UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN RESEARCH STUDY
Consent to be a Research Subject – Data and Biological specimens not yet collected
Study Title: Skin Pigment and Pulse Oximetry

This is a clinical research study. Investigators at UCSF and their associates are conducting this research study and will explain this study to you by phone, video conference, or in person.

If you are the Legally Authorized Representative, the person you are representing (hereafter referred to as the 'subject') is being asked to participate in a research study but is unable to consider whether to give consent to participate because of their medical condition. You, as the subject's legally accepted representative, are being asked to consider whether to give consent for the subject to participate in this study.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Drs. Philip Bickler, Michael Lipnick, Carolyn Hendrickson and their colleagues.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

Purpose of the Study: To understand how the pulse oximeter devices (finger clips that measure blood oxygen levels) may work differently in hospitalized patients with different skin pigmentation (lighter or darker skin color).

Study Procedures: If you choose to be in this study, we will collect information from your medical record and the monitors that your doctors are using to care for you. We may also take a few small blood samples from an arterial catheter your doctors placed to help take care of you (no additional needle sticks for blood draws). We will ask permission to take about ¼ teaspoon of blood up to 10 times over two weeks of your hospital stay or until your condition improves enough to have the arterial catheter removed.

You will be in this study for about two weeks or until the arterial catheter is removed.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- Donating clinical data may involve a loss of privacy

- Mild discomfort: It is possible that you may find one of the finger clip devices uncomfortable or annoying to wear. It will most likely feel the same as the device your doctors and nurses are using to monitor you and it can be removed by your research or clinical care team at any time you request
- There is low risk associated with collecting blood samples. Because the maximum amount of blood collected in this study is very small and taken from a catheter already placed by your doctors, there is very little risk of discomfort and it is unlikely to cause infection or anemia (low levels or red blood cells from drawing blood).

We'll tell you about the other risks later in this information packet.

Possible Benefits: There will be no direct benefit to you from participating in this study. What we learn from this study will help us take better care of future patients who are in the hospital and need blood oxygen levels measured for their care.

Your Other Options: You are free to choose not to participate in the study. You can still get your care from our institution the way you normally do without being in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. You may keep this from for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Drs. Phillip Bickler, Michael Lipnick, Carolyn Hendrickson and their colleagues are conducting this research study. The research staff will be contacting you by phone, videoconference (Zoom), or in person to discuss this study with 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, friends, and health care team. If you have any questions, you may ask your study doctor.

Why this study being done and what is the purpose?
You have been asked to participate in this study because you are a patient in the Intensive Care Unit (ICU) or the Operating Room and you have an arterial catheter placed by your doctors in order to take care of you in the hospital. We want to understand if the pulse oximeters (finger clip devices) give accurate blood oxygen measurements in people in the hospital with a variety of skin colors who also have low oxygen levels.

Who pays for this study?
The U.S. Food and Drug Administration pays for the conduct of this study. There are no financial conflicts of interest with the doctors and associates running this study. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study.

How many people will take part in this study?
Up to 272 patients will be enrolled into this study at the University of California, San Francisco.

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

Clinical Data: We will collect information from your medical record and the monitors and machines your doctors and medical team are using to care for you. This information includes oxygen levels, certain medicines, and a categorization of the pigmentation or darkness/lightness of your skin. We will continue to collect information from your medical record and monitors while you are in the study, for up to two weeks total. This information includes oxygen levels and medicines. We may measure your oxygen levels with FDA-approved pulse oximeter devices that are put on the finger as a finger clip for short periods of time.

Blood Samples: We may collect up to 10 total small samples of blood taken from the arterial catheter placed by your doctors to measure the oxygen content of your blood. This totals just over two teaspoons of blood that may be collected for research in addition to what your doctors have ordered for your care. We will not keep or store any of these samples. Some results will be added as part of your medical record and shared with your medical team. The medical team will order blood tests and provide care for you no differently than they would if you chose not to participate in this study. There will be no additional needle sticks to collect blood. When the arterial catheter is removed, your study participation will end. Please note, you may participate in the study without the additional research study blood draws. However, we believe these additional measurements are scientifically very important and allowing us to take these measurements will maximize our ability to learn from this research and help future patients.

Participation in the study should take a total of approximately 45-60 minutes over two weeks, including this consent conversation.

How long will I be in the study?
We will collect your data and possibly more samples for up to two weeks total.

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. The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped. If you withdraw from the study, your data will still be studied unless you specifically request that they be destroyed.

