PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: Controlled Desaturation Study for Perin Health Patch Validation

STUDY INVESTIGATOR: Ian McLane, PhD

STUDY SITE: Perin Health Devices
21241 Ventura Blvd., Suite 268
Woodland Hills, CA 91364

TELEPHONE: 310-997-8176

SPONSOR: Perin Health Devices

KEY INFORMATION FOR YOU TO CONSIDER

We (the researchers) are asking if you would like to be in a research study. Some key information is provided in the boxes below to help you decide if you want to participate or not. Read the entire form and ask questions before you decide. The researchers will go over this form with you and you can ask any questions.

What is the purpose of this research?	The purpose of this research is to see if an investigational chest-worn medical device called the Perin Health Patch (PHP) can measure blood oxygen saturation accurately.
What will happen to you during the study?	During the study, you will wear a mask placed on your face that will control the air that you breathe and simulate high altitudes. The air you breath through the mask will slowly be adjusted to decrease your blood oxygen level. We will aim to achieve a blood oxygen level between 70% and 73% before returning the air to normal and letting your blood oxygen level return to your healthy baseline. This will be done two times with a break in between each. You may be asked to walk at a slow and comfortable pace during this testing. After the second run, you will be done with the study.
How long will you be in the research?	You will be in the research study for about 1 to 1 1/2 hours total.
Could being in this research harm you?	You should understand the risks of this research study before you decide to participate. Medical staff will be present during your study visit to monitor you and provide care if needed. If you participate in this study, you might experience some minor risks and discomforts that might include the following: ▪ You may feel uncomfortable, anxious, or scared when your oxygen levels drop.

	▪ You might experience light-headedness, shortness of breath, or a fast heartbeat during low oxygen levels. ▪ Some people may feel their heart beating irregularly or quickly. ▪ Low oxygen could cause confusion or trouble thinking. ▪ In rare cases, oxygen levels could drop too low, leading to fainting or loss of consciousness. ▪ Long periods of low oxygen levels can be life-threatening. ▪ Wearing the Perin Health Patch (PHP) on your chest might feel a bit uncomfortable. ▪ You may have a reaction to the adhesive from the PHP.
What happens if you decide to stop being in the study?	You are free to leave the study at any time. If you decide to stop, there will be no negative consequences or loss of benefits. Please inform the study team if you want to stop, and they will help you finish the study in a safe way.
Will being in this study help you in any way?	You will not directly benefit clinically from being in this study. However, the information we learn from the study could help develop better ways to measure remotely monitor oxygen saturation, which might benefit other people in the future.
Are there other choices if you do not participate?	There are no alternative procedures or treatments involved in this research study. You are free to choose not to participate in the study, and it will not affect your medical care in any way.
Are there any costs to participate?	It does not cost anything to be in the study.
How do researchers protect your information?	Researchers keep your personal information confidential and stored securely. Only the researchers approved to be on this study may see your information. Your information will be kept private to the extent allowed by law. The research team will do everything possible to keep your information confidential. However, records identifying you may be reviewed by the Food and Drug Administration (FDA), Institutional Review Board (IRB), or other regulatory agencies. These organizations may inspect the study records to make sure everything is done properly and safely.
Will you get any test results?	The results of research tests are not given to you. Results of research tests have no clear meaning for your health care.

ADDITIONAL DETAILED INFORMATION

What is the background and purpose of this study?

Blood oxygen level or oxygen saturation is a measurement of the amount of oxygen circulating in your blood that is available to your organs. Oxygen saturation is an important indicator of how well your lungs are working. When your lungs aren't working properly, your blood oxygen saturation can drop, which can lead to serious health conditions.

The most common device used to measure oxygen saturation is called a pulse oximeter. This device is a clip that is placed on a finger.

The study sponsor has developed an investigational chest-worn medical device called the Perin Health Patch (PHP). Investigational means that the PHP device has not been approved by the United States Food and Drug Administration (FDA). This study will compare the PHP's measurements to those from a commonly used pulse oximeter already approved by the FDA to make sure it meets the standards for accuracy. The results from this research will be used for a future FDA submission and approval.

Up to 25 people aged 18 to 65, inclusive, will participate in this study.

