

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	A SINGLE CENTER STUDY ON THE FUNCTIONALITY OF THE PULSE OXIMETER AND ACCELEROMETER PORTIONS OF A NOVEL WEARABLE DEVICE
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Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to test the function of a pulse oximeter (oxygen sensor) and accelerometer (movement sensor) in a novel wearable device. The function of the pulse oximeter prototype will be compared to a study-provided, FDA-approved pulse oximeter.

If you agree to join the study, you will be asked to complete the following research procedures: wear a prototype version of a novel device during the study visit in addition to your clinically necessary devices. The prototype device will be worn as a combination of a ring on your finger and bracelet on your wrist while the study-provided, FDA-approved pulse oximeter will be worn on your index finger. The study duration will not exceed 15hrs. The results obtained from the investigational device (DOVE) will not impact the clinical care you receive for hypoxic events. The results obtained from this trial are for research purposes, you will not obtain a report and this information will not be added to your medical record.

Your participation will last for the duration of one study visit. There are no benefits to your participation in this study. The most common risks of participation are irritation and/or rash at the site of device placement.

If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to volunteer for this research study because you might be experiencing hypoxic events and the device prototype will sense these changes if it works properly.

Your doctor may be an investigator in this research study. Participation in this research trial is voluntary. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to sign this form. After you sign this form, the study coordinator will provide you with a copy of this form.

What is the purpose of this research study?

The purpose of this research study is to test the function of a pulse oximeter (oxygen sensor) and accelerometer (movement sensor) in a novel device prototype. The signals from the prototype will be compared to a study-provided, FDA-approved pulse oximeter.

How long will I be in the study?

You will be in this study for the duration of one study visit. Overnight testing will not exceed 15hrs.

What am I being asked to do?

You are being asked to wear a prototype of a novel device to sense oxygen levels and movement for the duration of the study visit. This study will only involve one study visit. In the event you are being enrolled on the day you are completing an overnight sleep test the visit will last no more than 15hrs. The prototype device consists of a pulse oximeter (oxygen sensor) and an accelerometer (movement sensor). The prototype device will be worn as a combination of a ring on your finger and bracelet on your wrist while the study-provided, FDA-approved pulse oximeter will be worn on your index finger. At the time the device is collected the study team will administer a questionnaire about comfort while wearing the device. The results obtain from this trial are for research purposes, you will not obtain a report and this information will not be added to your medical record.

Table 1: Schedule of Study Procedures

Study Procedures	Screening / Device dispensing	Device Collection
Review Inclusion/Exclusion Criteria	X	
Informed Consent	X	

Skin Tone Assessment	X	
Questionnaire		X
Dispense Investigational Product DOVE prototype	X	
Dispense FDA-approved sensor (Contec CMS50DA Pulse Oximeter)	X	
Collect Investigational Product DOVE prototype		X
Collect FDA-approved sensor (Contec CMS50DA Pulse Oximeter)		X
Assessment of possible Adverse Events		X

What are the possible risks or discomforts?

While participating in this study, you may be at risk for the following side effects associated with the procedures required:

Risks of Wearable Devices: You will wear a novel device prototype for this study. There is a risk of irritation or rash developing at the site of device placement.

Risks of Loss of Confidentiality: Study personnel will collect some medical and personal information about you as part of completing the study. Although we will not be collecting any personal identifiers, there is a risk of accidental breach of confidential patient health information.

This research may involve risks that are currently unforeseeable.

Reproductive risks

Women who are pregnant will not be included in this study. If you are currently pregnant, it is important that you inform the investigator because you will not be able to participate in the study. All patients will be asked pregnancy status during enrollment but confirmation of a negative pregnancy test will not be done by the study team.

What if new information becomes available about the study?

Study participation will only involve one study visit. During the course of this study, we may find more information that could be important to you. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You are not expected to get any direct benefit from participating in this research study. However, while you may not benefit personally, the knowledge learned from your participation in this research study may benefit other patients in the future.

What other choices do I have if I do not participate?

Your participation in this study is entirely voluntary. Your alternative option is to not participate.

Will I be paid for being in this study?

You will be provided a \$25 gift card upon completion of the study.

Will I have to pay for anything?

There will be no charge for participating in the clinical trial. You are still responsible for any deductibles or applicable co-pays that would be done for your routine clinical care, such as office visits and bloodwork.

When is the Study over? Can I leave the Study before it ends?

The study is over after you have completed one study visit. However, you can withdraw your participation in this study at any time. This study may also be stopped at any time by your study doctor, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- For any other reason that is not known at this time.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care. If you are removed from the research study, your study doctor will explain to you why you were removed.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be 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. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records. All personal information collected will be immediately coded with an ID number. All research personnel will follow privacy guidelines as described in CITI training biomedical and good behavior protocols. Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Computer-based files will only be made available to personnel in the study through the use of access privileges and passwords. Wherever possible, identifiers will be removed from study-related information.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

What may happen to my information collected in this study?**Future Use of Data**

Your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the collected on this study

The information collected will be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Will I receive the results of research testing that may be relevant to my health?

Many tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

What information about me may be collected, used or shared with others?

The following health information will be collected and used for the purposes of this study and for the purpose of compensation:

- Name, address, telephone number, email address, date of birth
- Device identifiers/serial numbers
- Your hypoxic diagnosis
- Age, gender, race, skin tone

Data collected from the prototype device includes your blood oxygen levels and movement over the course of the study visit.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the

purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases. Survey answers will be entered into a RedCap database and responses will be aggregated and summarized using descriptive statistics.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?

As part of the study, the Principal Investigator, study team and others listed above may disclose your study-related records, including the results of the research study tests and procedures, to those listed below. This study data may be processed and transmitted using secure computer systems. No identifiable information will be collected nor transmitted.

Individuals or organizations responsible for administering the study:

Dr. Brenner, MD, PhD (PI of this study) and their designated representatives

Regulatory and safety oversight organizations

- U.S. Office of Human Research Protections (OHRP)
- Other regulatory agencies and/or their designated representatives, including international agencies

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	_____
Name of Subject (Please Print)	Signature of Subject	Date

_____	_____	_____
Name of Person Obtaining Consent (Please Print)	Signature	Date