What side effects or risks can I expect from being in the study?
Confidentiality: Donating clinical information may involve a loss of privacy, but information about you will be handled as confidentially as possible. Your name will not be used in any published reports from research performed using your specimen. Phillip Bickler, Michael Lipnick, Carolyn Hendrickson the research team will have access to information about you but

they will not release any identifying information about you to researchers using the database generated by this study.

Mild discomfort: It is possible that you may find one of the finger clip devices uncomfortable or annoying to wear. It will most likely feel the same as the device your doctors and nurses are using to monitor you and it can be removed by your research or clinical care team at any time you request. There are very minor risks from collecting small samples of blood. The amount of blood collected from this study is unlikely to cause health concerns or contribute to significant anemia or low blood counts.

Are there benefits to taking part in the study?
There will be no direct benefit to you from allowing your clinical data or blood samples to be used for research. Research results from these studies will not be returned to you. However, we hope we will learn something that will help in the treatment of future patients.

What other choices do I have if I do not take part in this study?
The alternative to participating in the study is not participating in the study. If you choose not to participate in the study, your care will not be affected.

How will information about me be kept confidential?
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. Some information from your medical records will be collected and used for this study. Your signed consent form be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Information gathered directly from you by the researchers will be part of your research records and may be added to your medical record. 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.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the Sponsor, the Food and Drug Administration (FDA)
- Representatives of the University of California
- Representatives of the Office of Human Research Protections (OHRP)

Are there any costs to me for taking part in this study?
No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?
You will not be paid for being in this study.

How will my specimens and information be used?

Your blood specimens will not be stored. The oxygen contents of the blood samples are measured immediately after they are drawn, and nothing is saved for future use. Researchers will use your information to conduct this study. Your information will be stored in a deidentified database for up to 30 years and may be used for future research. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

Some results will be added as part of your medical record and shared with your medical team. Your clinical information used only for research and will not be sold. In some instances, these data may have potential commercial value. You will not receive any payment or financial benefit from any products, tests, or discoveries.

We will give all research records a secret study number identity and try very hard to protect your privacy. Only Drs. Bickler, Lipnick, and Hendrickson and their team will know your secret study number identity, which will be kept here in a locked file.

What happens if I am injured because I took part in this study?
It is important that you tell your study doctor, Dr. Philip Bickler if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call them 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, 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 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 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. 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 your questions about this study?
If you have any further questions about this study, you may call Caroline Hughes, the Clinical Research Coordinator, at (628) 206-3194. Caroline works for Dr. Philip Bickler, who is in charge of this study.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice concerns you may have about the study, please call the office of the Institutional Review Board (415) 476-1814.

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STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

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.

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate

Participant's Name	Signature and Date
Authorized Representative's Name	Signature and Date
Investigator/Delegate's Name	Signature and Date

If it is not possible to sign this consent document in person or electronically, a verbal agreement to participate in this research study will be used in place of the participant or authorized representative signatures above. You will be asked to provide verbal consent to the authorization of access, use, creation, or disclosure of health information about you. Information about health information authorization is found in a separate information packet.

You will be asked to provide verbal consent to the fields below:

1. My clinical data may be collected for research on pulse oximeters.
_____I agree _____I do not agree

2. My blood may be collected for research use to study pulse oximeters. (*Samples yet to be collected*)
_____I agree _____I do not agree

CONSENT OF THE SUBJECT TO CONTINUE TO BE IN THE STUDY

Your legally authorized representative gave their consent for you to be in this research study. This is because you were not able to make your own decision due to your illness. Your condition has now improved. You are being asked to decide whether to continue to be in this study. Your decision is voluntary. This means the decision is up to you.

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to continue to participate.

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

_____	_____
Participant's Name	Signature and Date
_____	_____
Authorized Representative's Name	Signature and Date
_____	_____
Investigator/Delegate's Name	Signature and Date

If it is not possible to sign this consent document in person or electronically, a verbal agreement to participate in this research study will be used in place of the participant signatures above. You will be asked to provide verbal consent to the authorization of access, use, creation, or disclosure of health information about you. Information about health information authorization is found in a separate information packet.

You will be asked to provide verbal consent to the fields below:

1. I consent to continue participating in this study.
_____I agree _____I do not agree

2. My already collected clinical data and blood test results may be stored secure for research use to study pulse oximeters.
_____I agree _____I do not agree

3. My clinical data may be collected for research on pulse oximeters. (*Information from now until the end of my study participation*)
_____I agree _____I do not agree

4. My blood may be collected for research use to study pulse oximeters. (*Samples yet to be collected*)
_____I agree _____I do not agree