What will happen to you if you decide to be in the study?

Your participation in this study will involve one visit that will take about 1 to 1 ½ hours. This will include about 15-30 minutes for the initial consent form review, screening and baseline measurements and 10-15 minutes for each desaturation run, with 2 runs for a total of up to 30 minutes. You will have a 5 to 10 minute break between runs and an additional 5-10 minutes at the end of the study to return you to normal levels and to remove all the equipment.

Before any study-related procedures are performed you will be asked to read and sign this consent form. The following procedures will be done during your visit:

1. You will complete an intake form to collect your age, sex, height, weight, and medical history information. You will have a COVID-19 test performed and your temperature will be taken. If you are a woman who is able to have children, a urine pregnancy test will be performed.
2. You may be asked to shave the area on your chest where the device will be placed. The study team members will then measure the skin tone where the PHP will be placed.
3. The application site will be cleaned using an alcohol wipe and the PHP will be adhered to your chest.
4. Pulse oximeters will be placed on your ring fingers of both hands.
5. Other monitoring tools such as ECG (electrocardiogram) and a blood pressure cuff will be placed on you.
6. Baseline measurements of your ECG, blood pressure and oxygen saturation will be collected.
7. You will be asked to sit in a slightly reclined position and relax for at least 5 minutes for baseline measurements to be taken.
8. The altitude trainer mask will be placed over your nose and mouth. You will be asked to breathe normally. The amount of oxygen you breathe in will be slowly decreased to reduce your oxygen saturation from 100% down to 70%.
9. You may be asked to walk during this process. If you agree, you will walk at a slow and comfortable pace on a treadmill as the oxygen level is decreased. You can choose not to walk. You can also choose to stop walking at any time.
10. Once you reach the target oxygen saturation level, you will be quickly brought back to your normal baseline by changing the air you are breathing to pure oxygen.
11. After 5 to 10 minutes Steps 6 through 10 will be repeated a second time.
12. You will be monitored for another 5 minutes after the runs are complete, for your safety.
13. The PHP and all other monitoring equipment will then be removed and you will be done with the study.

Who can participate in this study?

You can participate if **all** of the following apply to you:

- Adults aged 18 years to 50 years
- In good general health with no evidence of any medical problems
- Fully vaccinated for COVID-19
- Fluent in both written and spoken English
- Willing and able to provide informed consent
- Able to perform the study procedure.

You cannot participate if **any** of the following apply to you:

- Children (under the age of 18)
- Adults above 50 years old
- History of heart, lung, kidney, or liver disease
- Obesity (BMI > 30)
- Diagnosis of asthma, sleep apnea, or use of CPAP
- Diagnosis of Raynaud's disease
- Unacceptable circulation based on an exam by the study investigator
- Pregnant, lactating or trying to get pregnant
- Current smoker
- History of diabetes
- Blood clotting disorder
- Hemoglobinopathy or history of anemia
- History of fainting or vasovagal response
- Any other serious systemic illness
- Any other condition which, in the opinion of the study investigators, would make you unsuitable for the study,
- Any injury, deformity, or abnormality at the sensor sites that in the opinion of the study investigators would interfere with the sensors working correctly
- Any evidence, in the opinion of the study investigators, of medical problems or poor general health
- Any symptoms related to COVID-19
- Not vaccinated for COVID-19
- Recent injection with methylene blue
- History of reactions to medical adhesives
- Unable or unwilling to provide informed consent
- Inability to perform the study procedure
- Non-english speaker.

Could being in this research harm you? (Detailed Risks)

You may feel uncomfortable when your oxygen levels drop during the study. You may feel anxious or scared because of the low oxygen levels. If this happens, the medical team will help calm you down or stop the test if you feel too stressed.

You may feel tired, light-headed, or short of breath if you are asked to walk during the study.

You might feel light-headed, short of breath, or notice your heart beating faster when your oxygen levels are low. A doctor and nurse will check your vital signs the entire time, and oxygen will be given right away to bring your levels back to normal if needed.

You may feel your heart beating strangely or faster than normal. If this happens, the medical team will watch your heart closely to keep you safe.

