UCSF University of California San Francisco
IRB NUMBER: 10-00437
IRB APPROVAL DATE: 04/05/2016
IRB EXPIRATION DATE: 04/21/2017

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

Study Title: **Accuracy of pulse oximeters with profound hypoxia**

This is a medical research study. Your study doctors, Philip Bickler, MD, John Feiner, MD, Jeffrey Sall, MD, Mark Rollins, MD, Helge Eilers, MD, Jennifer Lucero, MD, Andrew Schober, MD, or Michael Lipnick, MD, 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 50 years of age and willing to participate in breathing studies with or without blood samples in San Francisco.

**Why is this study being done?**
The aim of this study is to determine the accuracy of devices called pulse oximeters, which measure blood oxygen by shining light through fingers, ears or other skin, without requiring blood sampling.

**How many people will take part in this study?**
About 150 volunteer subjects will participate in this study each year.

**What will happen if I take part in this research study?**
For studies requiring arterial blood sampling by the sponsor, you will have a small plastic tube placed in a wrist artery under local anesthesia. Most studies will require arterial blood sampling, however, some sponsors may choose not to collect blood samples; in these instances, no anesthesia will be used and no arterial catheter will be placed. The study staff will notify you whether this does or does not apply to your particular study date. Standard and test pulse oximeters will be attached to your fingers, forehead, chest, or ears. You will be asked to rapidly breathe in and out of a tube through a mouthpiece, with a nose clip on your nose. The gas you will breathe will be adjusted to lower your blood oxygen saturation from its normal value of 95% - 98% to as low as 40% for less than 30 seconds.

During studies requiring arterial blood sampling, 20-25 small blood samples (each less than 2 ml or 1 teaspoon) will be taken from the wrist arterial catheter, for a total of less than two ounces of blood. Some sponsors may add additional blood samples for their particular study date; up to 35 samples total may be drawn.
**____Please initial here to indicate you have been informed that your study will require additional blood samples (up to 35).**

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During some of the testing you may lay flat, or with your head up or down to measure low perfusion. During some of the studies, Testing may also be done with your hand fixed to a motion machine, which rhythmically moves your hand up or down a few inches.

**____Please initial here to indicate you have been informed that your study will be examining low perfusion ☐ or motion testing ☐.**

During some parts of the testing you may be asked to hyperventilate for a few minutes of to breathe air with slightly increased or decreased amounts of carbon dioxide (CO2).

**____Please initial here to indicate you have been informed that your study will require measurements of high or low CO2.**

During some of the studies, you may be asked to complete non-invasive experimental 'eye-tracking' tests. Small cameras will track the movement of your eyes throughout the duration of the test.

**____Please initial here to indicate you have been informed that your study will be measuring eye-movements during your tests.**

**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.

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

Participation in the study will take a total of about 1 hour, 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 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, dissection or thrombosis. If the sponsor for your study is not collecting arterial blood samples, this risk does not apply to your participation.

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

c. The risks of hyperventilating include feeling light-headed or dizzy. The risks of breathing air with increased amounts of carbon dioxide include feeling short of breath and developing a headache.

d. For studies requiring eye-tracking, you may experience some watering of your eyes from keeping your eyes open during the test. This can be relieved by blinking.

- **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 low oxygen levels in their blood.

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

None

## 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, 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, effort and expenses, you will be reimbursed $75 for a 20-sample test, and $100 for a 25-sample test. If you are participating in a non-blood study, you will be reimbursed $75 for study completion. For studies requiring additional blood samples, motion evaluations, low perfusion, or high or low carbon dioxide for specific

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sponsor requests, you may receive an additional $25. The study staff will notify you if this applies to your particular study participation date. If you do not complete the study, you will be reimbursed $25 per breathing test. A check will be mailed to you 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, 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 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 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.

_____

**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)**