

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

Study Title: Accuracy of detection of methemoglobin with pulse oximetry

This is a medical research study. One of your study doctors, Philip Bickler, MD, John Feiner, MD, Jeff Sall, MD, Helge Eilers, MD, Mark Rollins, 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 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 an experimental type of pulse oximeter that detects the presence of methemoglobin, a form of hemoglobin (the protein that carries oxygen in the blood) that forms during exposure to a variety of agents, including the local anesthetic benzocaine, nitrates used in meat treatment, and nitric oxide gas now used to treat diseases. The oximeter detects methemoglobin by absorption of light passed through the finger or ear.

How many people will take part in this study?

About 84 volunteer subjects will participate in this study each year.

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

1. I will lie on a bed and an arterial catheter will be inserted into one of my wrist arteries under local anesthesia.
2. An intravenous catheter will be placed in a vein in one of my hands or arms. The oximeter probes will be attached to my fingers, ears, or forehead.
3. I will receive intravenous sodium nitrite to produce methemoglobinemia. Blood samples (1 ml) will be taken every five minutes for analysis of methemoglobin levels. My blood pressure will be checked every five minutes. If methemoglobin levels exceed 15%, I will receive oxygen by facemask and intravenous methylene blue, which returns the methemoglobin to the normal type of hemoglobin in my body.
4. I will then breathe rapidly in and out of a tube through a mouthpiece, with a nose clip on my nose. The gas I breathe will be adjusted to lower my blood oxygen saturation from its normal value of 95-98% to as low as 60% 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. The study will last two to three hours.

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 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.

b. 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.c. The sodium nitrite may decrease my blood pressure for a few minutes. This may make me feel dizzy or light-headed for a few minutes. I may have a mild headache afterwards.d. The methylene blue that may be given to eliminate methemoglobin will make my 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?

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 \$200 if you complete the study. If you withdraw before the completion of the study you will be reimbursed \$25 for the arterial line and an amount proportional to the fraction of the study completed. A check will be mailed to you approximately 4 weeks after your participation in the study has ended. The university requires that subjects provide their social security number in order to be paid by check.

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 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) 476-8624

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**.

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.

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)