You might feel confused or have trouble thinking clearly due to low oxygen. The medical team will be there to help and keep you safe.

Although it's not likely because of the close monitoring, your oxygen could drop too low (below 70%), which may cause you to faint or even lose consciousness. Long periods of low oxygen levels can be life-threatening. If this happens, the medical team will give you oxygen right away to get your levels back to normal. The medical team may take emergency precautions if needed.

You might feel like you can't breathe well or start breathing faster than normal. If this happens, the medical team will give you oxygen and make sure your breathing returns to normal.

You might start breathing too quickly, which could make your body feel off-balance. The medical team will watch for this and help adjust the test if needed.

There is a very small chance of long-term problems from the low oxygen, especially if you already have heart, lung, or sleep problems. We will screen people to make sure those with higher risks aren't part of the study.

You may feel discomfort or have a skin reaction from the adhesive patches used in the study.

We will protect your personal information, but there is a very small chance that your data could be seen by someone outside the study. We will take strong measures to keep it safe.

Please let a study team member know if at any moment you feel discomfort. It is okay if you wish to discontinue your participation at any time.

There may be unknown risks in this research. Tell the researchers if you develop a new condition or injury.

Is there any available medical treatment or compensation if you are injured in the study?

This study is slightly greater than minimal risk. Treatment will be available at the time of the study with the onsite clinical team.

If you are injured as a result of this study, medical treatment will be provided to you. The clinical staff on site will administer treatment if necessary, during the study. The cost of any medical care due to injury during this study may depend on various factors. You or your insurance might need to cover some costs, but Perin Health Devices will pay for expenses incurred as a direct result of injury from your participation in this study. Perin Health Devices may reimburse you for the costs of such treatment instead of direct payment to the provider.

The coverage of costs may depend on many things, include a written notification of the injury in a reasonable time after discovery, demonstration that the injury resulted directly from your participation in the study, and a documentation for a reimbursement claim. For more information about this, you can contact the research coordinators at +1 (818) 606-9389.

Who can you talk to about the research?

Contact the researcher listed on the first page if you have questions, concerns, complaints, or get hurt.

Sterling Institutional Review Board (IRB) oversees this research for the protection of human subjects. If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department at telephone number 1-888-636-1062 (toll free) or info@sterlingirb.com.

Will the researchers return results and incidental findings to you?

In general, we will not give you any individual results from the study. If new information becomes available during the study that might affect your decision to continue participating, we will share it with you. This could include new findings about the safety or risks of the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Are there any conflicts of interests reported for this study?

Dr. McLane is an officer of the sponsor institution, Perin Health Devices, but does not contain any financial ownership in Perin Health Devices. The outcome of this research study could be of interest to Perin Health Devices, however Dr. McLane will not financially benefit from the outcomes of this study. If you want more information about this relationship please ask the study staff.

How do researchers protect your information?

As a part of this research, records that contain information or data about you and your health may be collected and used. These records may identify you and will be kept as confidential as possible. To the extent permitted by applicable laws and regulations, the records identifying you will not be made publicly available.

The researchers will keep information about you in a secure location with limited access. If the results of this study are made public, information that identifies you will not be used.

The results of the study, including your information, may also be presented at meetings or in articles written about the study (publications). If the results of the study (including your research or health information) are published, your identity will remain confidential.

Will the researchers share your de-identified information for future research?

Please indicate below if you agree to the future use of your de-identified study information as described here:

- The researchers approved for this current study will deidentify your materials immediately.
- The researchers doing future research with the deidentified materials cannot identify you.
- The following materials may be used in future research: raw recordings from the PHP, oxygen saturation measurements from reference devices, ECG and blood pressure measurements from monitoring devices, information from the intake form.
- Future research may include time series analysis of ECG, PPG, auscultation, BioZ, motion, or temperature; refinement of oxygen saturation algorithms.
- Your deidentified information will be maintained for as long as it is useful for research purposes, after which time the data and information will be destroyed.
- Your deidentified information will not be sold or used for commercial profit; the data will only be retained for research purposes.
- You will not be able to get individual research results about you because the researchers who receive your materials will not have your identifiers.

