.

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

You can decide not to participate in the study.

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 University of California, the study sponsor 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 and effort you will be paid $150 for taking part in this study. The payment will be by check than will be mailed to you 2-4 weeks after you complete the study. The University requires that you give us your social security number so that you can get paid. If you begin the study but withdraw before completion there will be no payment.

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

It is important that you tell your study doctors (Bickler, Feiner, Sall, Rollins) 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) 476-1412.

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 Institutional Review Board 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) 476-1412

For questions about your rights while taking part in this study, call the office of 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 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 or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

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

_____
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)**