Please initial the ONE option that you choose below:

_____ *(initials)* YES. *You still have the right to withdraw this authorization later.*

_____ *(initials)* NO.

What information about this study is available to the public?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Can your participation end early?

You may end your participation in this study at any time by communicating with the study investigator. Please let the study team know if you have any discomfort and would like to end early. You are free to leave the study at any time. If you decide to stop, there will be no negative consequences or loss of benefits. The study team will help you with a safe and orderly exit from the study. If you withdraw before completing the study, your information that was already collected may still be used for research purposes.

The study investigator may stop your participation without your consent for any of the following reasons:

- If the research becomes harmful
- If you do not follow the instructions or the research requirements given to you by the study investigator or study staff

Will you receive anything for being in the research?

You will receive $150.00 for your participation in this study.

Will it cost you anything to be in the research?

There is no cost to you from participating in this study.

SIGNATURES

I have read this document and have been told of the risks and benefits of this study. A member of the research team answered questions to my satisfaction. I voluntarily agree to participate in this study and know that I can withdraw from the study at any time without penalty. I do not waive any legal rights by signing this form.

I will receive a signed copy of this document.

_____

Print the Name of the Adult Research Participant
(18 years of age or older)

_____ _____

Signature of the Adult Research Participant **Date Signed**

Completed by the Study Investigator obtaining informed consent:

☐ In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be, associated with this research, and to answer any further questions.

☐ Check to confirm participant agreed to participate in the study and signed the informed consent form(s) and all questions were answered.

_____

Print Name of Investigator Obtaining Informed Consent

_____ _____

Signature of Investigator Obtaining Informed Consent **Date Signed**

HIPAA AUTHORIZATION

STUDY TITLE: **Controlled Desaturation Study for Perin Health Patch Validation**

STUDY INVESTIGATOR: **Ian McLane, PhD**

We are required by law to protect the privacy of your health information. The Health Insurance Portability and Accountability Act (HIPAA) gives you certain rights over your health information. By signing this form, you are allowing the researchers to use and disclose your health information for the purposes of this study. You are also agreeing that this information can be shared with certain parties involved in the study, such as study sponsors or regulatory agencies like the FDA or Institutional Review Board (IRB).

1. What Information Will Be Used and Disclosed?

Federal law protects your right to privacy concerning Protected Health Information (PHI). There are certain things you need to know. PHI is any information from your medical record or obtained from the study linked to you and that refers to your mental or health conditions in the past, the present or the future. No PHI will be collected in relation to this study.

The information collected during this study will be deidentified. It will not be sold or used for commercial profit. The data will only be kept for research purposes.

The following information will be collected and shared as part of this research study: your demographic details (such as age, gender, race, and ethnicity), medical history, results from this study (including oxygen saturation levels), and any related health information collected during the study.

2. Who Will See My Information?

Only authorized personnel involved in this research will have access to your information. This may include the research team, the study sponsor, the FDA, and the IRB. Your information will be kept confidential to the extent required by law, but absolute confidentiality cannot be guaranteed.

3. What Are My Rights?

You have the right to see and get a copy of your health information. You may also withdraw your authorization at any time, except to the extent that the research team has already used or shared your information. If you withdraw your authorization, you will no longer be able to participate in the study.

If you choose to withdraw your permission, you must do so in writing to the study investigator. The study investigator's mailing address is Perin Health Devices, 21241 Ventura Blvd., Suite 268, Woodland Hills, CA 91364. The study doctor will still be able to use the health information collected about you before you withdrew your permission. Information that has already been sent to the sponsor of the study cannot be taken back.

If you withdraw your permission after you have entered the study, you cannot continue participating in the study. If you refuse to give permission or withdraw your permission, your medical care and your relationship with the health care providers at the study center will not be affected.

4. How Long Will My Information Be Used?

Your authorization for the use and disclosure of your health information expire 50 years from the date of this consent form, unless you choose to withdraw it earlier.

5. Who Can I Contact?

If you have questions about your health information, you may contact the research team or the HIPAA Privacy Officer at Perin Health Devices.

PARTICIPANT AUTHORIZATION

I give my permission to the study doctor to use and disclose my protected health information as described in this consent form.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date